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Monoclonal Antibodies

Second Edition

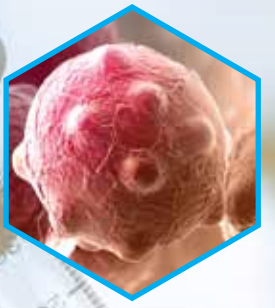
Understanding Cancer Immunotherapy

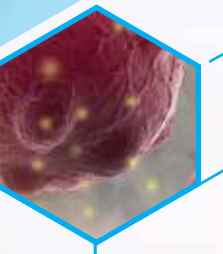
WHERE INFORMATION EQUALS HOPE

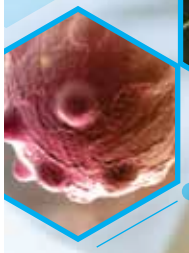
Adoptive T Cell Transfer

Immune Checkpoint Inhibitors

Cancer Vaccines







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Second Edition

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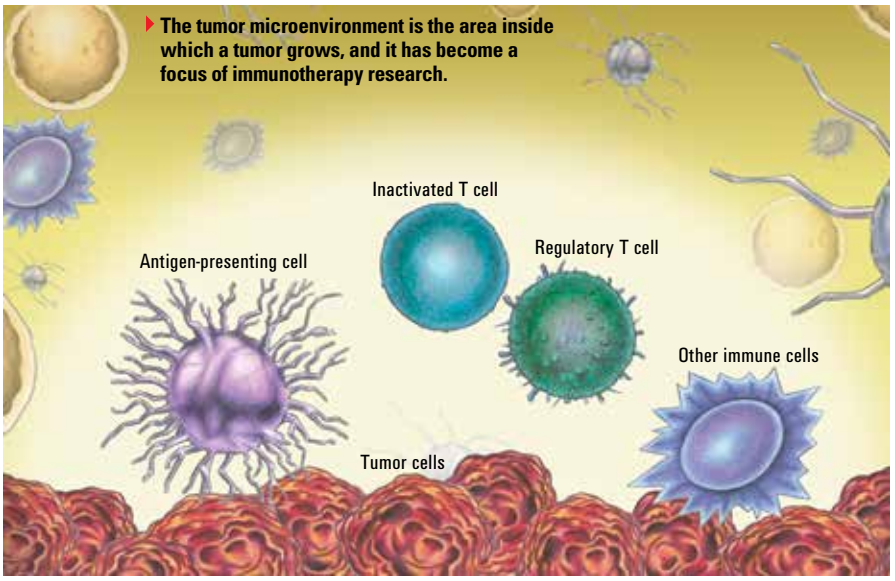
IMMUNOTHERAPY TODAY

TUMOR MICROENVIRONMENT



The tumor microenvironment is the area inside which a tumor grows, and it has become a focus of immunotherapy research.

Even though the study of immunotherapy has been around for more than a century, its value to the treatment of cancer is greater today than ever. Drug development is progressing rapidly, data from clinical trials continues to impress, and, most important, more and more patients are experiencing remarkable responses to these treatments that allow them to lead longer, healthier lives. As news stories highlight these groundbreaking results, patients are beginning to wonder, "What is it? Is it a cure? Could it be right for me?"

Simply stated, immunotherapy is a type of treatment that helps the body's immune system attack cancer. And recent breakthroughs in immunotherapy for melanoma and lung cancer continue to significantly impact the treatment of both of these common cancers, and influence progress in the treatment of several other cancer types.

An increasing number of immunotherapy drugs have been approved by the FDA (U.S. Food and Drug Administration) to treat different cancer types—some drugs even being used across several cancers. Their success has been so impressive that it has launched immunotherapy into a standard-of-care spot next to long-standing treatment options such as chemotherapy and radiation. This treatment is still relatively new, however, so many of these "astonishing" results are coming from patients participating in clinical trials, which are the studies of drugs or treatment combinations not yet approved by the FDA. Patients can still gain access to these treatments through the clinical trials, so it's important to discuss this opportunity with your doctor when considering treatment options.

Immunotherapy and the immune system are both very complicated, and scientists continue to learn more every day. Whether you've just heard of immunotherapy or you're considering it as a treatment option, it's important to learn as much as you can so you can make informed decisions about your cancer care. ■

ADDITIONAL RESOURCES

- **TheAnswerToCancer.org:**
  www.theanswertocancer.org
  How Your Immune System Fights Cancer
- **Cancer Research Institute:**
  www.cancerresearch.org
- **National Cancer Institute:**
  www.cancer.gov
  Immunotherapy: Using the Immune System to Treat Cancer
- **Society for Immunotherapy of Cancer:**
  www.sitcancer.org

THE 3 E's | CANCER vs. THE BODY

In the 1950s, researchers thought the immune system did two things: it protected your body against bacteria and viruses, and it looked for abnormal cells and killed them before they could become tumors. Called the cancer immunosurveillance theory, it was initially rejected. In the last 10 years, however, studies have shown that immune cells are indeed important in the prevention of cancer. Although tumors may develop in a functioning immune system, the way a tumor grows and develops is influenced by the body's immune response. Based on this new evidence – and confirmed by the mouse tumor studies conducted by Dr. Robert Schreiber – the theory has been renamed "cancer immunoediting."

The three E's of Dr. Schreiber's theory of cancer immunoediting are elimination, equilibrium and escape:

1 ELIMINATION – In this phase, the immune system sees and destroys cancer cells. This phase suggests that our bodies may be regularly introduced to cancerous changes and that our immune systems are capable of handling and eliminating them.

2 EQUILIBRIUM – If the cancer cells are not destroyed right away, they may exist in a delicate balance between growth and control by the immune system. During equilibrium, the body's immune system is able to keep the cancer cells under control but is unable to kill them completely. In this phase, a tumor may remain dormant for an unknown length of time and may evade medical testing. According to the theory, however, the constant interactions between the tumor cells and the T cells of the immune system may actually lead to tumors that can adapt to the immune response (see page 3 for more information). This means the immune system may no longer be able to find tumors and attack them. Tumors that avoid the immune response can no longer be controlled and move on to the third phase.

3 ESCAPE – The escape phase refers to the disruption of equilibrium (balance) that leads to immunosuppression. This allows the tumors to escape and begin growing in an environment of immune "tolerance." It's at this point that the symptoms of cancer begin to appear. Tumors in the escape phase use a number of methods to alter the body's immune response in such a way that actually allows them to grow.

The body's natural defense

To better understand how specific immunotherapy strategies work, a basic understanding of the immune system and how it interacts with cancer may be helpful.

The immune system is the body's natural defense against infection and disease, responsible for protecting the body from substances that can cause harm, such as bacteria and viruses (sometimes called "germs"). The cells of the immune system continuously flow through the body, looking for germs invading the body. These invaders are recognized by their "antigens," which are tiny proteins on their surface (Figure 1). Every cell or substance has its own specific antigens, and the body's cells carry "self" antigens that are specific to that individual. Cells bearing self antigens typically pose no threat. Invading germs, however, carry "non-self" antigens because they did not originate in the body. The immune system is designed to recognize this kind of antigen as harmful and respond appropriately. Most immune cells release messengers called cytokines to help them communicate with other immune cells; this allows them to control the immune system response against any threats.

RESPONDING TO A NORMAL INVADER

When you skin your knee, you break the immune system's first barrier, the skin, and harmful substances can easily enter the body (Figure 2). Luckily, as soon as the injury occurs, immune cells that have been circulating in your body start to gather at the site and call other immune cells to help defend the body against invasion. Any bacteria or foreign substance that enters should be recognized by the immune cells as an invader. Immune cells known as natural killer cells begin to destroy the invaders with a general attack. Although this attack can kill some, it may not be able to destroy all of the invaders or prevent them from multiplying. Meanwhile, other immune cells called dendritic cells start to "eat" the invaders and their non-self antigens. This causes the dendritic cells to transform into antigen-presenting cells (APCs). Throughout the process, these APCs gather information which they then present to the primary immune cells of the immune system—the B and T cells. Once an antigen has been identified, B cells work rapidly to produce antibodies against the invading germs, to help eliminate invaders that are bacterial. Viruses, unlike bacteria, like to hide inside normal cells and may be more difficult for the immune system to "see." T cells, however, are designed to find abnormal fragments inside normal cells. Before these T cells have been activated to fight viruses and other invaders, they're known as "naïve" T cells.

In order for the APCs to communicate with and activate the naïve T cells, they must connect to the T cell through protein molecules on their surfaces. A specific molecule on the APC, called the Major Histocompatibility Complex (MHC) molecule, must successfully connect to the receptor on the T cell (Figure 3). This first important connection is sometimes referred to as Signal 1. This connection allows the T cell to "see" the antigens and recognize them as a threat.

Before a T cell can fully activate, however, a second connection between additional molecules on the surfaces of both cells is required. This connection confirms that an attack against the invader is, in fact, necessary. This second signal is known as the co-stimulatory signal, or Signal 2. If a T cell receives Signal 1 but not Signal 2, the cell will die, ending the attack before it really even started. The delicate balance of these positive and negative signals controls the strength and duration of the immune response.

If the T cell receives both signals, it's now able to recognize the invader and destroy it.

FIGURE 1
TYPES OF ANTIGENS

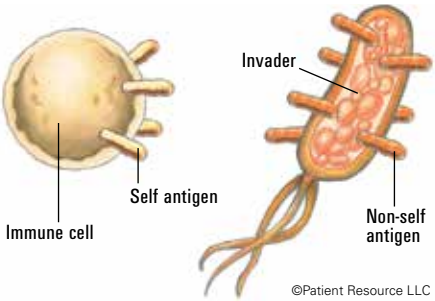
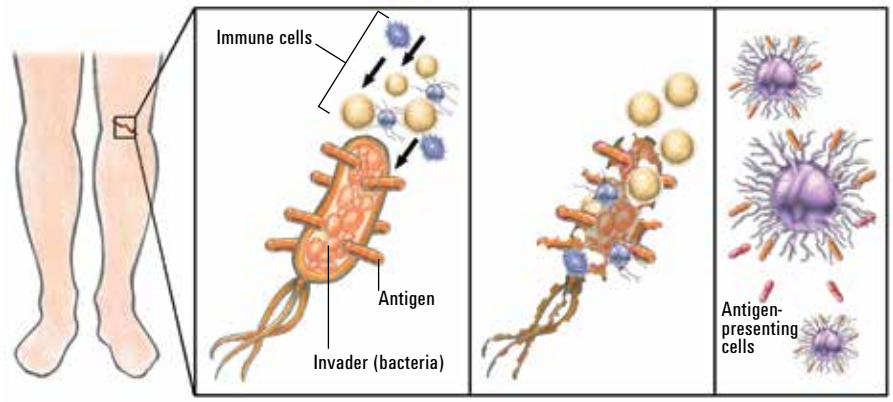


FIGURE 2
NORMAL IMMUNE RESPONSE



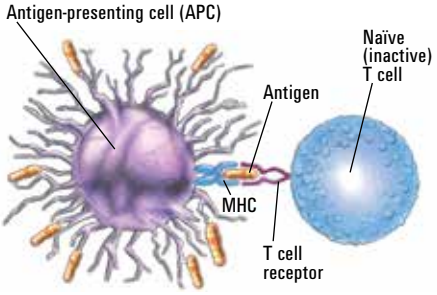
Skinned knee: First barrier of protection is broken.

An invader enters the body through the cut, where immune cells have begun to gather to protect the body.

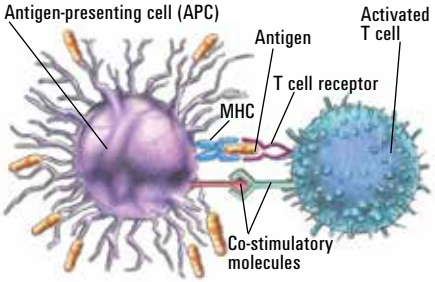
The immune cells begin to destroy and digest the invader and its antigens.

Some of the immune cells transform into antigen-presenting cells that tell other immune cells about the invader.

FIGURE 3
CELL INTERACTIONS

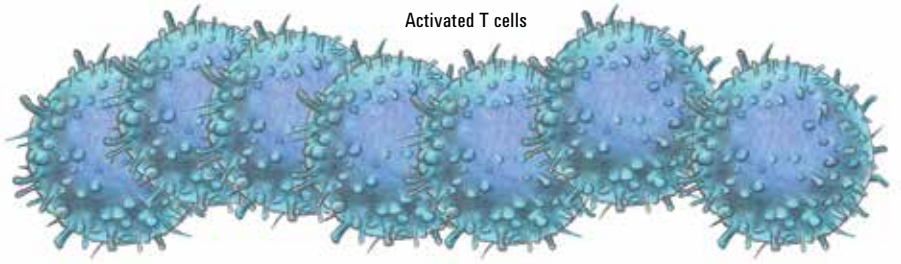


Antigen-presenting cell presents antigen to naïve T cell, known as Signal 1.



T cell recieves co-stimulatory signal to fully activate, known as Signal 2.

FIGURE 4
MULTIPLYING T CELLS



When a T cell receives both signals to fully activate, it multiplies.

This fully activated T cell then multiplies to develop an army of T cells equipped with the necessary mechanisms to defeat the threat (Figure 4). After multiple generations of immune cells have been created by the same immune response, some T cells transform into "regulatory" T cells, which are responsible for slowing and shutting down the immune response once the threat is gone.

Other T cells may become "memory" T cells, which can stay alive for months or years to fight off the same invader again. This is the basis of immune protection against disease and explains why we don't get the same diseases twice, such as measles or chicken pox.

If the body can't tell the difference between the tumor cells and normal cells, the tumor cells may be able to hide.

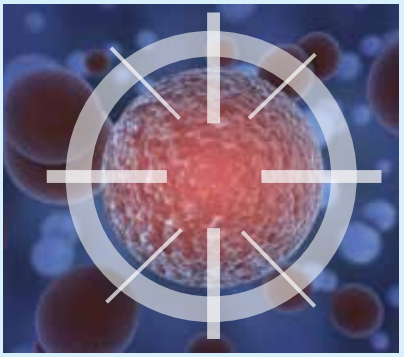
RESPONDING TO CANCER

Because cancer cells are created by the body, the normal ways used to find and fight foreign invaders are not always effective. If the body can't tell the difference between the tumor cells and normal cells, the tumor cells may be able to hide. In some cases, however, the DNA changes (mutations) that cause the cancer may be different enough to stimulate an immune response, much like how immune cells notice virally infected cells. If the immune system does detect the cancer, the APCs must share the information with the T cells, which are the primary players in the fight against cancer (Figure 5). The molecules on an APC must connect to receptors on the T cell, and the T cells must receive positive signals before they can activate and multiply. Negative signals will shut down the response (Figure 6, page 4). A T cell can only function properly against the cancer if it recognizes the cancer as harmful, receives the proper signals to activate, and then continues to get positive signals to keep up the attack.

Because immune cells communicate with each other through cytokines produced by the body, tumor cells also have the ability to create cytokines. This means that cancer cells can

TOLERATING CANCER

HOW CANCER CELLS EVADE DETECTION

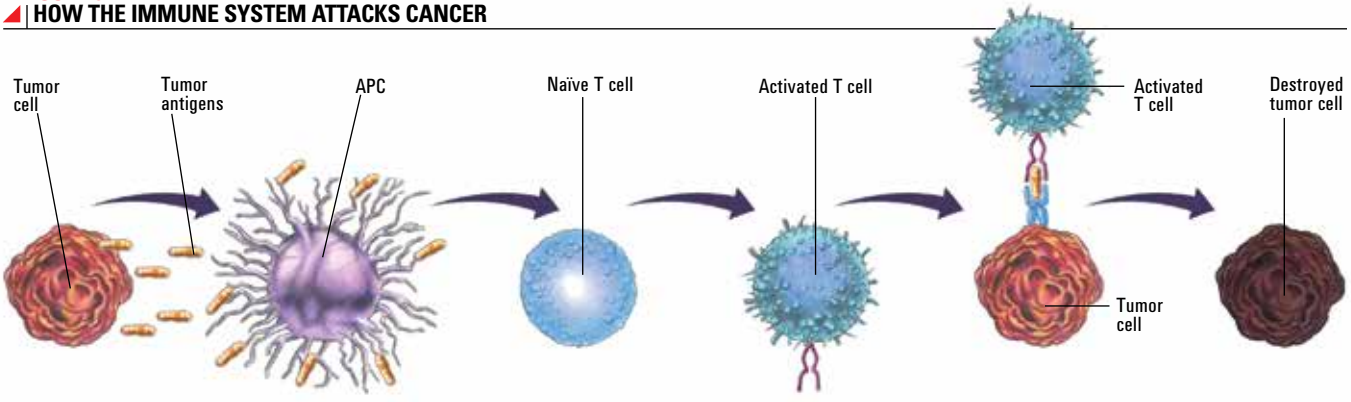


If you suffer from an allergy – pollen, for example – you might see your doctor for periodic allergy shots. These shots work much like a vaccine: As the amount of the particular allergen is injected in increasing doses over a series of visits, your body begins to develop a tolerance to pollen. This type of therapy can eventually lead to decreased symptoms from a pollen exposure, or even may eliminate your symptoms altogether. Because your body no longer sees pollen as an invader, the immune system stops attacking it.

Cancer often uses this same trick. In early stages, cancer cells may shed proteins into your body. As these proteins circulate through your bloodstream, you begin to develop a tolerance. And once that tolerance exists, your body may not recognize these cancer cells as a threat. Then, just like the pollen, the cancer cells may be safe from an immune system attack.

Immunotherapy seeks to reverse this tolerance, to once again identify the cancer cells as a threat and a target for destruction.

FIGURE 5
HOW THE IMMUNE SYSTEM ATTACKS CANCER



Tumor cells release tumor antigens.

APCs gather tumor antigens and prepare to present to naïve T cells.

T cells are activated by the APC.

Activated T cells find the tumor cells with the same tumor antigens and destroy them.

communicate with and confuse other immune cells, allowing the cancer to take control of certain parts of the process that the body uses to regulate the immune response. So, even if the immune system recognizes the cancer, it may not be able to successfully start or maintain an attack long enough to kill the cancer cells.

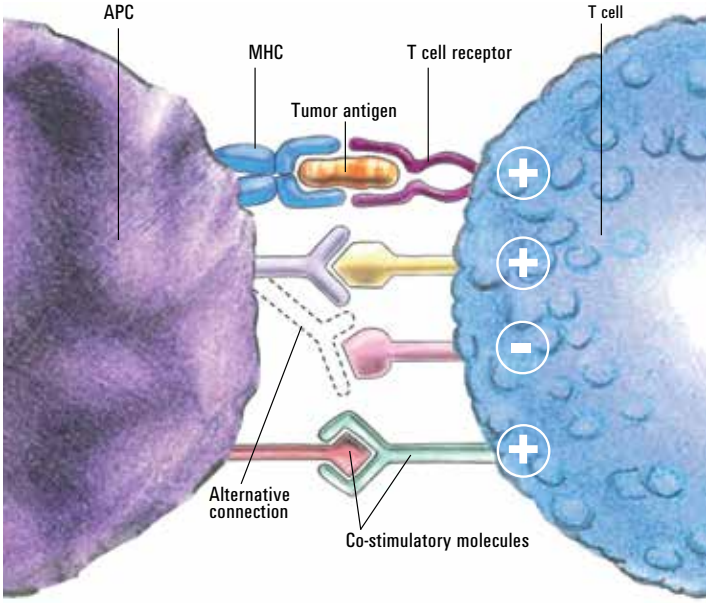
The T cell's ability to activate and attack cancer is at the heart of immunotherapy research. One specific area of research focuses on the cancer cells' ability to trick the immune system into prematurely turning on "checkpoint pathways." Checkpoint pathways are part of the system of checks and balances that allow the immune cells to evaluate the attack against the threat at multiple stages; pathways essentially function as the "brakes" when the body determines the response is no longer needed. By using signals to confuse other immune cells into engaging the brakes, the cancer can shut down the attack prematurely and continue to grow. Recent research has shown that blocking the effect of these checkpoint pathways can restore the normal function of the immune cells. Recent breakthroughs in immunotherapy research have involved two main checkpoint pathways: the CTLA-4 immune checkpoint pathway and the PD-1/PD-L1 immune checkpoint pathway (Figure 7).

The longer the cancer cells are subjected to a weakened immune response, the more they're able to adapt, and the easier it is to manipulate immune cells inside the tumor's microenvironment – the area inside which the tumor grows. This area typically contains cancer cells; normal connective tissues responsible for the tumor's structure; access to blood vessels that fuel tumor growth; and several other different cell types that contribute to tumor development.

Immune cells, often referred to as tumor-infiltrating lymphocytes (TILs), are also found inside the tumor microenvironment. Because the tumor can control the cells inside the microenvironment, sometimes these TILs are tricked into becoming useless, or even becoming helpful to the tumor growth. For example, APCs within the environment may be confused by tumor cell signaling, preventing them from functioning properly, and making them incapable of sounding the alarm. In some cases, tumors are capable of upregulating (increasing) the activity of regulatory T cells inside the environment. This means that the regulatory T cells are actually working to reduce the immune response around the tumor by turning off the other T cells. It's as if the tumor recruits the body's own immune cells to fight off the attack, using the very mechanisms that normally protect the body. The longer the exposure to the tumor, the weaker the immune response becomes. Immunotherapy research focuses on identifying different ways tumors manipulate the immune system, and reversing them. ■

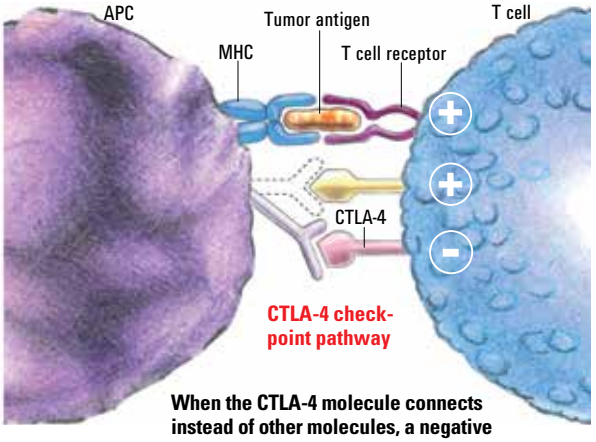
The delicate balance of these positive and negative signals regulates the strength and duration of the immune attack.

FIGURE 6
POSITIVE AND NEGATIVE SIGNALS

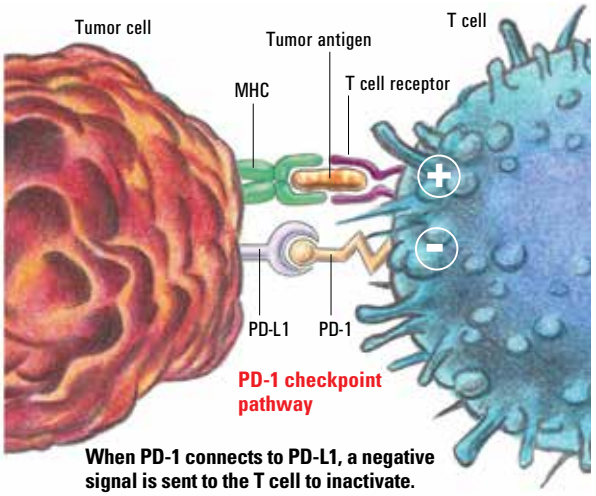


Positive signals are necessary to activate a T cell, and negative signals are necessary to shut it down. A molecule on one cell may have the ability to connect with different receptors on another cell. When the connection creates a positive signal, the immune response continues. Alternatively, if the connection creates a negative signal, the immune response begins to shut down. The delicate balance of positive and negative signals regulates the strength and duration of the immune response.

FIGURE 7
CHECKPOINT PATHWAYS



When the CTLA-4 molecule connects instead of other molecules, a negative signal is sent to the T cell.



When PD-1 connects to PD-L1, a negative signal is sent to the T cell to inactivate.

IMMUNOTHERAPY STRATEGIES

Immunotherapy is a type of cancer treatment that seeks to stimulate your own immune system to fight cancer. Because cancer cells have the ability to evade the immune system by using a number of clever techniques, immunotherapy is based on understanding these techniques and developing different strategies to restore the immune system's ability to destroy tumors. Immunotherapy is constantly evolving, differing from any previous "standard" treatment:

- **Chemotherapy** uses drugs to kill rapidly multiplying cells, which includes cancer cells but sometimes healthy tissue as well. The destruction of healthy cells and tissues often leads to the side effects commonly associated with this kind of treatment, including hair loss, nausea and vomiting, and low blood cell counts.
- **Radiation therapy,** which targets a specific region of the body, uses high-energy X-rays to destroy cancer cells. While often very effective, it's not guaranteed to kill all of the cancer cells and usually involves the destruction of nearby healthy tissue as well.
- **Surgery** to remove a tumor, although common, can be invasive and may leave behind cancer cells that have the potential to develop into new tumors.

Targeted therapy is another common treatment for some types of cancer. These drugs go after specific mutations in the DNA of cancer cells. Although targeted therapy has been shown to produce a dramatic response against cancer cells without harming normal cells, this type of treatment doesn't always totally destroy the cancer. Cancer cells have the ability to adapt and develop alternative ways to grow, essentially becoming resistant to the treatment over time. Tumors may shrink or disappear, but remaining cells that are able to adapt may begin growing again.

Immunotherapy is fundamentally different from these other treatments because it focuses on activating the immune system to fight cancer wherever it may be, and uses the body's own immune cells and mechanisms to destroy the cancer. Because the immune system can be activated broadly against cancer cells throughout the body, it's more difficult for cancer cells to hide from therapy or develop ways to escape destruction.

Immunotherapy also has the potential to remain effective for long intervals far beyond the end of treatment—a feature called "memory." This feature is the same one that allows a tetanus vaccine, for example, to remain effective for many years. In cancer patients, this effect can lead to long-term, cancer-free remission and increased overall survival. Because it's less likely that immunotherapy will affect healthy tissues and cells, side effects may be less common and either less severe or more easily treatable. As with any treatment, however, there are still associated risks that should be discussed with your doctor (see page 14).

Immunotherapy may be an option alone or in combination with other treatments, including traditional treatments and other immunotherapies. Several different immunotherapy strategies are currently being studied or used as cancer treatment.

MONOCLONAL ANTIBODIES

One of the body's natural immune responses to foreign substances is the creation of antibodies specific to the antigens found on the surface of invaders. Monoclonal antibodies (mAbs) are manmade antibodies engineered to target specific tumor antigens. They work in a few different ways:

- **Flagging targeted cancer cells for destruction** – The mAb acts as a flag that attaches to parts found only on the surface of specific cancer cells, marking them for destruction by other immune cells.
- **Blocking growth signals and receptors** – Some mAbs are engineered to block the mechanisms that cancer cells use to grow, such as access to the blood vessels necessary for growth.
- **Delivering other therapeutic agents directly to targeted cancer cells** – The mAbs can be engineered to carry cancer drugs, radiation particles or manmade cytokines (chemical messengers) directly to cancer cells. When a mAb is combined with a toxin, it travels through the system until it reaches the targeted cancer cell, where it attaches to the surface, gets swallowed by the tumor cell and then breaks down inside the cell, releasing the toxin and causing cell death (Figure 1). Combining mAbs with radiation particles, a treatment known as radioimmunotherapy, allows for radiation to be delivered in lower doses over a longer period of time directly to specific cancer cells. This direct form of delivery typically damages only the targeted cells.

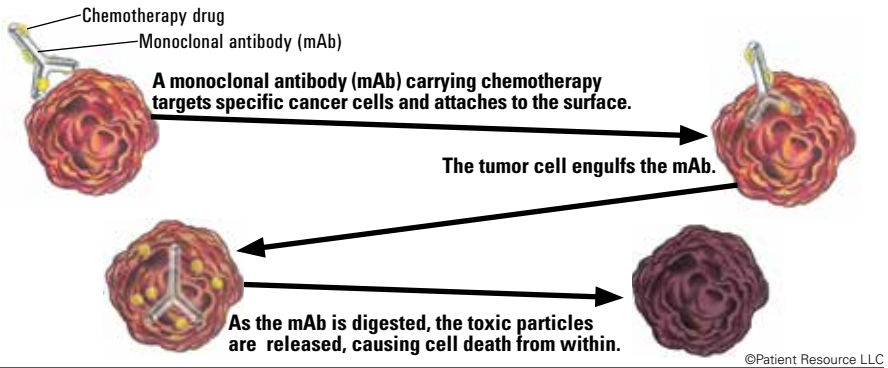
NON-SPECIFIC IMMUNE STIMULATION

Non-specific immune stimulation involves giving the immune system an overall boost, and it can be used alone or in combination with other treatments in order to produce increased and longer-lasting immune responses. Different types of non-specific immune stimulation include:

- **Cytokine immunotherapy** – Cytokines are the messengers of the immune system, aiding in communication among immune cells and playing a big role in the full activation of an immune response. Cytokine immunotherapy treatments involve introducing large amounts of manmade cytokines to the immune system to promote specific immune responses:
  - Interleukins are cytokines that help regulate the activation of certain immune cells. The drug IL-2 (Proleukin) is currently used in the treatment of multiple cancers, and several molecules similar to IL-2 are being developed.
  - Interferons are cytokines that boost the ability of certain immune cells to attack cancer cells, and have been developed into the drug interferon alfa (Intron A).
  - GM-CSF (granulocyte-macrophage colony stimulating factor) is a cytokine that stimulates the bone marrow, promoting immune and blood cell growth and

FIGURE 1

DELIVERING THERAPEUTIC AGENTS TO CANCER CELLS WITH MONOCLONAL ANTIBODIES



dendritic cell development. The drug sargramostim (Leukine) is currently being used and studied as a boost when given with other types of immunotherapy.

■ **Modified bacteria** – Bacillus Calmette-Guerin (BCG), approved to treat bladder cancer, is tuberculosis bacteria modified to ensure they will not spread disease. Treatment causes inflammation in the bladder that stimulates an immune response and guides immune cells to the bladder.

■ **Toll-like receptor agonists** – The immune system often detects germs through a series of receptors (called toll-like receptors) found on the surface of most immune cells. When these toll-like receptors "see" patterns in bacteria or viruses, they produce a signal that activates the immune cell to attack. Several of these specialized receptors have been evaluated for use in cancer, and one such agent, imiquimod (Aldara, Zyclara), binds to specific toll-like receptors, resulting in an immune response that kills cancer cells in patients with basal cell carcinoma and possibly other early-stage skin cancers.

CANCER VACCINATIONS

Cancer vaccines are treatments created from either modified viruses or tumor cells, engineered to direct immune cells to the cancer cells. In some cases these vaccines are developed from a patient's own tumor, but usually they are "off-the-shelf" and contain one to more than 100 antigens that are common to the patient's type of cancer. There are two types of cancer vaccines: prophylactic vaccines used to prevent the viruses that cause cancers, and therapeutic vaccines used to treat existing cancers. Currently, prophylactic vaccinations are available for the human papillomavirus (HPV), the cause of many cervical, anal, and head and neck cancers, and hepatitis B (HBV), a known risk factor for liver cancer.

Therapeutic cancer vaccinations include:

■ **Tumor cell vaccines** – These are made from tumor cells that are similar to a patient's cancer type. (These vaccines are made from a patient's own tumor only in rare cases.) In some cases the tumor cells are genetically engineered to express a new property, or treated with drugs that make the tumor cells or their components easier for the immune system to recognize. The vaccines are treated with radiation to prevent spreading and are then injected back into the body to help the immune system recognize any remaining cancer cells.

■ **Antigen vaccines** – These vaccines are typically made from one to five of the antigens that are either unique to or overexpressed by tumor cells. They may be specific to a certain type of cancer but are not patient-specific.

■ **Dendritic (or APC) cell vaccines** – These are made from white blood cells extracted from the patient. The cells are sent to a lab, exposed to chemicals that turn them into dendritic cells, and then exposed to tumor antigens so that they'll transform into matured APCs. When they're injected back into the patient, they share the antigen information with the T cells, and any other cells that release that specific antigen are targeted and destroyed. Sipuleucel-T (PROVENGE) is an FDA-approved drug consisting of dendritic cells exposed to a prostate cancer antigen and combined with GM-CSF cytokines. These matured APCs are injected into the body to help train the immune system to recognize and destroy prostate cancer cells.

■ **Vector-based vaccines** – These are made from altered viruses or bacteria that are injected into the body to create an immune response, both specific and overall. Tumor-specific vectors are genetically modified to train the immune system to recognize, target and destroy cancer cells. One vector-based vaccine currently being studied to treat leukemia is an HIV virus (modified to no longer cause disease) that targets B cells, the cells primarily affected by leukemia.

ONCOLYTIC VIRUS IMMUNOTHERAPY

Oncolytic virus immunotherapy is the use of viruses to directly infect tumor cells and induce an immune response against those infected cells. One of the most-studied approaches uses a modified, weakened version of the herpes simplex virus called talimogene laherparepvec (TVEC), which also contains the cytokine GM-CSF. The virus targets specific cancer cells, infects them and replicates continuously within the cell until it ruptures. This kills the cell and releases the GM-CSF protein induced by the virus to promote an overall immune boost against the cancer. This increases the chance that the attack can also begin killing cancer cells that have not been infected with the virus.

IMMUNE CHECKPOINT INHIBITORS

Immune checkpoint pathways are specific connections between molecules on the surfaces of immune cells – specifically between antigen-presenting cells and T cells, or between T cells and tumor cells – that help regulate the immune response. Some tumor cells have proteins on their surface that bind to activated immune cells and inhibit their function. This connection effectively puts the brakes on the attack (known as tumor-induced immunosuppression).

Immune checkpoint inhibitors are drugs that block the checkpoint from being engaged, which essentially turns the immune response back on. Immune checkpoint inhibitors currently being used to treat cancer include:

■ **Anti-CTLA-4** – CTLA-4 is a protein receptor found on the surface of T cells. When activated, CTLA-4 is capable of suppressing the immune system response. Anti-CTLA-4 antibodies block the connection necessary to engage this protein, allowing the T cells to continue fighting cancer cells, rather than shutting down the immune response.

■ **Anti-PD-1** – The PD-1 checkpoint pathway is another pathway for putting the brakes on the T cells. When the PD-1 receptors on the surface of T cells connect with the PD-L1 molecules on the surface of cancer cells or other immune cells, signals are sent to the T cells to dampen the response. Anti-PD-1 drugs block the connection necessary to engage this protein, allowing the T cells to continue their response against the cancer cells.

■ **Anti-PD-L1** – Cancer cells have the ability to make certain molecules appear on the surface, including PDL-1 and PDL-2 of the PD-1 checkpoint pathway. Cancer cells may also cause immune cells near the cancer to express PD-L1. These molecules bind to the PD-1 on the T cells and turn them off.

ADOPTIVE T CELL TRANSFER (T CELL THERAPY)

Adoptive T cell transfer focuses on enhancing the body's own T cells to fight cancer. There are two main types of adoptive immunotherapy. One type involves the doctor isolating T cells from a patient's tumor (tumor-infiltrating lymphocytes, or TIL), expanding them to large numbers, and then administering them to patients. In the second strategy, T cells collected from the patient are engineered with new receptors (chimeric antigen receptor T cells, or CAR-T) to recognize specific antigens on the surface of cancer cells, and then infused back into the patient. In both cases the T cells multiply, seek and destroy the cancer cells that carry those specific antigens.

This type of immunotherapy treatment is still investigational and available only through clinical trials. Studies have shown promise in the treatment of leukemia, lymphoma, metastatic melanoma, neuroblastoma and synovial cell sarcoma. ■

TIMELINE OF IMMUNOTHERAPY

2015
- Nivolumab (Opdivo) is the first checkpoint inhibitor approved for lung cancer.
- Ramucirumab (Cyramza) is approved for metastatic colorectal cancer.

2014
- Blinatumomab (BLINCYTO), a monoclonal antibody, is approved for ALL.
- Nivolumab (Opdivo), a PD-1 inhibitor, is approved for advanced melanoma.
- Pembrolizumab (Keytruda) is the first PD-1 inhibitor approved for advanced melanoma.
- Ramucirumab (Cyramza), a monoclonal antibody, is approved for advanced gastric and lung cancers.

2013
- The first phase III trial of oncolytic virus immunotherapy shows improvement in the long-term response rate in melanoma patients.
- The combination of agents targeting CTLA-4 and PD-1 checkpoints shows activity against melanoma.

2012
- Several clinical studies of T cell checkpoint inhibitors targeting PD-1 and PD-L1 demonstrate therapeutic activity in many types of cancers.

2011
- Pegylated interferon (PEG-Intron) is approved for adjuvant therapy of selected melanoma patients.
- Ipilimumab (Yervoy) is approved to treat advanced melanoma.

2010
- The first therapeutic cancer vaccine, sipuleucel-T (PROVENGE), is approved for advanced prostate cancer.
- Gemtuzumab ozogamicin is discontinued due to safety concerns and lack of benefit.

2009
- Anti-CD20 monoclonal antibody ofatumumab (Arzerra) is approved for CLL.

2006
- Panitumumab (Vectibix), a monoclonal anti-epidermal growth factor receptor antibody, is approved for colorectal cancer.

2004
- Cetuximab (Erbitux), a mAb, is approved for colorectal cancer.
- Monoclonal anti-vascular endothelial growth factor antibody bevacizumab (Avastin) is approved for colorectal cancer (the first of many types for this drug).

2003
- Tositumomab and Iodine I 131 tositumomab (Bexxar), a radioimmunotherapeutic regimen for CD-20 positive follicular lymphoma, is approved.

2002
- Ibritumomab tiuxetan (Zevalin), a mAb with a radioisotope, is approved for some non-Hodgkin lymphomas.

2000
- The drug gemtuzumab ozogamicin (Mylotarg), which combines a mAb and a toxin from the bacteria Micromonospora echinospora, is approved for AML.

1999
- Denileukin diftitox (Ontak), a fusion of IL-2 and diphtheria toxin, is approved to treat certain lymphomas.

1998
- IL-2 is approved to treat metastatic melanoma.
- The mAb drug trastuzumab (Herceptin) is approved to treat breast cancer.

1997
- The first monoclonal antibody (mAb), rituximab (Rituxan), is approved to treat B cell malignancies.

1996
- Interferon alfa-2b (Intron A) is approved for the adjuvant treatment of high-risk melanoma.

1992
- High-dose IL-2 is approved to treat metastatic kidney cancer.

1991
- Sargramostim (Leukine), a granulocyte macrophage-colony stimulating factor (GM-CSF), is approved to boost white blood cell counts.

1990
- Bacillus Calmette-Guerin is approved for bladder cancer.
- First treatment with genetically modified TIL.

1988
- First results for tumor-infiltrating lymphocytes (TILs) therapy are reported.

1986
- The Extramural IL-2/LAK Working Group is formed with funding from the National Cancer Institute to confirm results of the high-dose IL-2/LAK cell regimen in the treatment of melanoma and renal cell cancer.

1985
- Results from IL-2 and lymphokine activated killer cell (LAK) therapy in various tumors are first reported.
- Adoptive T cell transfers are studied as a possible cancer treatment.

1984
- Society for Immunotherapy of Cancer (formerly SBT) is founded.

1978
- Bacillus Calmette-Guerin (BCG) is first studied as a possible treatment;
- Interleukin-2 (IL-2) is discovered.
- Tumor-specific monoclonal antibodies (mAbs) are discovered.

1973
- Dendritic cells are identified as "antigen-presenting cells" (APCs).

1956
- Tumor-specific cell antigens are discovered.

1890
- **Dr. Coley creates the first immunotherapy treatment when he injects bacteria directly into inoperable tumors to stimulate an immune response that fights the cancer.**

HISTORY OF IMMUNOTHERAPY

Immunotherapy is a cancer treatment more than 100 years in the making, beginning most notably with Dr. William B. Coley, who worked with patients and doctors to study how cancer tumors reacted to bacterial infections. He treated cancer patients with inoperable tumors by injecting a combination of bacteria, which became known as Coley's Toxins, directly into their tumors. His results showed that this kind of treatment shrank the tumors and sometimes even cured the patient. He believed that the body's increased response to the bacteria also helped fight off the cancer.

In the modern era, Dr. Donald Morton was an early proponent of immunotherapy, particularly cancer vaccines. His work with bacillus Calmette-Guerin (BCG) for melanoma led to the use – and eventual approval – of BCG for bladder cancer, the first successful immunotherapy treatment against a human tumor.

While melanoma has often been difficult to treat using standard therapies, it's been one of the most responsive cancers to newly developed immunotherapy treatments. More and more patients are experiencing treatment success, including shrinking tumors, a reduced risk of the cancer coming back, and longer lives.

Typically, the standard of care for melanoma includes surgery as the main treatment for Stages 0 through III, and as a palliative (supportive) treatment to relieve symptoms of advanced disease. If cancer cells have spread or are likely to spread to lymph nodes in earlier stages of melanoma, treatment with immunotherapy after surgery may be recommended. Treatment for advanced stages of melanoma may include radiation, immunotherapy, targeted therapy or chemotherapy.

Since 2011, seven new melanoma treatments have been approved by the FDA, including four new immunotherapy drugs for advanced melanoma. These new therapies have resulted in significant advancements in the evolution of immunotherapy in melanoma and melanoma treatment in general.

The first immunotherapy for melanoma was interferon alfa-2b (Intron A), approved in 1996 as treatment after surgery for patients at high risk of the cancer coming back (recurrence). It's also currently used to treat some metastatic melanomas, either alone or in combination with other treatments. In 1998, interleukin-2 (Proleukin) was approved to treat metastatic melanoma, sometimes in combination with other treatments. Both of these treatments may be given in high doses to increase effectiveness. In 2011, peginterferon alfa-2b (SYLATRON), another type of cytokine therapy, was approved. Pegylated drugs stay in the blood longer than non-pegylated interferons, allowing fewer doses while maintaining or even increasing effectiveness. SYLATRON is approved as treatment after surgery to reduce the risk of recurrence in patients with metastatic melanoma. Side effects of cytokine treatments like these often include flu-like symptoms (fever, chills, tiredness, muscle or joint aches, nausea), mood changes, low blood cell counts and buildup of bodily fluids.

There are currently three immune checkpoint inhibitors approved to treat patients with advanced melanoma: the anti-CTLA-4 antibody ipilimumab (Yervoy), the anti-PD-1 antibody pembrolizumab (Keytruda), and the anti-PD-1 antibody nivolumab (Opdivo):

- **Ipilimumab (Yervoy),** an intravenous (IV) injection, was approved in 2011 as a first-line treatment for unresectable (unable to be removed surgically) or metastatic melanoma. It works by blocking the CTLA-4 checkpoint to allow a more lasting response against the cancer (Figure 1). Side effects for this drug often include diarrhea, fatigue, itching and skin rash.
- **Pembrolizumab (Keytruda) and nivolumab (Opdivo)** are IV injections, both approved in 2014 as second-line treatment for patients with metastatic melanoma who are no longer helped by ipilimumab and, if applicable, a BRAF inhibitor (if the patient's tumor contains the BRAF genetic mutation). These drugs work by blocking the PD-1 checkpoint, a secondary receptor that functions after the CTLA-4 checkpoint, in order to either maintain or shut down an immune response. Blocking this checkpoint provides a boost to the immune system, allowing the immune response to continue (Figure 2). Side effects for these drugs often include cough, constipation, decreased appetite, diarrhea, fatigue, itching, skin rash and joint pain.
- **Clinical trials** are also studying the effectiveness of combining CTLA-4 and PD-1 checkpoint inhibitor drugs to create a longer-lasting immune response against melanoma.

Additional immunotherapy treatments sometimes used to treat melanoma include the bacillus Calmette-Guerin (BCG) vaccine and imiquimod (Aldara, Zyclara) topical cream. Both cause an increased, general immune response inside or near the melanoma tumor. BCG, an altered tuberculosis virus, is sometimes injected directly into Stage III tumors to begin an immune response inside the tumor. Imiquimod cream is applied directly onto Stage 0 tumors to create an immune response near the surface of the skin where the melanoma cells are located. It's often used on sensitive areas where surgery to remove the melanoma may cause excessive scarring.

Immunotherapy is a major focus in cancer research and drug development. As newer treatments are discovered for multiple cancer types, including melanoma, they first become available in clinical trials for qualified patients (see page 16). Talk to your doctor to see whether a clinical trial is right for you. ■

FIGURE 1
CTLA-4 CHECKPOINT PATHWAY

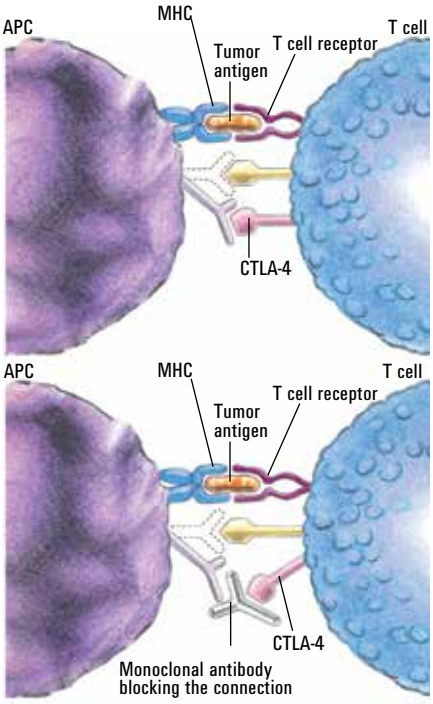


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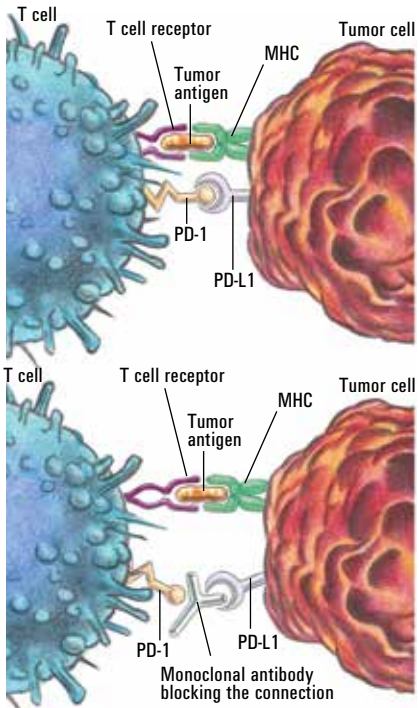
FIGURE 2
PD-1 CHECKPOINT PATHWAY



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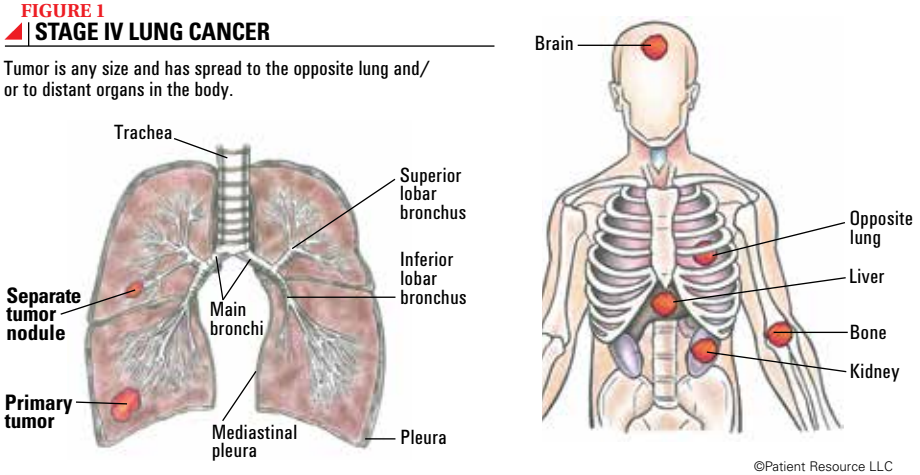
ADDITIONAL RESOURCES

- **Melanoma International Foundation:** www.melanomainternational.org
- **Melanoma Research Foundation:** www.melanoma.org

FIGURE 1
STAGE IV LUNG CANCER

Tumor is any size and has spread to the opposite lung and/or to distant organs in the body.



With the 2015 approval of the checkpoint inhibitor nivolumab (Opdivo) to treat lung cancer, the disease has emerged as an exciting new focus in the immunotherapy field. Previously, lung cancer wasn't believed to be immunogenic; in other words, it wasn't a cancer likely to cause an immune response. Recent trial results, however, have shown otherwise, and even the most mutated lung cancers have responded to anti-PD-1 therapy. This offers great promise to patients for whom traditional treatments have proven ineffective. Researchers have also begun studying the effect of immunotherapy on less heavily mutated lung cancers.

In addition to the monoclonal antibodies bevacizumab (Avastin) and ramucirumab (Cyramza), nivolumab is the third immunotherapy treatment approved for non-small cell lung cancer (NSCLC). This intravenous drug, used specifically for metastatic squamous NSCLC (Figure 1) that has progressed after a platinum-based chemotherapy (such as cisplatin or carboplatin), works by blocking the PD-1 checkpoint from engaging, allowing for a more effective immune attack against the cancer cells. Bevacizumab and ramucirumab are intravenous drugs that work by targeting the vascular endothelial growth factor (VEGF), a signaling protein that contributes to the growth of blood vessels within the tumor that are necessary for tumor growth. Bevacizumab is used in combination with carboplatin and paclitaxel as first-line therapy for unresectable, locally advanced, recurrent or metastatic disease. Ramucirumab is used in combination with docetaxel for metastatic NSCLC that has progressed during or after treatment with a platinum-based chemotherapy.

The standard treatments for lung cancer include surgery, chemotherapy and radiation. When possible, surgery is the primary treatment option for tumors caught early. When surgery is not possible, radiation may be used as the primary treatment. Chemotherapy, however, remains the primary treatment for all stages of small cell lung cancers, unless health or other medical conditions prevent it from being used.

Some patients with specific lung cancer biomarkers, including anaplastic lymphoma kinase (ALK), epidermal growth factor receptor (EGFR) and KRAS mutations, also respond to targeted therapy drugs. Researchers are also testing a new generation of biomarkers that hold promise for an even more tailored approach.

As an increasing number of clinical trials test the effectiveness of immunotherapy drugs in lung cancer (Table 1), additional options are becoming available. ■

TABLE 1
LUNG CANCER IMMUNOTHERAPY TREATMENTS IN CLINICAL TRIALS

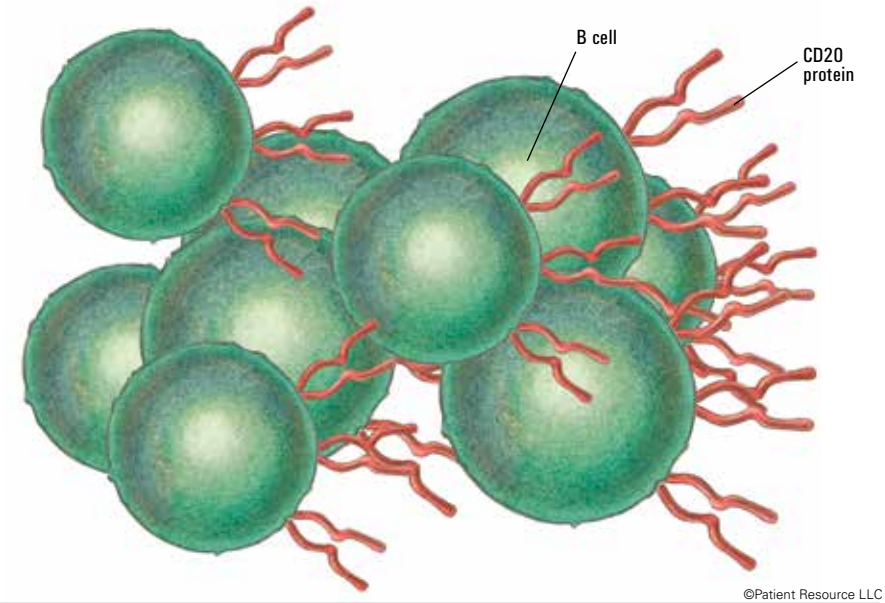
Treatment strategies	Clinical trials
Non-small cell lung cancer (NSCLC)	
Checkpoint inhibitors	• Anti-CTLA-4 antibodies, including ipilimumab (Yervoy)* and tremelimumab • Anti-PD-1 antibodies, including pembrolizumab (Keytruda)* and CT-011 • Anti-PD-L1 antibodies, including avelumab (PF-06834635, MSB0010718C), MPDL3280A and MEDI4736
Monoclonal antibodies	• cetuximab (Erbitux)*, which targets the epidermal growth factor receptor (EGFR) • bavituximab, which targets a molecule on tumor blood vessels • rilotumumab, which targets the hepatocyte growth factor (HGF)
Therapeutic cancer vaccines	• tergenpumatucel-L (HyperAcute), which consists of genetically modified lung cancer cells • GV1001, which is specific for a protein called telomerase • TG4010, which targets the antigen MUC1 • CV9202 RNActive-derived cancer vaccine, which consists of six different cancer antigens • DRibble (DPV-001), which is a DC targeted vaccine containing more than 100 antigens overexpressed by the average lung cancer, plus toll-like receptor (TLR) adjuvants • racotumomab (Vaxira), which is specific for an antigen found on the surface of tumor cells
Adoptive T cell transfer	• Transfer as treatment for patients with lung cancers expressing the NY-ESO-1 cancer antigen
Oncolytic virus therapy	• Reolysin, which uses a modified human reovirus (respiratory enteric orphan virus)
Small cell lung cancer (SCLC)	
Adjuvant immunotherapy	• MGN1703, a TLR
Checkpoint inhibitor	• ipilimumab (Yervoy)*, an anti-CTLA-4 antibody
Mesothelioma of the lung	
Adoptive T cell transfer	• Treatment for patients with cancers expressing the mesothelin antigen, including mesothelioma
Checkpoint inhibitor	• tremelimumab, which targets CTLA-4
Therapeutic cancer vaccine	• MVA-5T4 (TroVax), which targets an antigen called 5T4, for several types of cancer, including mesothelioma

*This drug is already approved for the treatment of a certain cancer (or cancers) and is being studied for additional uses or as part of different treatment combinations.

ADDITIONAL RESOURCES

- **International Association for the Study of Lung Cancer:** www.iaslc.org
- **LUNGevity Foundation:** www.lungevity.org

FIGURE 1
B CELLS AND CD20 PROTEIN



Lymphoma represents a group of blood cancers that develop from certain immune cells, including T cells, B cells and natural killer cells. The two most common types of lymphoma are Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL), and both have become major areas of focus in immunotherapy research.

NHL, which represents approximately 90 percent of all lymphomas, may be treated with chemotherapy, immunotherapy, targeted therapy, radiation and stem cell transplant, or a combination of treatments. HL, which makes up the remaining 10 percent, is most commonly treated with chemotherapy, radiation therapy or a combination of both. The type of treatment you receive depends on the type of lymphoma you have, the stage or category, and various other prognostic factors.

The first successful immunotherapy for lymphoma was the monoclonal antibody (mAb) rituximab (Rituxan), approved to treat NHL in 2012. It works by targeting proteins on the surface of B cells, specifically the CD20 protein (Figure 1), and is now the standard treatment for all B cell lymphomas. Other drugs that work similarly include alemtuzumab (Campath), brentuximab vedotin (Adcetris), ibritumomab tiuxetan (Zevalin), obinutuzumab (Gazyva) and ofatumumab (Arzerra). Monoclonal antibodies used to treat Hodgkin lymphoma include rituximab and brentuximab vedotin. Common side effects from monoclonal antibodies include chills, diarrhea, low blood pressure, headache, nausea, vomiting, rash and weakness.

Other immune-stimulating drugs that may be used to treat lymphoma include thalidomide (Thalomid) and lenalidomide (Revlimid). These drugs work by modifying immune system function, sometimes through altering levels of cytokines. They are more commonly used to treat multiple myeloma, however.

In 2014, the checkpoint inhibitor nivolumab (Opdivo) was granted FDA "Breakthrough Therapy" designation status for Hodgkin lymphoma. Breakthrough Therapy status is meant to help expedite the process of approving drugs that show promise in the treatment of serious or life-threatening conditions, especially for diseases that may otherwise have limited available treatment options. This designation was based on encouraging trial results that tested nivolumab alone or in combination with ipilimumab (Yervoy) for hematological cancers. Nivolumab is currently FDA-approved to treat melanoma and lung cancer.

Additional immunotherapy strategies being studied for lymphoma include adoptive T cell transfer, checkpoint inhibitors, monoclonal antibodies and therapeutic cancer vaccines (Table 1). ■

TABLE 1
LYMPHOMA IMMUNOTHERAPY TREATMENTS IN CLINICAL TRIALS

Treatment strategies	Clinical trials
Adoptive T cell transfer	• Chimeric antigen receptor (CAR) T cell therapy
Checkpoint inhibitors	• nivolumab (Opdivo, BMS-936558)*, an anti-PD-1 antibody for Hodgkin lymphoma • ipilimumab (Yervoy)*, an anti-CTLA-4 antibody • urelumab (BMS-663513, anti-4-1BB/CD137) • Anti-LAG-3 (BMS-986016) for hematologic cancers • CDX-1127 (varlilumab), an anti-CD27 antibody for adult patients with several cancers, including lymphoma • pembrolizumab (Keytruda, MK-3475)*, an anti-PD-1 antibody • PF-05082566, an anti-4-1BB/CD137 antibody for adult patients with non-Hodgkin lymphoma
Monoclonal antibodies	• KW-0761 (mogamulizumab), an anti-CCR4 antibody for patients with cutaneous T cell lymphoma and patients with adult T cell leukemia/lymphoma • Several anti-CD19 antibodies: MOR00208 for non-Hodgkin lymphoma, MEDI-551 for diffuse large B cell lymphoma and DI-B4 for patients with B cell lymphoma • milatuzumab (IMMU-115), an anti-CD74 antibody for non-Hodgkin lymphoma
Therapeutic vaccines	• dasiprotimut-T (BiovaxID), a vaccine for follicular non-Hodgkin lymphoma and potentially other B cell cancers • Imprime PGG for non-Hodgkin lymphoma • CDX-301 (anti-Flt3L) • Immunotransplantation for mantle cell lymphoma, using patient's own tumor cells activated with an immune modulator and used as a vaccine for patients in remission after chemotherapy

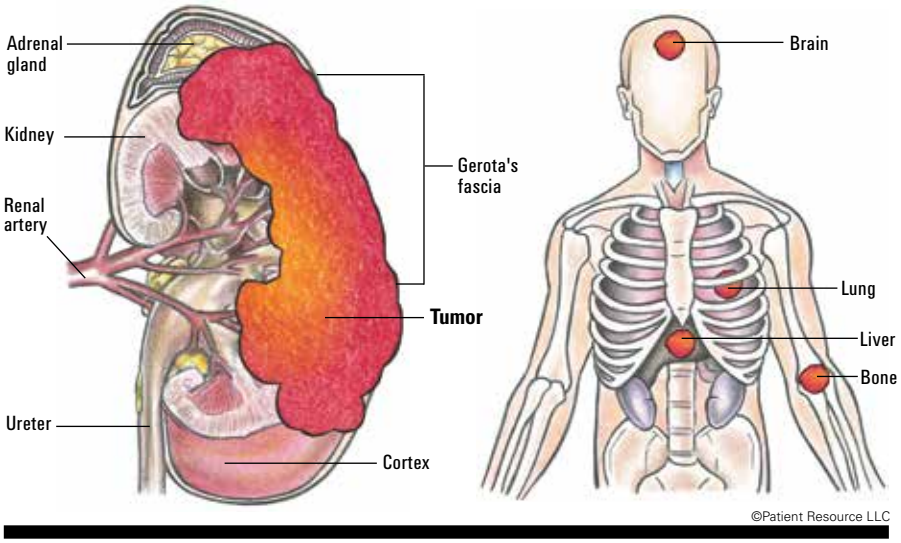
*This drug is already approved for the treatment of a certain cancer (or cancers) and is being studied for additional uses or as part of different treatment combinations.

ADDITIONAL RESOURCES

- **The Leukemia & Lymphoma Society:** www.lls.org
- **Lymphoma Foundation of America:** www.lymphomahelp.org
- **Lymphoma Information Network:** www.lymphomainfo.net
- **Lymphoma Research Foundation:** www.lymphoma.org

FIGURE 1
STAGE IV KIDNEY CANCER

The tumor may be any size and has likely spread to nearby lymph nodes and/or distant sites in the body.



Kidney cancer develops in the kidneys, most commonly in the lining of the tubules (very small tubes) inside the kidneys. This type of kidney cancer is known as renal cell carcinoma (RCC), which accounts for 90 percent of all diagnoses. Surgery is often the primary treatment for most kidney cancers, and ablative techniques (using heat or cold to destroy tumor tissue) may be used when surgery is not an option. Because kidney cancer is usually resistant to chemotherapy and radiation therapy, targeted therapy is typically the first line of treatment for advanced kidney cancer. This means the development of additional targeted therapies and immunotherapy treatments is extremely important in the fight against this disease.

Immunotherapy strategies already used to treat kidney cancer include the monoclonal antibody bevacizumab (Avastin), as well as treatment with cytokines. For more than a decade, the manmade cytokines interleukin-2 (Proleukin) and interferon-alfa (Intron A) have been used to shrink kidney tumors and reduce the risk of recurrence. The two drugs are used commonly and work by functioning as immune system messengers designed to elicit a desired response—for example, preventing cancer cell growth or making the cancer cells more susceptible to an attack. Side effects may be severe, especially with interleukin-2, so it's important to follow all instructions provided by your doctor regarding care during and following treatment. Common side effects include nausea, vomiting, diarrhea, loss of appetite, fever, chills, rash and fatigue.

Bevacizumab is an intravenous drug approved in 2009 for metastatic renal cell carcinoma (Figure 1). It works by targeting the vascular endothelial growth factor (VEGF), a signaling protein that contributes to the development of blood vessels within the tumor, which are necessary for tumor growth. It's usually given in combination with interferon-alfa.

Several of the immunotherapy treatment strategies in clinical trials for use against kidney cancer (Table 1) have shown success against other types of cancer, therefore leading researchers to anticipate an increased benefit for kidney cancer patients. ■

TABLE 1
KIDNEY CANCER IMMUNOTHERAPY TREATMENTS IN CLINICAL TRIALS

Treatment strategies	Clinical trials
Adoptive cell transfer	• Anti-VEGFR2 gene engineered CD8+ cells for metastatic cancer, including renal cancer • Therapy using natural killer (NK) cells in patients with advanced cancer, including kidney cancer
Cancer vaccines	• Dendritic cell immunotherapy AGS-003, plus standard treatment, for advanced RCC (ADAPT) • DCVax for solid tumors • Vaccine therapy, with or without sirolimus (Rapamune), for patients with NY-ESO-1 expressing solid tumors
Checkpoint inhibitors	• pembrolizumab (Keytruda, MK-3475)*, a PD-1 antibody for advanced urothelial cancer, including the renal pelvis; previously untreated advanced RCC; advanced RCC; and advanced, biomarker-positive solid tumors. • nivolumab (Opdivo)*, a PD-1 antibody, with ipilimumab (Yervoy), a CTLA-4 antibody, for patients with previously untreated advanced or metastatic RCC • MPDL3280A, a PD-L1 antibody, as monotherapy or in combination with bevacizumab for untreated advanced RCC • tremelimumab (anti-CTLA-4) and MEDI4736 (anti-PD-L1), for patients with advanced solid tumors, including RCC • varlilumab (CDX-1127), an anti-CD27 antibody for several cancers, including RCC • MGA217, an antibody that targets B7-H3, for refractory cancer, including RCC • SGN-CD70A, an antibody that targets CD70, for RCC • lirilumab, a KIR antibody, in combination with nivolumab (anti-PD-1) for advanced solid tumors • BMS-986016, a LAG-3 antibody, with or without nivolumab (anti-PD-1), for solid tumors • urelumab, a 4-1BB/CD137 antibody, for advanced cancers • MSB0010718C, a PD-L1 antibody, for solid tumors • TRX518, a GITR antibody, for advanced cancer • MK-4166, a GITR antibody, for advanced cancer
Cytokines	• AM0010, a recombinant human interleukin-10 (IL-10), for advanced solid tumors, including RCC • interleukin-15 (IL-15) for select cancers, including kidney cancer; and for advanced cancers • interleukin-12 (IL-12) for solid tumors
Monoclonal antibodies	• Anti-VEGFR2 gene engineered CD8+ cells for metastatic cancer, including RCC • Therapy using natural killer (NK) cells in patients with advanced cancer, including kidney cancer

*This drug is already approved for the treatment of a certain cancer (or cancers) and is being studied for additional uses or as part of different treatment combinations.

ADDITIONAL RESOURCES

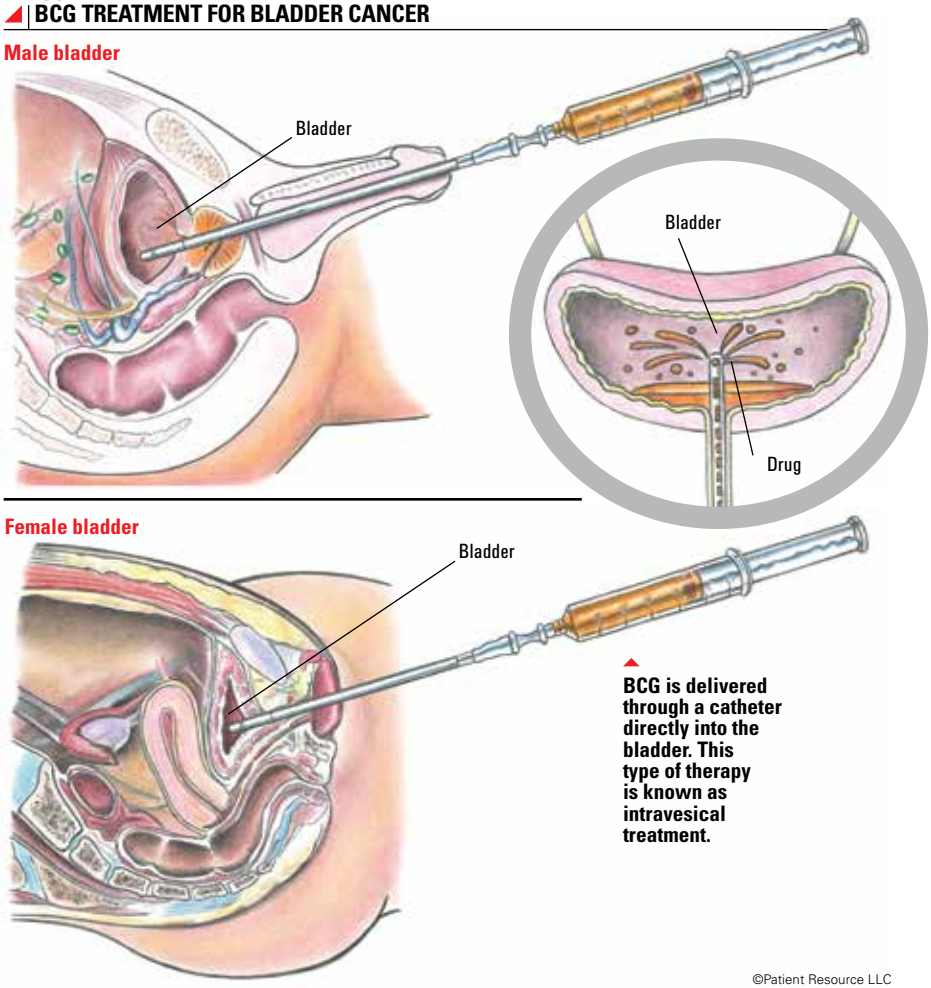
- **Action to Cure Kidney Cancer:** www.ackc.org
- **American Cancer Society:** www.cancer.org *Kidney Cancer*
- **Kidney Cancer Association:** www.kidneycancer.org
- **National Kidney Foundation:** www.kidney.org

The first immunotherapy drug approved to treat any cancer was the modified tuberculosis bacteria called bacillus Calmette-Guerin (BCG). Approved in 1990, the intravesical (delivered through a catheter directly into the bladder) treatment is used for early-stage bladder cancer, and as treatment to reduce the risk of recurrence in noninvasive bladder cancers, commonly after surgery to remove the tumors. Treatment with BCG is proven to increase the chance of a complete response after surgery. As a type of nonspecific immune stimulation, BCG is injected into the bladder to cause inflammation that results in an immune response (Figure 1). By bringing the response directly to the bladder, the immune cells also come into contact with and eliminate any remaining bladder cancer cells.

In addition to BCG, atezolizumab (MPDL3280A), an experimental PD-L1 checkpoint inhibiting drug, was given "Breakthrough Therapy" designation for bladder cancer in June 2014 by the FDA. Breakthrough Therapy status is meant to help expedite the process of approving drugs that show promise in the treatment of serious or life-threatening conditions, especially for diseases that may otherwise have limited available treatment options. This designation was based on promising results from a trial targeting the overexpression of the PD-L1 protein on tumor cells, which is a counterpart to the more commonly known PD-1 protein. This drug blocks the connection between PD-1 on the T cell and PD-L1 on the tumor cell to prevent the resulting negative signal that can prematurely shut down an immune response against the cancer.

Although bladder cancer was the first cancer type with an approved immunotherapy drug, other treatment advancements have been slow for this disease. No new drugs have been approved for bladder cancer since 1998, and with no routine screening – and symptoms that are far too easily attributed to common ailments – many patients are diagnosed after the cancer has progressed to an advanced stage. And to date, there are no FDA-approved second-line chemotherapy drugs for patients with metastatic bladder cancer. However, with several drugs in clinical trials (Table 1), immunotherapy continues to show promise for additional bladder cancer treatment options in the near future. ■

FIGURE 1
BCG TREATMENT FOR BLADDER CANCER



BCG is delivered through a catheter directly into the bladder. This type of therapy is known as intravesical treatment.

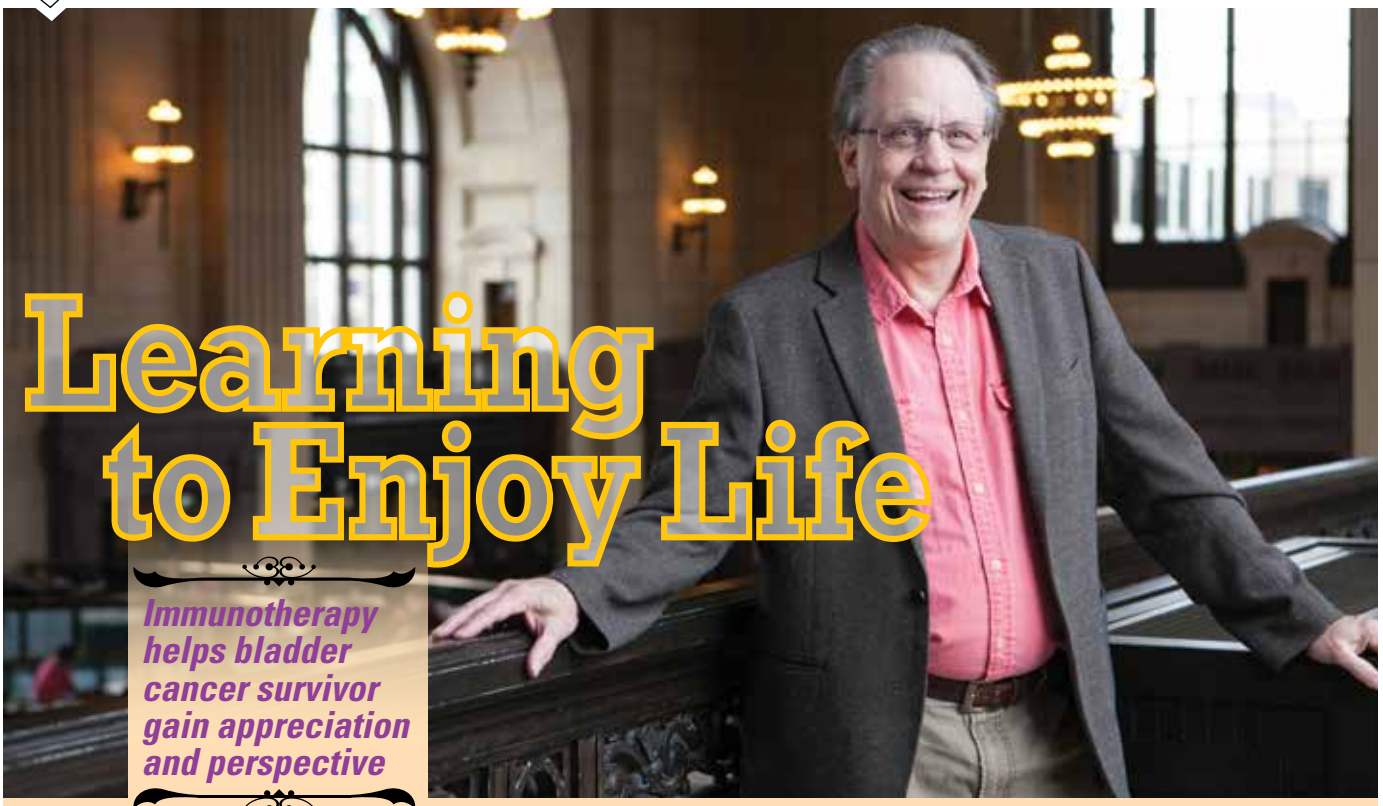
TABLE 1
BLADDER CANCER IMMUNOTHERAPY TREATMENTS IN CLINICAL TRIALS

Treatment strategies	Clinical trials
Checkpoint inhibitors	• MPDL3280A, an anti-PD-L1 for metastatic bladder cancer • nivolumab, an anti-PD-1 antibody, and ipilimumab (Yervoy)*, an anti-CTLA-4 antibody, for patients with several different types of cancers, including bladder cancer
Monoclonal antibodies	• ALT-801, a fusion of the cytokine interleukin-2 (IL-2) and an antibody that recognizes peptides on the surface of tumor cells • ALT-801 in combination with gemcitabine (Gemzar)* for non-muscle invasive bladder cancer; in combination with gemcitabine and cisplatin* for muscle invasive bladder cancer
Oncolytic virus therapy	• CG0070, an oncolytic adenovirus, with GM-CSF for carcinoma in situ (CIS) of the bladder, or non-muscle invasive bladder cancer plus CIS of the bladder
Therapeutic vaccines	• HS-410, a therapeutic vaccine made from a human bladder cancer cell line irradiated and engineered to express soluble gp96, a chaperone protein for high-risk, non-muscle invasive bladder cancer • DEC-205-NY-ESO-1, a fusion protein vaccine, with or without the biological therapy sirolimus (Rapamune) for a variety of solid tumors, including recurrent and metastatic bladder cancer

*This drug is already approved for the treatment of a certain cancer (or cancers) and is being studied for additional uses or as part of different treatment combinations.

ADDITIONAL RESOURCES

- **Action on Bladder Cancer:** www.actiononbladdercancer.org
- **American Bladder Cancer Society:** www.bladdercancersupport.org
- **Bladder Cancer Advocacy Network:** www.bcan.org
- **Bladder Cancer Webcafe:** www.blcwebcafe.org
- **United Ostomy Associations of America Inc.:** www.ostomy.org



Learning to Enjoy Life

Immunotherapy helps bladder cancer survivor gain appreciation and perspective

I knew it wasn't normal when I saw blood in my urine. I went to see my doctor, who put a scope into my bladder. It was pretty easy to diagnose after that.

I had an idea of what it was before I was given my official diagnosis. I'd been doing some research on the symptoms and happened across a cancer forum where a woman told me I had exactly the same symptoms as her mother. I was 55 and had high-grade, superficial transitional cell carcinoma (TCC) of the bladder. A CT scan immediately following the scope confirmed I also had tumors in my right kidney and right ureter.

I didn't get a second opinion right away. My urologist was very informative, and I could understand what he was telling me. The cancer in the bladder wasn't invasive; it hadn't gone into the muscle. He suggested a transurethral resection of the bladder (TURB) to scrape the superficial tumors off the bladder wall. I was in the hospital for three days. This surgery was followed by an instillation of chemotherapy injected directly into my bladder.

A second surgery removed my kidney and ureter, and I was in the hospital for four days. I tried to tell people not to visit until I got home because I knew how I'd feel, but they came anyway—and I appreciated the support. After the surgeries, I received bacillus Calmette-Guerin (BCG) with interferon alfa (Intron A), a type of immunotherapy. It was injected directly into my bladder, just like the chemo. It seemed like I had a lot of treatments over the years, but my doctor followed all of the protocol for that treatment regimen. The maintenance therapy finally ended a couple of years ago.

For quite some time, I didn't have a lot of strength and felt pretty uncomfortable. Physically, you're not going to feel like your old self for a while. And getting poisons pumped into your bladder burns a bit; it might throw some people for a loop. I haven't had any noticeable, lasting effects, though. I do get the occasional muscle cramp in my side where the incision was, but beyond that I feel fine. As for follow-up care, because my doctor told me my remaining kidney functions at around 50 percent, I underwent an annual kidney and bladder scope for several years to be sure there was no recurrence. Unfortunately, I couldn't have PET scans because the contrast medium could damage my remaining kidney. It's still functioning, and I plan to keep it that way.

I've stuck with my doctor all these years because he was always very open to talking about other options. He actually helped me coordinate a visit with another doctor after surgery for another opinion. That doc told me, "The bladder will come out." At first it made me question the procedures I'd already had done. But I haven't had the need to remove my bladder yet, and it's been 10 years. I'm always aware the cancer could return, but I enjoy every day as much as I can and try not to worry. For a while it might be like a record playing over and over in your head, but eventually it'll subside. If it doesn't, I definitely recommend talking to someone.

When I had symptoms – and after the official diagnosis – I did a lot of self-educating. One of the most helpful sites I found was www.acor.org (Association of Cancer Online Resources). They connected me with forums and research I found extremely helpful. I firmly believe that you're in charge of your own education. You have to ask the questions, look for the answers and do your research. If you find yourself overwhelmed by all of the information available, shut it down for a while. You may have to take a step back and sift out what it is that you want to know because there are many different layers of information.

When you visit the doctor, take notes. I recommend bringing someone along to do the note taking—preferably someone who will also pursue the questions because you'll be a little bit dazed. Also, find other survivors! They can tell you firsthand what they've been through and how they coped with it. Finally, leave room in your life for the small things. For me, those are the ski trips I try to take every year now, and being able to volunteer at the Komen 3-Day walk in the Twin Cities each summer. They often matter the most but are the easiest to overlook when you're in the middle of a busy work schedule or raising a family. ■

DISCUSSION WITH YOUR DOCTOR

Be sure to discuss immunotherapy with your doctor to see if it's the best treatment option for your particular diagnosis, or if there's any added benefit to including immunotherapy as a part of your comprehensive cancer care. Below are some topics you should discuss and information to help you begin the conversation:

What makes immunotherapy so different from other treatments?

Immunotherapy activates your body's own immune cells to find and attack cancer cells. Every day the immune system fights off viruses and infections, but because cancer is so similar to normal cells, the immune system's typical response may not work. Different types of immunotherapy trigger the body's immune system in different ways to find and destroy the cancer.

Is it like chemotherapy?

No. Immunotherapy is a completely different method of treatment. Unlike chemotherapy, which uses powerful drugs to kill rapidly multiplying cells, immunotherapy focuses on re-engaging the immune system so that it recognizes and kills only specific cancer cells.

What are the possible side effects?

With immunotherapy, cancer cells are targeted and destroyed by the body's own immune system rather than by drugs or radiation. Because of this, damage to healthy tissue is often less than with other therapies. This means immunotherapy doesn't normally cause many of the side effects commonly associated with standard cancer treatments. However, flu-like symptoms, infusion reactions, rashes, and moderate to severe diarrhea have been reported with the use of some immunotherapy drugs. And because immunotherapy can activate the immune system, there is a risk that certain immunotherapy drugs may cause more serious autoimmune reactions, known as immune-related adverse events (IRAEs), when the immune system reacts against normal body organs. However, most side effects associated with immunotherapy are easily managed if treated early, so be sure to talk to your doctor before treatment begins about what to expect, and carefully monitor how you feel during and after treatment.

Is immunotherapy right for me?

Some immunotherapy treatments are patient-specific and depend on the exact type of cancer you have, and your doctor will need to determine your eligibility based on treatment criteria. Participation in an immunotherapy clinical trial will also have specific qualification guidelines, which may include diagnosis, general health and treatment history. Because cancer immunotherapy is dependent on a functioning immune system, it will likely be important that you not have any autoimmune disorders and are not taking any chronic immunosuppressive medications. Be sure to discuss all of your available treatment options with your doctor to determine the best treatment for your specific diagnosis. Immunotherapy may be considered as treatment alone or in combination with other treatments (including other immunotherapies).

How are immunotherapy treatments administered?

Your treatment regimen will depend on the treatment you receive. For example, the immunotherapy cancer vaccine sipuleucel-T (PROVENGE) requires biweekly visits – one for collecting the immune cells and another for the intravenous vaccination injection – every other week, for three injections. Typically, immunotherapy treatments are given intravenously and may require specialized centers with physicians and staff members who have been trained in the delivery of specific immunotherapy drugs. If you're participating in a clinical trial, you may be required to receive your treatments in a specific facility on a very strict regimen. Some treatments require being hospitalized, while others can be given safely in an outpatient clinic or doctor's office.

How long until we know whether treatment is effective?

Immunotherapy is different from other cancer treatments, so measuring results can also be different. The effectiveness of standard treatments is typically measured in both progression-free survival and overall survival. With chemotherapy, an increase in tumor size or the presence of new tumors is considered disease progression and often means the treatment isn't working. With immunotherapy, however, the immune system needs time to mount an effective immune attack, which may result in a delayed response. During this time, tumors may continue to grow or new tumors may appear before the body can effectively target and destroy the cancer cells. As a result, many immunotherapy treatments may not show a significant increase in progression-free survival but over time may offer more long-lasting and life-extending benefits.

The duration of your treatment will depend on the specific treatment type and your individual response to the medication. Some patients may need to continue treatments over an extended period of time in order to keep the immune system engaged. Some immunotherapy treatments, however, have shown responses that last beyond the end of treatment. You should discuss your response with your doctor and remember that sometimes an effect on the cancer may take several weeks or even months.

What if I've already tried several therapies?

Like many cancer patients, you may have already received one or more treatments, or have already enrolled in a clinical trial. This doesn't necessarily mean you won't have success with additional treatments or trials. In fact, several immunotherapy treatments and trials are intended for patients whose cancer has progressed or recurred after first- or second-line therapies. ■

ADDITIONAL RESOURCES

- **American Cancer Society:** www.cancer.org
- **TheAnswertoCancer.org:** www.theanswertocancer.org
- **Cancer*Care*:** www.cancercare.org
- **Cancer Research Institute:** www.cancerresearch.org
- **Cancer Support Community:** www.cancersupportcommunity.org
- **Patient Resource:** www.PatientResource.com
- **Society for Immunotherapy of Cancer:** www.sitcancer.org

GLOSSARY OF TERMS

QUICK REFERENCE GUIDE

The Immune System and Immunotherapy

Antibody – A protein created by B cells in direct response to specific antigens. An antibody attaches itself to its respective antigen, marking it for other immune cells to "see" and destroy.

Antigen – Commonly a protein produced by a cell, virus or bacteria. In the case of cancer antigens, the protein or part of a protein is on the surface of the cancer cell or substance that alerts the immune system. This causes the production of antibodies or creates T cells that can recognize and potentially destroy the cancer cell expressing that antigen.

Antigen-presenting cells (APCs) – Special cells that digest harmful materials in the body to "show" to the T cells and B cells so they know what to attack.

B cells – Immune cells responsible for producing antibodies for specific antigens that will bind to the antigens and mark them for destruction by other immune cells.

Biological product – Biological products are medications made from living organisms, such as vaccines, human cells and tissues and gene therapies.

Biosimilar – A biosimilar is a product approved as an alternative to an FDA-approved biological product based on its similarities and meeting standards for interchangeability, with no clinically meaningful differences between the two. The first FDA-approved biosimilar is filgrastim-sndz (Zarxio), approved in 2015.

Cancer cells – Cells with damaged DNA that causes mutations in normal cell growth and division. New cancer cells grow uncontrollably and old cancer cells don't die when they should, resulting in a malignant tumor.

Co-stimulatory signal – The second stimulation required for T cells to become fully activated (Signal 2).

CTLA-4 (cytotoxic T lymphocyte associated antigen 4) – A protein receptor found on the surface of T cells. This protein is part of the CTLA-4 checkpoint pathway, which can shut down an immune system response in its early stages. Certain cancer cells have the ability to engage this checkpoint, which stops the immune response against the cancer cells.

Cytokines – Proteins released by immune cells to communicate with other immune cells; certain cytokines, such as interferon and interleukin, help regulate specific immune system functions.

Dendritic cell (DC) – A type of antigen-presenting cell responsible for processing antigen material and presenting it to the T cells and B cells for activation. DCs are also able to help regulate other immune cells.

Downregulation – Reducing either the overall immune system response or the specific responses of certain immune cells.

GM-CSF (granulocyte-macrophage colony stimulating factor) – A protein responsible for stimulating bone marrow and promoting the growth of immune cells, especially dendritic cells. GM-CSF is currently used to restore white blood cells that have been depleted in chemotherapy patients, and is being used and studied as a treatment boost when combined with other immunotherapy treatments.

Immune cells – The cells of the immune system involved in defending the body against infectious disease and foreign invaders.

Immune checkpoint inhibitors – Drugs that block the activation of specific immune checkpoint pathways.

Immune checkpoint pathways – The system of checks and balances in place to prevent overactivation of the immune system. Different pathways function at different stages of the immune response to help regulate the length and intensity of T cell activity; engaging an immune checkpoint typically results in shutting down the immune system response.

Immunosuppression – Preventing the immune system from launching a successful attack to protect the body against infection and disease.

Immunotherapy – An innovative type of cancer treatment that focuses on using the body's own immune system to fight cancer.

Immune-related adverse events (IRAEs) – Autoimmune reactions that occur as a result of boosting the immune system. Severe reactions may include colitis, dermatitis and hepatitis.

Interferon – A protein released by immune cells that helps regulate different immune cell activity; types of interferon include alfa, beta and gamma. Different types help regulate different functions, including prompting increased T cell activity, stimulating natural killer cells or affecting certain cell functions that influence tumor cell growth. Manmade versions of the IFN-alfa protein are currently FDA-approved to treat certain types of cancer.

Interleukin – A protein produced by cells of the immune system that helps regulate the production of certain immune cells, how they function during an immune response and their production of cytokines. The manmade version of this protein, aldesleukin (Proleukin), is currently FDA-approved to treat metastatic melanoma and metastatic renal cell carcinoma (kidney cancer).

Ligands – Protein molecules on the surface of a cell that bind to the receptor on the surface of another cell. Most ligands are signal-triggering molecules, which means they send out immune cell signals when engaged by a receptor. These signals help to regulate specific immune system functions.

Major Histocompatibility Complex (MHC) – A set of molecules on the surface of certain immune cells that influence the interaction of normal cells with immune cells. Antigen-presenting cells present digested antigens to T cells through the MHC molecules on their surface; this allows the T cell to "see" the antigen and recognize it as foreign when it sees the same antigen presented by MHC molecules on the surface of tumor cells. The MHC–T cell receptor (TCR) connection is the first signal necessary to activate the T cell to respond to a tumor and destroy it.

Memory cells – T cells and B cells from a specific immune reaction that continue to circulate the body even after the infection is resolved. They "remember" specific antigens and can multiple rapidly upon subsequent exposure, creating an immediate immune response already trained to eliminate the threat.

Monoclonal antibodies (mAbs) – Manmade antibodies engineered to target specific parts of cancer cells, which may include certain proteins or molecules on the surface of the cancer cells; they are meant to stimulate an immune response just as naturally produced antibodies do.

Natural killer cells – White blood cells that contain enzymes that kill virally infected cells and tumor cells. They also communicate with T cells to help regulate their development and response.

Oncolytic virus – Viruses that have the ability to infect and multiply within cancer cells, leading to cell death. These viruses are tumor-selective, may be engineered or naturally occurring, and can be used to target and destroy specific tumor cells. They may also induce an immune response.

PD-1 (programmed cell death-1) – The receptor in the PD-1 checkpoint pathway that sends negative signals to the T cell when it connects to a PD-L1 or PD-L2 ligand. These negative signals normally slow down or stop the immune response when it's no longer necessary. Certain cancer cells have the ability to influence the engagement of this checkpoint, which puts the brakes on the immune response.

Proliferation – Cell division and development (growth).

Receptors (immune receptors) – Proteins on the surface of immune cells that bind to ligands on the surface of other immune cells; this connection typically results in immune cell signaling that regulates specific immune system functions.

Regulatory T cells – T cells that help maintain the necessity, strength and duration of an immune response by regulating T cell activity. They shut down the other T cells at the end of an immune reaction. Certain tumor cells have the ability to increase regulatory T cell activity, which decreases the overall immune response.

Signal 1, Signal 2 – The primary and secondary cell signals necessary for the immune system to activate. Signal 1 is the MHC–TCR interaction between the antigen-presenting cell and the T cell; Signal 2 can be any number of connections formed by the molecules and receptors on the surfaces of both the APC and the T cell.

T cells – Immune cells responsible for recognizing specific antigens during antigen presentation; T cells are the major players in the immune system's fight against cancer. Their activation and activity are two of the main focuses in immunotherapy research.

T cell receptors (TCRs) – Molecules found only on the surface of T cells. TCRs must bind to special molecules on the surface of antigen-presenting cells before they can receive information about the threat. This connection is the first signal necessary to activate the T cell to respond to the tumor.

Tumor microenvironment – The area surrounding a tumor inside which normal cells, molecules and blood vessels help sustain the tumor. The microenvironment contributes to the behavior, proliferation and spread of the tumor; the tumor itself is capable of affecting its own microenvironment.

Upregulate – Increasing either the overall immune system response or the specific responses of certain immune cells.

ABOUT CLINICAL TRIALS

Prior to approval, new drugs being tested for safety and effectiveness are called "investigational" or "experimental" medications. Clinical trials are the controlled studies of these investigational drugs. The main goal of clinical trials is to validate a drug's safety and effectiveness, but they also help determine a variety of other factors, including the drug's associated side effects and recommended dosages. The results of clinical trials help the FDA decide whether to approve the drugs and release them for public use.

In some cases, patients may want to participate in a clinical trial to gain access to certain medications before they're officially approved by the FDA. Patients who participate in clinical trials are offered a number of benefits, including early access to potentially revolutionary new medications, playing an important role in advancing medical research, and receiving the very best standard of care with close monitoring by experts in the field.

Cancer immunotherapy clinical trials study ways to treat cancer through immunotherapy. There are currently hundreds of clinical trials in various stages studying innovative immunotherapy drugs as new treatments, in combination with other treatments or as new uses for already approved treatments. Without patient participation in clinical trials, the immunotherapy treatments that exist today wouldn't be available.

To qualify for a clinical trial, each patient must meet certain eligibility criteria. Cancer type, overall health and treatment history may be considerations, depending on the type or phase of the trial. Because cancer immunotherapy is dependent on immune system function, a properly functioning immune system is often a qualifying factor for immunotherapy trials. The clinical trial staff will be able to determine whether you are eligible to participate in a specific trial.

Current clinical trials with open recruitment as of June 11, 2015 are displayed on pages 16-33. Each trial listed is categorized as "cancer immunotherapy" on www.clinicaltrials.gov, and is either "Recruiting" or "Not yet recruiting," which means the studies are either actively recruiting participants or getting ready to start the recruiting process. The trial record number is a unique identification code assigned to each clinical study. You can find more information about a specific trial by entering the trial record number into the search box located at the top of each Web page.

CANCER IMMUNOTHERAPY CLINICAL TRIALS BY DISEASE

Includes all open and/or recruiting studies categorized as "cancer immunotherapy" (as of June 11, 2015) by the U.S. National Institutes of Health at www.clinicaltrials.gov.

ANAL

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Human Papillomavirus-Associated Cancers	Cervical Cancer; Oropharyngeal Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: Young TIL; Drug: aldesleukin	MD	NCT01585428
T Cell Receptor Immunotherapy Targeting HPV-16 E6 for HPV-Associated Cancers	Vaginal Cancer; Cervical Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: E6 TCR; Drug: aldesleukin	MD	NCT02280811

BLADDER

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
A Study of ALT-801 in Combination With Cisplatin and Gemcitabine in Muscle Invasive or Metastatic Urothelial Cancer	Transitional Cell Carcinoma of Bladder; Urethra Cancer; Ureter Cancer; Malignant Tumor of Renal Pelvis	Drug: cisplatin; Drug: gemcitabine; Biological: ALT-801	AZ; CA; FL; GA; IA; IL; KS; LA; MI; MO; NC; NY; OK; PA	NCT01326871
A Study of ALT-801 in Patients With Bacillus Calmette-Guerin (BCG) Failure Non-Muscle Invasive Bladder Cancer	Non-Muscle Invasive Bladder Cancer	Biological: ALT-801; Drug: gemcitabine	AL; CA; FL; NC; OK; PA	NCT01625260
A Phase I/II Study of HS-410 in Patients With Non-Muscle Invasive Bladder Cancer After TURBT	Bladder Cancer	Biological: HS-410; Biological: Placebo; Biological: BCG	CA; CO; IL; IN; KS; MA; MD; NC; SC; TX	NCT02010203
Study of Bacillus Calmette-Guerin (BCG) Combined With PANVAC Versus BCG Alone in Adults With High Grade Non-Muscle Invasive Bladder Cancer Who Failed At Least 1 Course of BCG	Bladder Cancer	Biological: TICE bacillus Calmette-Guerin (BCG); Biological: PANVAC	MD; NJ	NCT02015104
A Study of Intravesical Bacillus Calmette-Guerin (BCG) in Combination With ALT-803 in Patients With BCG-Naive Non-Muscle Invasive Bladder Cancer	Non-Muscle Invasive Bladder Cancer	Biological: ALT-803	HI	NCT02138734
Study of the Combination of ACP-196 and Pembrolizumab in Subjects With Platinum-Refractory Metastatic Bladder Cancer	Metastatic Bladder Cancer	Drug: pembrolizumab; Drug: ACP-196 in combination with pembrolizumab	NC; SC	NCT02351739

BRAIN

Title	Cancer Type	Treatment	Location	NCT Number
Study of a Drug [DCVax-L] to Treat Newly Diagnosed GBM Brain Cancer	Glioblastoma Multiforme; Glioblastoma; GBM; Grade IV Astrocytoma; Glioma; Brain Cancer; Brain Tumor	Drug: Dendritic cell immunotherapy	AR; CA; CO; DC; FL; GA; IL; IN; KS; MA; MI; MN; MO; NC; NJ; NY; OH; PA; RI; SC; TN; TX; WA	NCT00045968

BRAIN (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Basiliximab in Treating Patients With Newly Diagnosed Glioblastoma Multiforme Undergoing Targeted Immunotherapy and Temozolomide-Caused Lymphopenia	Malignant Neoplasms Brain	Biological: RNA-loaded dendritic cell vaccine; Drug: basiliximab	NC	NCT00626483
A Phase I Study of AdV-tk + Prodrug Therapy in Combination With Radiation Therapy for Pediatric Brain Tumors	Malignant Glioma; Recurrent Ependymoma	Biological: AdV-tk; Drug: valacyclovir; Radiation: Radiation	IL; MA	NCT00634231
Vaccine Immunotherapy for Recurrent Medulloblastoma and Primitive Neuroectodermal Tumor	Medulloblastoma; Neuroectodermal Tumor	Biological: TTRNA-xALT; Biological: TTRNA-DCs	FL	NCT01326104
Imiquimod/Brain Tumor Initiating Cell (BTIC) Vaccine in Brain Stem Glioma	Diffuse Intrinsic Pontine Glioma	Biological: Tumor lysate vaccine; Drug: imiquimod; Radiation: Radiation therapy	MN	NCT01400672
CAR T Cell Receptor Immunotherapy Targeting EGFRvIII for Patients With Malignant Gliomas Expressing EGFRvIII	Malignant Glioma; Glioblastoma; Brain Cancer	Biological: Anti-EGFRvIII CAR transduced PBL; Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide	MD	NCT01454596
Imiquimod and Tumor Lysate Vaccine Immunotherapy in Adults With High-Risk or Recurrent Grade II Gliomas	High-Risk WHO Grade II Glioma; Recurrent/ Post-Chemotherapy WHO Grade II Glioma	Biological: Tumor lysate vaccine; Drug: imiquimod	PA	NCT01678352
Derivation of Tumor Specific Hybridomas	Glioblastoma	Biological: Tumor vaccine	NH; VT	NCT01702792
NK White Blood Cells and Interleukin in Children and Young Adults With Advanced Solid Tumors	Solid Tumors; Brain Tumors; Sarcoma; Pediatric Cancers; Neuroblastoma	Biological: Recombinant human interleukin-15 (rhIL-15); Biological: NK cell infusion	MD	NCT01875601
Phase I Study of a Dendritic Cell Vaccine for Patients With Either Newly Diagnosed or Recurrent Glioblastoma	Glioblastoma; Glioblastoma Multiforme; Glioma; Astrocytoma; Brain Tumor	Biological: Dendritic cell vaccination, in addition to standard temozolomide chemotherapy and involved field radiation therapy; Biological: Dendritic cell vaccination, with optional bevacizumab treatment for patients previously treated with bevacizumab	CA	NCT02010606
Efficacy Study of Oral Arginine to Improve Immune Function in Glioblastoma Multiforme	Glioblastoma Multiforme	Drug: arginine in powder form	VA	NCT02017249
A Study of ICT-121 Dendritic Cell Vaccine in Recurrent Glioblastoma	Glioblastoma Multiforme	Biological: ICT-121 DC vaccine	CA	NCT02049489
Safety and Efficacy Study of SL-701, a Glioma-Associated Antigen Vaccine To Treat Recurrent Glioblastoma Multiforme	Adult Brain Glioblastoma; Glioblastoma Multiforme	Biological: SL-701; imiquimod cream 5%; Leukine 150 micrograms; Drug: imiquimod cream 5%; Drug: Leukine 150 micrograms	AZ; IL; MA; MI; NY	NCT02078648
RESIST: Patients With IDH1-Positive Recurrent Grade 2 Glioma Enrolled in a Safety and Immunogenicity Study of Tumor-Specific Peptide Vaccine	Brain Cancer; Brain Neoplasm, Primary; Brain Neoplasms, Recurrent; Brain Tumor; Cancer of the Brain	Biological: PEPIDH1M vaccine	NC	NCT02193347
DNX-2401 With Interferon Gamma (IFN-γ) for Recurrent Glioblastoma or Gliosarcoma Brain Tumors	Glioblastoma; Gliosarcoma	Drug: Single intratumoral injection of DNX-2401; Drug: interferon gamma	AR; FL; OH; TX	NCT02197169
Genetically Modified T Cells in Treating Patients With Recurrent or Refractory Malignant Glioma	Adult Anaplastic Astrocytoma; Adult Anaplastic Ependymoma; Adult Anaplastic Oligodendroglioma; Adult Brain Stem Glioma; Adult Ependymoblastoma; Adult Giant Cell Glioblastoma; Adult Glioblastoma; Adult Gliosarcoma; Adult Mixed Glioma; Adult Pineal Gland Astrocytoma; Recurrent Adult Brain Tumor	Biological: IL13Ra2-specific, hinge-optimized, 41BB-costimulatory CAR/ truncated CD19-expressing T lymphocytes; Other: Laboratory biomarker analysis; Other: Quality-of-life assessment	CA	NCT02208362
Phase II Study of MEDI4736 in Patients With Glioblastoma	Glioblastoma	Drug: MEDI4736; Radiation: Radiotherapy; Biological: bevacizumab	CA; MA; MD; MO; NY	NCT02336165
A Pilot Study to Evaluate PBR PET in Brain Tumor Patients Treated With Chemoradiation or Immunotherapy	Intracranial Tumors; Glioblastoma; Melanoma	Other: PBR PET; Biological: Cancer immunotherapy; Radiation: Radiation and chemotherapy	MA	NCT02431572
Using Ferumoxytol-Enhanced MRI to Measure Inflammation in Patients With Brain Tumors or Other Conditions of the CNS	Brain Injury; Central Nervous System Degenerative Disorder; Central Nervous System Infectious Disorder; Central Nervous System Vascular Malformation; Hemorrhagic Cerebrovascular Accident; Ischemic Cerebrovascular Accident; Primary Brain Neoplasm; Brain Cancer; Brain Tumors	Drug: ferumoxytol; Other: Tissue analysis; Procedure: Magnetic resonance imaging	CA	NCT02452216
Vaccine Therapy for the Treatment of Newly Diagnosed Glioblastoma Multiforme	Glioblastoma Multiforme; Glioblastoma; Malignant Glioma; Astrocytoma, Grade IV; GBM	Biological: pp65 DC with GM-CSF; Biological: Influenza DC with GM-CSF; Biological: PBMC with GM-CSF; Drug: Td; Drug: Saline	FL	NCT02465268

BREAST

Title	Cancer Type	Treatment	Location	NCT Number
Targeted T Cells After Neoadjuvant Chemotherapy in Treating Women With Stage II or III Breast Cancer Undergoing Surgery	Breast Cancer	Biological: HER2Bi-armed activated T cells; Drug: cyclophosphamide; Drug: doxorubicin hydrochloride; Drug: paclitaxel; Other: Laboratory biomarker analysis; Procedure: Neoadjuvant therapy; Procedure: Therapeutic conventional surgery	MI	NCT01147016

BREAST (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Vaccine Therapy in Treating Patients With Metastatic Solid Tumors	Malignant Solid Tumor; Breast Cancer; Malignant Tumor of Colon; GIST; Ovarian Cancer	Biological: HER2 vaccine	OH	NCT01376505
Toll-like Receptor (TLR) 7 Agonist, Cyclophosphamide, and Radiotherapy for Breast Cancer With Skin Metastases	Breast Cancer; Metastatic Breast Cancer; Recurrent Breast Cancer	Radiation: Radiation; Drug: imiquimod; Drug: cyclophosphamide	NY	NCT01421017
A Phase I Study To Evaluate The Antitumor Activity And Safety Of AVX901	HER2+ Cancer	Biological: AVX901	NC	NCT01526473
Pilot Study of a Breast Cancer Vaccine Plus Poly-ICLC for Breast Cancer	Breast Cancer	Biological: 9 peptides from HER2, CEA & CTA + poly-ICLC	VA	NCT01532960
Combination Immunotherapy With Herceptin and the HER2 Vaccine NeuVax	Breast Cancer	Drug: Herceptin; Drug: NeuVax vaccine; Drug: GM-CSF	CA; DC; HI; IN; MD; OR; PA; TX; VA; WA	NCT01570036
Vaccine Therapy With or Without Polysaccharide-K in Treating Patients With Stage IV HER2+ Breast Cancer Receiving HER2 Targeted Monoclonal Antibody Therapy	HER2+; Recurrent Breast Carcinoma; Stage IV Breast Cancer	Biological: HER2 intracellular domain protein; Other: Laboratory biomarker analysis; Biological: pertuzumab; Other: Placebo; Biological: Polysaccharide-K; Biological: trastuzumab	WA	NCT01922921
Exemestane and Cyclophosphamide for Metastatic Breast Cancer	Metastatic Breast Cancer	Drug: exemestane; Drug: cyclophosphamide	NY	NCT01963481
Intrapleural AdV-tk Therapy in Patients With Malignant Pleural Effusion	Malignant Pleural Effusion; Lung Cancer; Mesothelioma; Breast Cancer; Ovarian Cancer	Biological: AdV-tk + valacyclovir	PA	NCT01997190
DC Vaccine for Patients With Ductal Carcinoma In Situ	Breast Cancer; DCIS	Biological: HER2 pulsed dendritic cell vaccine	PA	NCT02061332
HER2 Pulsed DC Vaccine to Prevent Recurrence of Invasive Breast Cancer Post Neoadjuvant Chemotherapy	Breast Cancer	Biological: HER2 pulsed dendritic cell vaccine	PA	NCT02061423
HER2 Pulsed DC Vaccine to Prevent Recurrence of Invasive Breast Cancer	Breast Cancer	Biological: HER2 pulsed dendritic cell vaccine	PA	NCT02063724
A Phase I Safety Study of Intradermal ID-LV305 in Patients With Locally Advanced, Relapsed or Metastatic Cancer Expressing NY-ESO-1	Breast Cancer; Melanoma; Non-Small Cell Lung Cancer; Ovarian Cancer; Sarcoma	Biological: ID-LV305	CT; MA; MN; TX; WA	NCT02122861
Phase II Trial of Combination Immunotherapy With NeuVax and Trastuzumab in High-Risk HER2+ Breast Cancer Patients	Breast Cancer	Biological: NeuVax vaccine; Drug: trastuzumab; Drug: GM-CSF	CA; DC; FL; IN; MD; NM; NY; TX; VA; WA	NCT02297698
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer	Biological: INO-1400; Biological: INO-9012	PA	NCT02327468
A Study of Ad-RTS-hIL-12 With Veledimex in Subjects With Breast Cancer	Metastatic Breast Cancer	Biological: Ad-RTS-hIL-12; Drug: veledimex	NY	NCT02423902

CERVICAL

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Human Papillomavirus-Associated Cancers	Cervical Cancer; Oropharyngeal Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: Young TIL; Drug: aldesleukin	MD	NCT01585428
ADXS11-001 High-Dose HPV+ Cervical Cancer	Effects of Immunotherapy; Metastatic/ Recurrent Cervical Cancer; Cervical Adenocarcinoma; Cervical Adenosquamous Cell Carcinoma; Cervical Squamous Cell Carcinoma; Cervical Small Cell Carcinoma; Stage III Cervical Cancer; Stage IVA Cervical Cancer; Stage IVB Cervical Cancer	Biological: ADXS11-001	GA	NCT02164461
T Cell Receptor Immunotherapy Targeting HPV-16 E6 for HPV-Associated Cancers	Vaginal Cancer; Cervical Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: E6 TCR; Drug: aldesleukin	MD	NCT02280811

COLORECTAL

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Cancer	Metastatic Colorectal Cancer; Metastatic Gastric Cancer; Metastatic Pancreatic Cancer; Metastatic Hepatocellular Carcinoma; Metastatic Cholangiocarcinoma	Biological: Young TIL; Drug: aldesleukin; Drug: cyclophosphamide; Drug: fludarabine	MD	NCT01174121
Anti-CD3 x Anti-Erbitux Armed Activated T Cells (Phase IB) for Gastrointestinal (GI Cancer)	Colorectal Cancer; Cancer of Pancreas; Pancreatic Neoplasm; Malignant Neoplasm of Large Intestine; Malignant Tumor of Colon; Colon Carcinoma; Cancer of Colon; Pancreatic Cancer	Drug: FOLFOX6; Biological: EGFRBi armed ATC Infusions	MI	NCT01420874

COLORECTAL (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy With CEA(6D) VRP Vaccine (AVX701) in Patients With Stage III Colorectal Cancer	Stage III Colon Cancer	Biological: AVX701	NC	NCT01890213
Combination Study of Urelumab and Cetuximab in Patients With Advanced/Metastatic Colorectal Cancer or Advanced/Metastatic Head and Neck Cancer	Colorectal Cancer; Head and Neck Cancer	Biological: urelumab; Biological: cetuximab	CA; IL; MA; MD; NY; OR; PA	NCT02110082
A Multicenter Study of Active Specific Immunotherapy With OncoVax in Patients With Stage II Colon Cancer	Stage II Colon Cancer	Biological: OncoVAX and Surgery; Procedure: Surgery	FL	NCT02448173

GASTROINTESTINAL

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Cancer	Metastatic Colorectal Cancer; Metastatic Gastric Cancer; Metastatic Pancreatic Cancer; Metastatic Hepatocellular Carcinoma; Metastatic Cholangiocarcinoma	Biological: Young TIL; Drug: aldesleukin; Drug: cyclophosphamide; Drug: fludarabine	MD	NCT01174121
A Study of Pembrolizumab (MK-3475) in Participants With Recurrent or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (MK-3475-059/KEYNOTE-059)	Gastric Adenocarcinoma; Gastroesophageal Junction Adenocarcinoma	Biological: pembrolizumab; Drug: cisplatin; Drug: 5-FU	IN; MA; NE	NCT02335411
A Phase IB/II Study of MEDI4736 With Tremelimumab, MEDI4736 or Tremelimumab Monotherapy in Gastric or GEJ Adenocarcinoma	Gastric or Gastroesophageal Junction Adenocarcinoma	Biological: MEDI4736 + tremelimumab; Biological: MEDI4736; Biological: tremelimumab; Biological: MEDI4736 + tremelimumab	FL; NY; OR; SC; TN	NCT02340975

HEAD & NECK

Title	Cancer Type	Treatment	Location	NCT Number
Vitamin D - Celecoxib Therapy	Mouth Neoplasms	Drug: celecoxib; Drug: 1,25-dihydroxyvitamin D3 + celecoxib; Drug: 1,25-dihydroxyvitamin D3	SC	NCT00953849
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Human Papillomavirus-Associated Cancers	Cervical Cancer; Oropharyngeal Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer	Drug: fludarabine; Drug: cycolphosphamide; Biological: Young TIL; Drug: aldesleukin	MD	NCT01585428
A Phase II Trial of Tadalafil in Patients With Squamous Cell Carcinoma of the Upper Aero Digestive Tract	Head and Neck Squamous Cell Carcinoma	Drug: tadalafil; Drug: Placebo	MD	NCT01697800
Recombinant Interleukin-15 in Treating Patients With Advanced Melanoma, Kidney Cancer, Non-small Cell Lung Cancer, or Squamous Cell Head and Neck Cancer	Head and Neck Squamous Cell Carcinoma; Keratinizing Head and Neck Squamous Cell Carcinoma; Nasopharyngeal Basaloid Squamous Cell Carcinoma; Salivary Gland Squamous Cell Carcinoma; Stage III Laryngeal Squamous Cell Carcinoma; Stage III Lip and Oral Cavity Squamous Cell Carcinoma; Stage III Nasal Cavity and Paranasal Sinus Squamous Cell Carcinoma; Stage III Oropharyngeal Squamous Cell Carcinoma; Stage III Renal Cell Cancer; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIA Skin Melanoma; Stage IIIB Non-Small Cell Lung Cancer; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Non-Small Cell Lung Cancer; Stage IV Renal Cell Cancer; Stage IV Skin Melanoma; Stage IVA Laryngeal Squamous Cell Carcinoma; Stage IVA Lip and Oral Cavity Squamous Cell Carcinoma; Stage IVA Nasal Cavity and Paranasal Sinus Squamous Cell Carcinoma; Stage IVA Oropharyngeal Squamous Cell Carcinoma; Stage IVB Laryngeal Squamous Cell Carcinoma; Stage IVB Lip and Oral Cavity Squamous Cell Carcinoma; Stage IVB Nasal Cavity and Paranasal Sinus Squamous Cell Carcinoma; Stage IVB Oropharyngeal Squamous Cell Carcinoma; Stage IVC Laryngeal Squamous Cell Carcinoma; Stage IVC Lip and Oral Cavity Squamous Cell Carcinoma; Stage IVC Nasal Cavity and Paranasal Sinus Squamous Cell Carcinoma; Stage IVC Oropharyngeal Squamous Cell Carcinoma; Tonsillar Squamous Cell Carcinoma	Other: Laboratory biomarker analysis; Other: Pharmacological study; Biological: recombinant human interleukin-15	CA; MD; MN; WA; WI	NCT01727076
Window of Opportunity Trial of ADXS 11-001 Vaccination Prior to Robotic Surgery of HPV-Positive Oropharyngeal Cancer	Head and Neck Cancer; Squamous Cell Carcinoma of the Head and Neck; Human Papillomavirus Positive Oropharyngeal Squamous Cell Carcinoma	Biological: ADXS11-001 (ADXS-HPV)	NY	NCT02002182
Combination Study of Urelumab and Cetuximab in Patients With Advanced/Metastatic Colorectal Cancer or Advanced/Metastatic Head and Neck Cancer	Colorectal Cancer; Head and Neck Cancer	Biological: urelumab; Biological: cetuximab	CA; IL; MA; MD; NY; OR; PA	NCT02110082

HEAD & NECK (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Study of HPV Specific Immunotherapy in Patients With HPV Associated Head and Neck Squamous Cell Carcinoma	Head and Neck Squamous Cell Cancer	Biological: 1.1 mL of VGX-3100 and INO-9012 delivered via IM EP	PA	NCT02163057
Pembrolizumab (MK-3475) Versus Standard Treatment for Recurrent or Metastatic Head and Neck Cancer (MK-3475-040/KEYNOTE-040)	Head and Neck Squamous Cell Cancer	Biological: pembrolizumab; Drug: methotrexate; Drug: docetaxel; Biological: cetuximab	CA; CO; CT; IL; MO; OH; OR; PA	NCT02252042
Study of MK-3475 (Pembrolizumab) in Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma After Treatment With Platinum-based and Cetuximab Therapy (MK-3475-055/KEYNOTE-055)	Head and Neck Squamous Cell Carcinoma (HNSCC)	Biological: pembrolizumab	DC; FL; IL; IN; MA; MD; MI; ND; NY; OH; OK; PA; SD; TN	NCT02255097
Anti-OX40 Antibody in Head and Neck Cancer Patients	Head and Neck Cancer	Drug: Anti-OX40 antibody administration; Procedure: Surgical resection	OR	NCT02274155
T Cell Receptor Immunotherapy Targeting HPV-16 E6 for HPV-Associated Cancers	Vaginal Cancer; Cervical Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: E6 TCR; Drug: aldesleukin	MD	NCT02280811
Immunotherapy With MK-3475 in Surgically Resectable Head and Neck Squamous Cell Carcinoma	Head and Neck Cancer; Neoplasms, Head and Neck; Carcinoma, Squamous Cell of Head and Neck; Squamous Cell Carcinoma of the Head and Neck; Squamous Cell Carcinoma, Head and Neck	Biological: MK-3475; Procedure: Surgery; Radiation: Intensity modulated radiation therapy; Radiation: Image-guided radiation therapy; Drug: cisplatin	MO	NCT02296684
A Study of Pembrolizumab (MK-3475) for First Line Treatment of Recurrent or Metastatic Squamous Cell Cancer of the Head and Neck (MK-3475-048/ KEYNOTE-048)	Metastatic Head and Neck Cancer	Biological: pembrolizumab; Drug: cisplatin; Drug: carboplatin; Drug: 5-FU; Biological: cetuximab	CT; NE; PA; SD	NCT02358031
In Situ, Autologous Therapeutic Vaccination Against Solid Cancers With Intratumoral Hiltonol	Melanoma; Head and Neck Cancer; Sarcoma; Non-Melanoma Skin Cancers	Biological: Hiltonol	GA; MD; NY; PA; SC	NCT02423863

KIDNEY

Title	Cancer Type	Treatment	Location	NCT Number
CAR T Cell Receptor Immunotherapy Targeting VEGFR2 for Patients With Metastatic Cancer	Metastatic Cancer; Metastatic Melanoma; Renal Cancer	Biological: Anti-VEGFR2 CAR CD8 plus PBL; Drug: cyclophosphamide; Biological: aldesleukin; Drug: fludarabine	MD	NCT01218867
AMG 172 First in Human Study in Patients With Kidney Cancer	Renal Cell Adenocarcinoma; Clear Cell Renal Carcinoma; Clear Cell Renal Cell Carcinoma; Renal Cell Carcinoma	Drug: AMG 172	AZ; MO	NCT01497821
Phase III Trial of Autologous Dendritic Cell Immunotherapy (AGS-003) Plus Standard Treatment of Advanced Renal Cell Carcinoma (RCC)	Advanced Renal Cell Carcinoma; Renal Cell Carcinoma; Metastatic Renal Cell Carcinoma	Drug: Standard treatment; Biological: AGS-003	AK; AZ; CA; CO; CT; FL; GA; IA; ID; IL; IN; KS; KY; LA; MA; MD; MI; MN; MO; NC; NE; NH; NJ; NM; NY; OH; OK; OR; PA; RI; SC; TN; TX; UT; VA; WA; WI	NCT01582672
High Dose IL-2 and Stereotactic Ablative Body Radiation Therapy for Metastatic Renal Cancer	Metastatic Clear Cell Renal Cell Carcinoma	Drug: IL-2; Radiation: Stereotactic ablative body radiation therapy	TX	NCT01896271
Immunotherapy Study for Metastatic Renal Cell Cancer	Metastatic Renal Cell Carcinoma; Metastatic Clear-cell Renal Cancer; Recurrent Renal Cell Carcinoma; Refractory Renal Cell Carcinoma; Metastatic Kidney Cancer	Biological: HyperAcute-Renal (HAR) immunotherapy	MD	NCT02035358
Vaccine Therapy Before Surgery in Treating Patients With Localized Kidney Cancer	Recurrent Renal Cell Carcinoma; Stage I Renal Cell Cancer; Stage II Renal Cell Cancer	Biological: Renal cell carcinoma/CD40L RNA-transfected autologous dendritic cell vaccine AGS-003; Procedure: Therapeutic conventional surgery; Other: Laboratory biomarker analysis	NY	NCT02170389

LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA

Title	Cancer Type	Treatment	Location	NCT Number
Biological Therapy in Treating Patients at High Risk or With Lymphoma, Lymphoproliferative Disease, or Malignancies	Leukemia; Lymphoma; Unspecified Adult Solid Tumor, Protocol Specific; Unspecified Childhood Solid Tumor, Protocol Specific	Biological: allogeneic Epstein-Barr virus-specific cytotoxic T lymphocytes	NY	NCT00002663
LMB-2 to Treat Hairy Cell Leukemia	Hairy Cell Leukemia	Drug: Anti-Tac(Fv)-PE38 (LMB-2) immunotoxin	MD	NCT00321555
Allogeneic Blood Stem Cell Transplantation and Adoptive Immunotherapy for Hodgkin Disease	Hodgkin Lymphoma	Drug: gemcitabine; Drug: fludarabine; Drug: melphalan; Drug: Antithymocyte Globulin; Procedure: Allogeneic stem cell infusion; Drug: tacrolimus; Drug: filgrastim (G-CSF); Drug: methotrexate	TX	NCT00385788

LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Neukoplast (NK-92) for the Treatment of Refractory or Relapsed Acute Myeloid Leukemia	Acute Myeloid Leukemia	Biological: Neukoplast (NK-92)	PA	NCT00900809
CAR T Cell Receptor Immunotherapy for Patients With B Cell Lymphoma	Primary Mediastinal B Cell Lymphoma; Diffuse, Large B Cell Lymphoma	Drug: fludarabine; Drug: cyclophosphamide; Biological: Anti-CD19-CAR PBL	MD	NCT00924326
Administration of Anti-CD19-chimeric-antigen-receptor-transduced T Cells From the Original Transplant Donor to Patients With Recurrent or Persistent B-cell Malignancies After Allogeneic Stem Cell Transplantation	Leukemia, B Cell; Lymphoma, Hodgkins; Lymphoma, Non-Hodgkin; Lymphoma, B Cell	Procedure: Allogeneic stem cell transplant; Biological: Anti-CD19-chimeric-antigen-receptor-transduced T cell; Drug: cyclophosphamide; Drug: pentostatin	MD	NCT01087294
Blockade of PD-1 in Conjunction With the Dendritic Cell/AML Vaccine Following Chemotherapy Induced Remission	Acute Myelogenous Leukemia; AML	Biological: DC AML Vaccine; Drug: CT-011	MA	NCT01096602
A Phase II Study of Ofatumumab-Based Induction Chemoimmunotheraphy Followed by Consolidation Ofatumumab Immunotherapy in Previously Untreated Patients With Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma	Small Lymphocytic Lymphoma; CLL (Chronic Lymphocytic Leukemia)	Drug: fludarabine phosphate; Biological: ofatumumab; Drug: cyclophosphamide	MD	NCT01145209
Immunotherapy for Asymptomatic Phase Lymphoplasmacytic Lymphoma	Lymphoma; Lymphoplasmacytic Lymphoma; Waldenström Macroglobulinemia	Biological: DNA vaccine	TX	NCT01209871
Th1/Tc1 Immunotherapy Following Stem Cell Transplantation in Multiple Myeloma	Multiple Myeloma	Procedure: Adoptive Immunotherapy; Biological: Rapamycin-generated autologous Th1/Tc1 Cells	MD; NJ	NCT01239368
Trial of Daily Pulse Interleukin-2 With Famotidine in Acute Myelogenous Leukemia	Acute Myelogenous Leukemia	Drug: interleukin-2	NC	NCT01289678
Study to Evaluate the Safety and Tolerability of Weekly Intravenous (IV) Doses of BMS-906024 in Subjects With Acute T Cell Lymphoblastic Leukemia or T-cell Lymphoblastic Lymphoma	Lymphoblastic Leukemia, Acute T Cell; Precursor T Cell Lymphoblastic Lymphoma	Drug: BMS-906024; Drug: dexamethasone	MA; NY; TX	NCT01363817
Ofatumumab With or Without Bendamustine for Patients With Mantle Cell Lymphoma Ineligible for Autologous Stem Cell Transplant	Mantle Cell Lymphoma	Biological: ofatumumab (This arm is closed); Other: ofatumumab + bendamustine	NJ; NY	NCT01437709
Yttrium-90-labeled Daclizumab With Chemotherapy and Stem Cell Transplant for Hodgkin Lymphoma	Hodgkin Lymphoma	Procedure: Auto stem cell transplant; Drug: BEAM; Radiation: 111In-daclizumab; Radiation: 90Y-daclizumab	MD	NCT01468311
Safety, Tolerability, Pharmacokinetics, and Immunoregulatory Study of Urelumab (BMS-663513) in Subjects With Advanced and/or Metastatic Solid Tumors and Relapsed/Refractory B Cell Non-Hodgkin Lymphoma	Cancer - Solid Tumors and B Cell Non-Hodgkin Lymphoma	Drug: urelumab (BMS-663513)	CA; IN; MA; MI; NJ; NY; OR; PA; VA	NCT01471210
Phase II Ofatumumab/Methylprednisolone Followed by Ofatumumab/Lenalidomide for Untreated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)	Chronic Lymphocytic Leukemia; Small Lymphocytic Lymphoma	Drug: High-dose methylprednisolone (HDMP); Drug: ofatumumab; Drug: lenalidomide	FL	NCT01496976
Continuous Infusion of rhIL-15 for Adults With Advanced Cancer	Lymphoma; Carcinoma	Biological: rh IL-15	MD	NCT01572493
Phase I/II Study of hLL1-DOX in Relapsed NHL and CLL	Non-Hodgkin Lymphoma; Chronic Lymphocytic Leukemia	Drug: hLL1-DOX (IMMU-115)	DE; FL; IN; MA; NJ; TX	NCT01585688
Safety Study in Nivolumab Alone and in Combination With Ipilimumab or Lirilumab in Lymphoma and Multiple Myeloma	Non-Hodgkin Lymphoma; Hodgkin Lymphoma; Multiple Myeloma	Biological: nivolumab; Biological: ipilimumab; Biological: lirilumab	CA; CT; MA; MD; MI; MN; NJ; NY; OR; PA; UT	NCT01592370
Anti-CD19 White Blood Cells for Children and Young Adults With B Cell Leukemia or Lymphoma	ALL; B Cell Lymphoma; Leukemia; Large Cell Lymphoma; Non-Hodgkin Lymphoma	Biological: Anti-CD19- CAR	MD	NCT01593696
This Trial is a Randomized, Open-label Two-arm Phase III Comparative Study Assessing the Role of Involved Mediastinal Radiotherapy After Rituximab Containing Chemotherapy Regimens to Patients With Newly Diagnosed Primary Mediastinal Large B-Cell Lymphoma	Primary Mediastinal B Cell Lymphoma	Other: Observation; Radiation: 3D-conformal radiotherapy (3D-CRT)	MN; NE	NCT01599559
Allogeneic Stem Cell Transplantation With Adoptive Immunotherapy in Epstein-Barr Virus Positive Recurrent/ Refractory Hodgkin Lymphoma	Hodgkin Lymphoma	Biological: Allogeneic donor derived LMP specific cytotoxic T lymphocyte	NY	NCT01636388
Laboratory-Treated T Cells in Treating Patients With High-Risk Relapsed Acute Myeloid Leukemia, Myelodysplastic Syndrome, or Chronic Myelogenous Leukemia Previously Treated With Donor Stem Cell Transplant	Acute Myeloid Leukemia Arising From Previous Myelodysplastic Syndrome; Adult Myelodysplastic Syndrome; Childhood Myelodysplastic Syndrome; Previously Treated Myelodysplastic Syndrome; Recurrent Adult Acute Myeloid Leukemia; Recurrent Childhood Acute Myeloid Leukemia; Recurrent Chronic Myelogenous Leukemia, BCR-ABL1 Positive; Secondary Acute Myeloid Leukemia; Therapy-Related Acute Myeloid Leukemia	Biological: WT1-sensitized allogeneic T lymphocytes; Biological: aldesleukin; Other: Laboratory biomarker analysis	WA	NCT01640301

LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Study of Infusion of Blood Cells (Lymphocytes) to Stimulate the Immune System to Fight Leukemia/ Lymphoma	Mantle Cell Lymphoma; Diffuse Large Cell Lymphoma; Burkitts Lymphoma; T Cell Lymphomas; Acute Myeloid Leukemia/Acute Lymphoblastic Leukemia	Biological: Cellular immunotherapy	RI	NCT01685606
A Study of DCDT2980S in Combination With MabThera/ Rituxan or DCDS4501A in Combination With MabThera/ Rituxan and Evaluation of Combination DCDS4501A and Obinutuzumab in Patients With Non-Hodgkin Lymphoma	Lymphoma, B Cell, Lymphoma, Follicular	Drug: DCDS4501A; Drug: DCDT2980S; Drug: obinutuzumab; Drug: rituximab (MabThera/Rituxan)	CA; CO; DC; FL; MI; NJ; NV; NY; OH; OR; TN; TX; VA; WA; WI	NCT01691898
Therapy for Pediatric Relapsed or Refractory Precursor B Cell Acute Lymphoblastic Leukemia and Lymphoma	Recurrent B Cell Childhood Acute Lymphoblastic Leukemia; Recurrent Childhood B Lymphoblastic Lymphoma	Drug: dexamethasone; Drug: vincristine sulfate; Biological: rituximab; Drug: clofarabine; Drug: cyclophosphamide; Drug: etoposide; Biological: aldesleukin; Drug: pegaspargase; Drug: methotrexate; Drug: mercaptopurine; Drug: cytarabine; Drug: mitoxantrone; Drug: teniposide; Drug: vinblastine; Biological: natural killer cell infusion; Other: Laboratory biomarker analysis; Drug: Therapeutic hydrocortisone; Procedure: Allogeneic hematopoietic stem cell transplantation	TN	NCT01700946
Phase III Frontline Therapy Trial in Patients With Advanced Classical Hodgkin Lymphoma	Hodgkin Lymphoma	Drug: brentuximab vedotin; Drug: doxorubicin; Drug: bleomycin; Drug: vinblastine; Drug: dacarbazine	AL; AZ; CA; CO; DC; FL; IL; IN; MA; MD; MI; MN; MO; NC; ND; NE; NJ; NM; NV; NY; OH; PA; SC; TN; TX; UT; WA; WI; WV	NCT01712490
A Study of Brentuximab Vedotin in Adults Age 60 and Above With Newly Diagnosed Hodgkin Lymphoma (HL)	Hodgkin Lymphoma	Drug: brentuximab vedotin; Drug: bendamustine; Drug: dacarbazine	AL; AZ; CA; CO; FL; GA; IL; MD; NE; NY; OR; TX; VA; WA	NCT01716806
Phase I Dose Escalation Study of IMMU-114 in Relapsed or Refractory NHL and CLL	Non-Hodgkin Lymphoma; Follicular Lymphoma; Mantle Cell Lymphoma; Marginal Zone Lymphoma; Chronic Lymphocytic Leukemia; Small Lymphocytic Lymphoma	Drug: IMMU-114	OH	NCT01728207
Combination Study of Urelumab and Rituximab in Patients With B Cell Non-Hodgkin Lymphoma	B Cell Malignancies	Biological: urelumab; Biological: rituximab	CA; FL; IA; MA; MI; NC; NJ; NY; OR; PA; TX, VA	NCT01775631
ECHELON-2: A Comparison of Brentuximab Vedotin and CHP With Standard-of-care CHOP in the Treatment of Patients With CD30-Positive Mature T-cell Lymphomas	Lymphoma, Large-Cell, Anaplastic; Lymphoma, Non-Hodgkin; Lymphoma, T Cell	Drug: brentuximab vedotin; Drug: doxorubicin; Drug: prednisone; Drug: vincristine; Drug: cyclophosphamide	AL; CA; CT; FL; IA; KS; MA; MD; MI; MN; MO; NJ; NY; OH; OK; PA; TN; TX; VA; WA	NCT01777152
Treatment for Advanced B Cell Lymphoma	Diffuse Large Cell Lymphoma; Burkitt's Lymphoma; High Grade B Cell Lymphoma	Drug: rituximab; Drug: IT cytarabine	NC; NY; OK; UT	NCT01859819
Autologous T Lymphocytes Genetically Targeted to the B Cell Specific Antigen CD19 in Pediatric and Young Adult Patients With Relapsed B Cell Acute Lymphoblastic Leukemia	Relapsed B Cell Acute Lymphoblastic Leukemia	Procedure: leukapheresis or collection of PBMCs; Drug: cyclophosphamide; Biological: Modified T cells	MA; NY	NCT01860937
Laboratory Treated T Cells in Treating Patients With Relapsed or Refractory Chronic Lymphocytic Leukemia, Non-Hodgkin Lymphoma, or Acute Lymphoblastic Leukemia	Chronic Lymphocytic Leukemia in Remission; Recurrent Adult Acute Lymphoblastic Leukemia; Recurrent Chronic Lymphocytic Leukemia; Recurrent Diffuse Large B Cell Lymphoma; Recurrent Mantle Cell Lymphoma; Recurrent Non-Hodgkin Lymphoma; Recurrent Small Lymphocytic Lymphoma; Refractory Chronic Lymphocytic Leukemia; Refractory Diffuse Large B-Cell Lymphoma	Biological: Autologous Anti-CD19CAR-4-1BB-CD3zeta-EGFRt-expressing T lymphocytes; Other: Laboratory biomarker analysis	WA	NCT01865617
A Safety Study of SGN-CD33A in AML Patients	Acute Myelogenous Leukemia; Acute Myeloid Leukemia; Acute Promyelocytic Leukemia	Drug: HMA; Drug: SGN-CD33A	AL; CA; FL; MA; NY; OH; UT; WA	NCT01902329
Study of Brentuximab Vedotin Combined With RCHOP or RCHP in Front-line Treatment of Patients With Diffuse Large B Cell Lymphoma (DLBCL)	Lymphoma, B Cell; Lymphoma, Large B Cell, Diffuse	Drug: brentuximab vedotin; Drug: brentuximab vedotin; Drug: rituximab; Drug: vincristine; Drug: cyclophosphamide; Drug: prednisone; Drug: doxorubicin	AZ; CA; CO; MN; MO; NJ; OH; OR; TX; UT; VA; WA	NCT01925612
Cellular Immunotherapy Treatment Antigen-Directed for EBV Lymphoma	Lymphoma, Extranodal NK-T Cell; EBV	Biological: CMD-003	CA; DC; MA; MN; NJ; NY; OH; OR; PA; TN; TX	NCT01948180
A Study of DCDS4501A in Combination With Rituximab, Cyclophosphamide, Doxorubicin and Prednisone in Patients With B Cell Non-Hodgkin Lymphoma	Lymphoma, B Cell, Non-Hodgkin Lymphoma	Drug: DCDS4501A; Drug: cyclophosphamide; Drug: doxorubicin; Drug: prednisone; Drug: rituximab [MabThera/Rituxan]	AL; AZ; MI; MO; OR; WA	NCT01992653
A Pediatric and Young Adult Trial of Genetically Modified T Cells Directed Against CD19 for Relapsed/Refractory CD19+ Leukemia	CD19+ Acute Leukemia	Biological: Patient derived CD19 specific CAR T cells also expressing an EGFRt	WA	NCT02028455

LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Study of Nivolumab in Subjects With Relapsed or Refractory Follicular Lymphoma (FL) (CheckMate 140)	Lymphoma	Drug: nivolumab	AZ; CA; GA; MA; MN; NC; NY; TN; TX; UT	NCT02038946
Central Memory Enriched T Cells Following Stem Cell Transplant in Treating Patients With Recurrent B Cell Non-Hodgkin Lymphoma	Recurrent Diffuse Large B Cell Lymphoma; Recurrent Mantle Cell Lymphoma; Refractory Diffuse Large B Cell Lymphoma; Refractory Mantle Cell Lymphoma; Transformed Recurrent Non-Hodgkin Lymphoma	Biological: autologous CD19CAR-CD28-CD3zeta-EGFRt-expressing Tcm-enriched T cells; Other: Laboratory biomarker analysis	CA	NCT02051257
Poly ICLC, Radiation, and Romidepsin for Advanced Cutaneous T Cell Lymphoma	Cutaneous T Cell Lymphoma	Drug: romidepsin; Drug: poly ICLC; Radiation: Focal lesional radiation	NY	NCT02061449
Immunotherapy Following Reduced Intensity Conditioning and Allogeneic Stem Cell Transplant for Poor Risk CD30+ Hodgkin Lymphoma Patients	Hodgkin Lymphoma	Drug: brentuximab vedotin; Procedure: Allogeneic stem cell transplantation; Drug: Reduced intensity conditioning	NY	NCT02098512
A Study of ALT-803 in Patients With Relapsed or Refractory Multiple Myeloma	Relapsed or Refractory Multiple Myeloma	Biological: ALT-803	MN	NCT02099539
A Pilot Study of Immunotherapy Including Haploidentical NK Cell Infusion Following CD133+ Positively Selected Autologous Hematopoietic Stem Cells in Children With High Risk Solid Tumors or Lymphomas	Neuroblastoma; Lymphoma; High-risk Tumor	Device: CD133+ selected autologous stem cell infusion; Biological: IL-2; Biological: hu14.18K322A; Drug: busulfan; Drug: melphalan; Biological: GM-CSF; Drug: bendamustine; Drug: etoposide; Drug: cytarabine; Drug: carboplatin; Device: Haploidentical natural killer cell infusion; Biological: G-CSF; Drug: etoposide phosphate	TN	NCT02130869
Cellular Immunotherapy After Cyclophosphamide in Treating Patients With High-Risk Acute Lymphoblastic Leukemia	B Cell Adult Acute Lymphoblastic Leukemia; Recurrent Adult Acute Lymphoblastic Leukemia	Drug: cyclophosphamide; Biological: autologous CD19CAR-CD28-CD3zeta-EGFRt-expressing Tcm-enriched T cells; Other: Laboratory biomarker analysis	CA	NCT02146924
Cellular Immunotherapy Following Cyclophosphamide in Treating Patients With Recurrent Non-Hodgkin Lymphomas, Chronic Lymphocytic Leukemia or B-Cell Prolymphocytic Leukemia	Post-transplant Lymphoproliferative Disorder; Prolymphocytic Leukemia; Recurrent Adult Burkitt Lymphoma; Recurrent Adult Diffuse Large Cell Lymphoma; Recurrent Grade 1 Follicular Lymphoma; Recurrent Grade 2 Follicular Lymphoma; Recurrent Grade 3 Follicular Lymphoma; Recurrent Mantle Cell Lymphoma; Recurrent Marginal Zone Lymphoma; Recurrent Small Lymphocytic Lymphoma; Refractory Chronic Lymphocytic Leukemia; Refractory Hairy Cell Leukemia; Waldenström Macroglobulinemia	Drug: cyclophosphamide; Biological: autologous CD19CAR-CD28-CD3zeta-EGFRt-expressing Tcm-enriched T cells; Other: Laboratory biomarker analysis	CA	NCT02153580
A Phase IB/II Study of IPI-145 Plus FCR in Previously Untreated, Younger Patients With CLL	Chronic Lymphocytic Leukemia	Drug: IPI-145; Drug: fludarabine; Drug: cyclophosphamide; Drug: rituximab	MA	NCT02158091
Genetically Modified T Cell Immunotherapy in Treating Patients With Relapsed or Refractory Acute Myeloid Leukemia	Adult Acute Megakaryoblastic Leukemia (M7); Adult Acute Minimally Differentiated Myeloid Leukemia (M0); Adult Acute Monoblastic Leukemia (M5a); Adult Acute Monocytic Leukemia (M5b); Adult Acute Myeloblastic Leukemia With Maturation (M2); Adult Acute Myeloblastic Leukemia Without Maturation (M1); Adult Acute Myeloid Leukemia With 11q23 (MLL) Abnormalities; Adult Acute Myeloid Leukemia With Del(5q); Adult Acute Myeloid Leukemia With Inv(16)(p13;q22); Adult Acute Myeloid Leukemia With t(16;16)(p13;q22); Adult Acute Myeloid Leukemia With t(8;21)(q22;q22); Adult Acute Myelomonocytic Leukemia (M4); Adult Erythroleukemia (M6a); Adult Pure Erythroid Leukemia (M6b); Recurrent Adult Acute Myeloid Leukemia	Drug: cyclophosphamide; Biological: anti CD123-CAR/CD28-costimulatory, retroviral vector-transduced autologous T lymphocytes; Other: Laboratory biomarker analysis	CA	NCT02159495
Micro Needle Array-Doxorubicin (MNA-D) in Patients With Cutaneous T Cell Lymphoma (CTCL)	Cutaneous T Cell Lymphoma	Drug: Micro needle array-doxorubicin (MNA-D)	PA	NCT02192021
Phase I Study of Ibrutinib and Immuno-Chemotherapy Using Dose-Adjusted-Temozolomide, Etoposide, Doxil, Dexamethasone, Ibrutinib, Rituximab (DA-TEDDI-R) in Primary CNS Lymphoma	Primary Central Nervous System Lymphoma	Drug: TEDDI; Biological: rituximab; Drug: cytarabine	MD	NCT02203526
Study of T Cells Targeting B Cell Maturation Antigen for Previously Treated Multiple Myeloma	Myeloma, Plasma-Cell; Myeloma, Multiple	Drug: cyclophosphamide; Drug: fludarabine; Biological: Anti-BCMA CAR T cells	MD	NCT02215967
Immunochemotherapy and AlloSCT in Patients With High Risk CD33+ AML/MDS	Acute Myelogenous Leukemia; Myelodysplastic Syndrome	Drug: gemtuzumab ozogamicin	NY	NCT02221310
Phase I Study of an Oncofetal Antigen Multi-Peptide Immunotherapy in Subjects With Hematologic Cancer	Acute Myelogenous Leukemia (AML); Multiple Myeloma (MM); Myelodysplastic Syndrome (MDS); Smoldering Multiple Myeloma (sMM)	Drug: sargramostim; Drug: BB-MPI-03; Drug: montanide	IL; MI; VA	NCT02240537

LEUKEMIA/LYMPHOMA/MULTIPLE MYELOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
A Phase I Open Label Study of the Safety and Tolerability of Elotuzumab (BMS-901608) Administered in Combination With Either Lirilumab (BMS-986015) or Urelumab (BMS-663513) in Subjects With Multiple Myeloma	Multiple Myeloma	Drug: elotuzumab; Drug: lirilumab; Drug: urelumab	AR; MD; NY; OH; OR; PA	NCT02252263
Study of the Safety and Tolerability of Urelumab Administered in Combination With Nivolumab in Solid Tumors and B Cell Non-Hodgkin Lymphoma	Advanced Solid Tumors; Advanced B Cell NHL	Biological: urelumab; Biological: nivolumab	FL; MA; MD; NY; PA; TX	NCT02253992
Cord Blood Natural Killer (NK) Cells in Chronic Lymphocytic Leukemia (CLL)	Leukemia	Drug: lenalidomide; Drug: rituximab; Drug: fludarabine; Drug: cyclophosphamide; Procedure: NK Cells	TX	NCT02280525
Anti-PD-1 (MK-3475) and IMiD (Pomalidomide) Combination Immunotherapy in Relapsed/Refractory Multiple Myeloma	Multiple Myeloma	Drug: MK-3475; Drug: Pomalidomide; Drug: Dexamethasone	MD	NCT02289222
Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults With Recurrent or Refractory CD22-expressing B Cell Malignancies	Follicular Lymphoma; ALL; NHL; Large Cell Lymphoma	Biological: CD22-CAR	MD	NCT02315612
Rituximab With or Without Yttrium Y-90 Ibritumomab Tiuxetan in Treating Patients With Untreated Follicular Lymphoma	Stage I Grade 1 Follicular Lymphoma; Stage I Grade 2 Follicular Lymphoma; Stage II Grade 1 Contiguous Follicular Lymphoma; Stage II Grade 1 Non-Contiguous Follicular Lymphoma; Stage II Grade 2 Contiguous Follicular Lymphoma; Stage II Grade 2 Non-Contiguous Follicular Lymphoma; Stage III Grade 1 Follicular Lymphoma; Stage III Grade 2 Follicular Lymphoma; Stage IV Grade 1 Follicular Lymphoma; Stage IV Grade 2 Follicular Lymphoma	Biological: rituximab; Radiation: Yttrium Y-90 ibritumomab tiuxetan; Other: Quality-of-life assessment; Other: Questionnaire administration; Other: Laboratory biomarker analysis	IA; MN	NCT02320292
A Safety Study of SGN-CD33A in Combination With Standard-of-care in Patients With AML	Acute Myeloid Leukemia; Acute Myelogenous Leukemia	Drug: Standard dose cytarabine for induction; Drug: SGN-CD33A; Drug: daunorubicin; Drug: High-dose cytarabine for consolidation	AL; CA; CO; MN; NJ; OH; TN; TX; WA	NCT02326584
A Study of Pembrolizumab (MK-3475) in Pediatric Participants With Advanced Melanoma or Advanced, Relapsed, or Refractory PD-L1-Positive Solid Tumors or Lymphoma (MK-3475-051/KEYNOTE-051)	Melanoma; Lymphoma; Solid Tumor	Biological: pembrolizumab	TN; WA	NCT02332668
PK, PD, Safety, Tolerability of Multiple Dose Regimens of MT-3724 for the Treatment of Patients With Relapsed Non-Hodgkin B Cell Lymphoma	Non-Hodgkin B Cell Lymphoma	Drug: MT-3724	NY; TX	NCT02361346
Safety and Efficacy Study of Apixaban to Prevent Clots in Children With Leukemia Who Have a Central Venous Catheter and Are Treated With PEG Asparaginase	Lymphoma; Acute Lymphoblastic Leukemia	Drug: apixaban; Other: No systemic anticoagulant prophylaxis	AZ; CA; FL; GA; IA; KY; LA; MD; MI; MN; MS; NC; NJ; NY; OH; OR; PA; TX; WI	NCT02369653
ALT-803 in Patients With Relapse/Refractory Indolent B Cell Non-Hodgkin Lymphoma (iNHL) in Conjunction With Rituximab	Relapsed/Refractory Indolent B Cell Non-Hodgkin Lymphoma	Biological: rituximab; Biological: ALT-803	MO	NCT02384954
Pilot Project for Creation of the Diffuse Large B Cell Lymphoma (DLBCL) Response Prediction Model	Lymphoma	Drug: 18F-fluorodeoxyglucose; Procedure: FDG PET/CT Imaging; Procedure: Blood draws	TX	NCT02405078
BI 695500 vs Rituxan First Line Treatment in Patients With Low Tumor Burden Follicular Lymphoma	Lymphoma, Non-Hodgkin	Drug: rituximab; Drug: BI 695500	UT	NCT02417129

LIVER

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Cancer	Metastatic Colorectal Cancer; Metastatic Gastric Cancer; Metastatic Pancreatic Cancer; Metastatic Hepatocellular Carcinoma; Metastatic Cholangiocarcinoma	Biological: Young TIL; Drug: aldesleukin; Drug: cyclophosphamide; Drug: fludarabine	MD	NCT01174121
Study to Evaluate the Effectiveness, Safety and Tolerability of Nivolumab in Subjects With Advanced Liver Cancer Anti-PD-1 HCC (Anti-Programmed-Death-1 Hepatocellular Carcinoma)	Hepatocellular Carcinoma	Biological: nivolumab	DC; GA; MA; MI; OR; TX	NCT01658878
Ipilimumab and Stereotactic Body Radiation Therapy (SBRT) in Advanced Solid Tumors	Liver Cancer; Lung Cancer	Drug: ipilimumab; Radiation: Stereotactic body radiation therapy (SBRT)	TX	NCT02239900
CAR-T Hepatic Artery Infusions and Sir-Spheres for Liver Metastases	Liver Metastases	Biological: anti-CEA CAR-T cells; Device: Sir-Spheres	RI	NCT02416466

LUNG

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
Randomized Study of Adjuvant WT-1 Analog Peptide Vaccine in Patients With Malignant Pleural Mesothelioma (MPM) After Completion of Combined Modality Therapy	Malignant Pleural Mesothelioma	Biological: WT-1-vaccine montanide + GM-CSF; Biological: montanide adjuvant + GM-CSF	NY	NCT01265433
Phase IIB/III Of TG4010 Immunotherapy In Patients With Stage IV Non-Small Cell Lung Cancer	Non-Small Cell Lung Carcinoma	Biological: TG4010; Drug: placebo	AZ; KS; KY; MD; MO; NC; OH; PA; TX	NCT01383148
Combination Immunotherapy of GM.CD40L Vaccine With CCL21 in Lung Cancer	Lung Cancer; Adenocarcinoma	Biological: GM.CD40L.CCL21 vaccinations; Biological: GM.CD40L cells vaccinations	FL	NCT01433172
Safety and Efficacy of Listeria in Combination With Chemotherapy as Front-line Treatment for Malignant Pleural Mesothelioma	Malignant Pleural Mesothelioma	Biological: Vaccine plus chemotherapy; Biological: Vaccine with cyclophosphamide plus chemotherapy	CA; FL; IL; MD; PA	NCT01675765
Immunotherapy Study in Progressive or Relapsed Non-Small Cell Lung Cancer	Non-Small Cell Lung Cancer; Progression of Non-Small Cell Lung Cancer; Non-Small Cell Lung Cancer Recurrent	Drug: docetaxel; Biological: HyperAcute-Lung Immunotherapy; Drug: gemcitabine; Drug: pemetrexed	CA; CT; FL; IL; IN; KS; MO; MS; NE; NY; OH; TN; VA; WI	NCT01774578
Phase II Study of Adjuvant WT-1 Analog Peptide Vaccine in MPM Patients After MSK10-134	Malignant Pleural Mesothelioma	Biological: WT-1-vaccine montanide + GM-CSF; Biological: montanide adjuvant + GM-CSF	NY; TX	NCT01890980
Combination Vaccine Immunotherapy (DRibbles) for Patients With Definitively-Treated Stage III Non-Small Cell Lung Cancer	Carcinoma, Non-Small Cell Lung	Drug: cyclophosphamide; Biological: DRibble vaccine; Drug: imiquimod; Drug: GM-CSF; Biological: HPV vaccine	LA; OR	NCT01909752
Intrapleural AdV-tk Therapy in Patients With Malignant Pleural Effusion	Malignant Pleural Effusion; Lung Cancer; Mesothelioma; Breast Cancer; Ovarian Cancer	Biological: AdV-tk + valacyclovir	PA	NCT01997190
A Phase IB Study of MEDI4736 in Combination With Tremelimumab in Subjects With Advanced Non-Small Cell Lung Cancer	NSCLC; Non-Small Cell Lung Cancer; Lung Cancer	Drug: MEDI4736; Drug: tremelimumab	CA; CT; FL; NY	NCT02000947
A Study of Pembrolizumab (MK-3475) in Combination With Chemotherapy or Immunotherapy in Participants With Lung Cancer (MK-3475-021/KEYNOTE-021)	Non-Small Cell Lung Carcinoma	Drug: pembrolizumab; Drug: paclitaxel; Drug: carboplatin; Biological: bevacizumab; Drug: pemetrexed; Biological: ipilimumab; Drug: erlotinib; Drug: gefitinib	MI; OH; PA; TX	NCT02039674
An Open-Label, Randomized, Phase 3 Trial of Nivolumab Versus Investigator's Choice Chemotherapy as First-Line Therapy for Stage IV or Recurrent PD-L1+ Non-Small Cell Lung Cancer (CheckMate 026)	Stage IV or Recurrent Non-Small Cell Lung Cancer	Biological: nivolumab; Drug: gemcitabine; Drug: cisplatin; Drug: carboplatin; Drug: paclitaxel; Drug: pemetrexed	AL; AZ; CA; CO; CT; FL; GA; IL; KY; LA; MA; MD; NC; NY; OH; OR; PA; SC; TN; TX; WA	NCT02041533
A Phase II Study of Viagenpumatucel-L (HS-110) in Patients With Non-Small Cell Lung Cancer	Non-Small Cell Lung Cancer	Drug: viagenpumatucel-L; Drug: Metronomic cyclophosphamide; Drug: Physician's choice regimen (vinorelbine, erlotinib, gemcitabine, paclitaxel, docetaxel, pemetrexed)	CA; MA; MO; OH; PA; TX	NCT02117024
T Cell Receptor Immunotherapy for Patients With Metastatic Non-Small Cell Lung Cancer	Metastatic Non-Small Cell Lung Cancer; Squamous Cell Carcinoma; Advanced NSCLC; Adenosquamous Carcinoma; Adenocarcinomas	Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide; Biological: Young TIL	MD	NCT02133196
Study of Pembrolizumab (MK-3475) Compared to Platinum-Based Chemotherapies in Participants With Metastatic Non-Small Cell Lung Cancer (MK-3475-024/KEYNOTE-024)	Non-Small Cell Lung Carcinoma	Drug: pembrolizumab; Drug: paclitaxel; Drug: carboplatin; Drug: pemetrexed; Drug: cisplatin; Drug: gemcitabine	AL; CA; CO; DC; DE; FL; GA; MD; MN; MO; NC; NE; NH; NV; OK; OR; TN; TX; WI	NCT02142738
Study of Combined Ionizing Radiation and Ipilimumab in Metastatic Non-Small Cell Lung Cancer (NSCLC)	Non-Small Cell Lung Cancer (NSCLC)	Drug: ipilimumab; Radiation: Radiotherapy (IMRT)	NY	NCT02221739
Ipilimumab and Stereotactic Body Radiation Therapy (SBRT) in Advanced Solid Tumors	Liver Cancer; Lung Cancer	Drug: ipilimumab; Radiation: Stereotactic body radiation therapy (SBRT)	TX	NCT02239900
Multiple Ascending Dose w/Expansion in Relapsed/Refractory SCLC	Small Cell Lung Cancer	Biological: BMS-986012 (anti-fucosyl-GM1)	NC; NY	NCT02247349
Double Blind Placebo Controlled Controlled Study of Adjuvant MEDI4736 In Completely Resected NSCLC	Non-Small Cell Lung Cancer	Drug: MEDI4736; Drug: Placebo	CA; CO	NCT02273375
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer	Biological: INO-1400; Biological: INO-9012	PA	NCT02327468
Trial of PBF-509 in Patients With Advanced NSCLC	Non-Small Cell Lung Cancer (NSCLC)	Drug: PBF-509; Drug: PBF-509; Drug: PBF-509	FL	NCT02403193
Genetically Modified T Cells in Treating Patients With Stage III-IV Non-Small Cell Lung Cancer or Mesothelioma	Advanced Pleural Malignant Mesothelioma; HLA-A*0201 Positive Cells Present; Recurrent Non-Small Cell Lung Carcinoma; Recurrent Pleural Malignant Mesothelioma; Stage III Pleural Mesothelioma; Stage IIIA Non-Small Cell Lung Cancer; Stage IIIB Non-Small Cell Lung Cancer; Stage IV Non-Small Cell Lung Cancer; Stage IV Pleural Mesothelioma	Biological: Autologous WT1-TCRc4 gene-transduced CD8-positive Tcm/Tn lymphocytes; Drug: cyclophosphamide; Biological: aldesleukin; Procedure: Therapeutic conventional surgery; Other: Laboratory biomarker analysis	WA	NCT02408016

LUNG (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
MK-3475 and Gemcitabine in Non-Small Cell Lung Cancer (NSCLC)	Carcinoma, Non-Small Cell Lung	Drug: MK-3475; Drug: gemcitabine	OR	NCT02422381
A Study of Combination Therapies With Viagenpumatucel-L (HS-110) in Patients With Non-Small Cell Lung Cancer	Non-Small Cell Lung Cancer	Biological: viagenpumatucel-L; Drug: theophylline; Other: High-flow oxygen	IN; MO	NCT02439450
A Study of the Safety, Tolerability, and Effects of Cobimetinib and GDC-0994 in Patients With Locally Advanced or Metastatic Solid Tumors	Non-Small Cell Lung Cancer, Metastatic Colorectal Cancer, Metastatic Non-Small Cell Lung Cancer, Metastatic Cancers, Melanoma	Drug: cobimetinib; Drug: GDO-994	CO; CT; MA; MO; TN	NCT02457793
A Pilot Study of MPDL3280A and HIGRT in Metastatic NSCLC	Non-Small Cell Lung Cancer	Drug: MPDL3280A; Radiation: Hypofractionated radiotherapy	MI; WA	NCT02463994
Study of Nivolumab in Combination With GM.CD40L Vaccine in Adenocarcinoma of the Lung	Lung Cancer; Adenocarcinoma of the Lung	Drug: nivolumab; Biological: GM.CD40L vaccine	FL	NCT02466568

MELANOMA

Title	Cancer Type	Treatment	Location	NCT Number
Evaluation for NCI Surgery Branch Clinical Studies	Synovial Cell Cancer; Melanoma; Colorectal Cancer; Lung Cancer; Bladder Cancer		MD	NCT00001823
A Phase I Trial of a Vaccine Combining Multiple Class I Peptides and Montanide ISA 51VG With Escalating Doses of Anti-PD-1 Antibody Nivolumab or Ipilimumab With Nivolumab For Patients With Resected Stages IIIC/ IV Melanoma	Melanoma (Skin)	Biological: NY-ESO-1 157-165 (165V); Drug: nivolumab; Biological: gp100:280-288 (288V); Drug: montanide ISA 51 vegetable grade (VG); Drug: ipilimumab; Procedure: Apheresis procedure	FL	NCT01176474
CAR T Cell Receptor Immunotherapy Targeting VEGFR2 for Patients With Metastatic Cancer	Metastatic Cancer; Metastatic Melanoma; Renal Cancer	Biological: Anti-VEGFR2 CAR CD8 plus PBL; Drug: cyclophosphamide; Biological: aldesleukin; Drug: fludarabine	MD	NCT01218867
Aldesleukin With or Without Ziv-Aflibercept in Treating Patients With Stage III-IV Melanoma That Cannot Be Removed by Surgery	Recurrent Melanoma; Stage IIIA Skin Melanoma; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Skin Melanoma	Biological: aldesleukin; Other: Laboratory biomarker analysis; Biological: ziv-aflibercept	CA; CO; GA; IA; IL; IN; MI; MN; NH; NY; OH; PA; TN; VA	NCT01258855
Tumor Cell Vaccines and ISCOMATRIX With Chemotherapy After Tumor Removal	Sarcoma; Melanoma; Epithelial Malignancies; Pleural Malignancy	Biological: Epigenetically Modified Autologous Tumor; Drug: cyclophosphamide; Drug: celecoxib	MD	NCT01341496
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Melanoma	Metastatic Melanoma; Skin Cancer	Drug: cyclophosphamide; Drug: fludarabine; Biological: Young TIL	MD	NCT01468818
RADVAX: A Stratified Phase I/II Dose Escalation Trial of Stereotactic Body Radiotherapy Followed by Ipilimumab in Metastatic Melanoma	Metastatic Melanoma	Drug: ipilimumab; Radiation: Stereotactic body radiation therapy	PA	NCT01497808
Neoadjuvant Combination Therapy With Ipilimumab and HighDose IFN-α2b for Melanoma	Melanoma	Drug: administration of ipilimumab 10mg/kg; Drug: administration of ipilimumab 3mg/kg plus HDI	PA	NCT01608594
PH 1 Biomarker Study of Nivolumab and Ipilimumab and Nivolumab in Combination With Ipilimumab in Advanced Melanoma	Advanced Melanoma; Metastatic Melanoma	Biological: nivolumab; Drug: ipilimumab	CA; IL; MA; MD; NY; OR; TN; TX; VA; WA	NCT01621490
Multiple Antigen-Engineered DC Vaccine for Melanoma	Melanoma	Biological: DC Vaccine plus IFN; Biological: AdVTMM2/DC vaccination	PA	NCT01622933
A Phase IB Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Combination With Vemurafenib (Zelboraf) or Vemurafenib Plus Cobimetinib in Patients With Previously Untreated BRAFV600-Mutation-Positive Metastatic Melanoma	Malignant Melanoma	Drug: MPDL3280A; Drug: vemurafenib (Zelboraf); Drug: cobimetinib	CA; CO; FL; MA; TX	NCT01656642
Vemurafenib With Lymphodepletion Plus Adoptive Cell Transfer & High-Dose IL-2 Metastatic Melanoma	Metastatic Melanoma	Drug: High-dose interleukin-2 (IL-2); Procedure: ACT with TIL Infusion; Drug: vemurafenib; Drug: Lymphodepletion	FL	NCT01659151
Phase II Randomized Trial of Ipilimumab Versus Ipilimumab and Radiotherapy in Metastatic Melanoma	Metastatic Melanoma	Drug: ipilimumab; Other: Radiation therapy and ipilimumab	NY	NCT01689974
Ipilimumab With Lymphodepletion Plus Adoptive Cell Transfer and High-Dose IL-2 in Melanoma Mets Patients	Metastatic Melanoma	Drug: ipilimumab; Procedure: Tumor infiltrating lymphocytes (TIL); Drug: Administration of lymphodepletion; Drug: cyclophosphamide as part of lymphodepletion; Drug: fludarabine as part of lymphodepletion; Drug: High-dose IL-2; Biological: Adoptive cell therapy with TIL	FL	NCT01701674
Ipilimumab With or Without Talimogene Laherparepvec in Unresected Melanoma	Melanoma	Drug: talimogene laherparepvec plus ipilimumab; Drug: ipilimumab	AZ; CA; FL; IA; IL; IN; KY; MN; NC; NJ; NY; OH; TN; UT	NCT01740297
Dendritic Cell Activating Scaffold in Melanoma	Melanoma	Biological: WDVAX	MA	NCT01753089

MELANOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Study Comparing the Efficacy of MEK162 Versus Dacarbazine in Unresectable or Metastatic NRAS Mutation-Positive Melanoma	Metastatic or Unresectable Cutaneous Melanoma	Drug: MEK162; Drug: dacarbazine	AL; AR; CA; CO; DC; FL; IA; IL; IN; MA; MD; ME; MI; MN; MO; NC; NE; NH; NJ; NV; NY; OH; OR; PA; TN; TX	NCT01763164
Aldesleukin Imaging in Viewing Tumor Growth in Patients With Stage IV Melanoma Receiving Ipilimumab or Pembrolizumab Therapy	Stage IV Skin Melanoma	Other: Laboratory biomarker analysis; Procedure: Radionuclide Imaging; Biological: Technetium Tc 99 Hydrazinonicotinamide-Tricine-linked interleukin-2	MN	NCT01789827
Tumor-Infiltrating Lymphocytes After Combination Chemotherapy in Treating Patients With Metastatic Melanoma	Recurrent Melanoma of the Skin; Stage IIIA Skin Melanoma; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Skin Melanoma	Drug: cyclophosphamide; Drug: fludarabine phosphate; Biological: Therapeutic tumor infiltrating lymphocytes; Biological: aldesleukin; Other: Laboratory biomarker analysis	WA	NCT01807182
NY-ESO-1 Vaccine in Combination With Ipilimumab in Patients With Unresectable or Metastatic Melanoma	Unresectable or Metastatic Melanoma	Biological: ipilimumab; Biological: NY-ESO-1 protein vaccine; Biological: NY-ESO-1 OLP4 vaccine	NY; PA; VA	NCT01810016
The Effects of Vemurafenib on Immunity in Patients With Melanoma	Melanoma	Drug: vemurafenib	DC	NCT01813214
Immunotherapy Using Tumor Infiltrating Lymphocytes for Patients With Metastatic Ocular Melanoma	Metastatic Ocular Melanoma; Metastatic Uveal Melanoma	Drug: aldesleukin; Drug: cyclophosphamide; Drug: fludarabine; Biological: Young TIL	MD	NCT01814046
HD IL-2 Plus Ipilimumab in Patients With Metastatic Melanoma	Metastatic Melanoma	Drug: High-dose interleukin-2; Drug: ipilimumab	AZ; CA; FL; IA; IL; MD; MI; NE; NC; NY; OH, TX	NCT01856023
Autologous Dendritic Cell-Tumor Cell Immunotherapy for Metastatic Melanoma	Stage IV Melanoma; Stage III Melanoma	Biological: Autologous dendritic cell-tumor cell immunotherapy (DC-TC); Biological: Autologous PBMCs in GM-CSF (MC)	CA	NCT01875653
Dendritic Cell Vaccines + Dasatinib for Metastatic Melanoma	Metastatic Melanoma	Biological: DC vaccine; Drug: dasatinib	PA	NCT01876212
Study Comparing Combination of LGX818 Plus MEK162 Versus Vemurafenib and LGX818 Monotherapy in BRAF Mutant Melanoma	Melanoma	Drug: LGX818; Drug: MEK162; Drug: vemurafenib	AL; AR; AZ; CA; CO; CT; FL; GA; HI; IA; ID; IL; IN; KY; LA; MA; MD; ME; MI; MN; MS; ND; NE; NJ; NM; NY; OK; OR; PA; SC; SD; TN; TX; UT; VA; VT; WA; WI	NCT01909453
Safety and Efficacy Study of Vemurafenib and High-dose Interferon Alfa-2b in Melanoma (12-107)	Melanoma	Drug: High-dose interferon alfa-2b; Drug: vemurafenib	PA	NCT01943422
INCB024360 and Vaccine Therapy in Treating Patients With Stage III-IV Melanoma	Multiple Cancer Types	Drug: IDO1 Inhibitor INCB024360; Biological: MELITAC 12.1 peptide vaccine; Other: Laboratory biomarker analysis	GA; NC; NH; VA	NCT01961115
Immunotherapy Using Tumor Infiltrating Lymphocytes Comparing 2 Different Conditioning Regimens for Patients With Metastatic Melanoma	Metastatic Melanoma	Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide; Biological: Young tumor infiltrating lymphocytes (young TIL)	MD	NCT01993719
Cellular Adoptive Immunotherapy Using Autologous CD8+ Antigen-Specific T Cells and Anti-CTLA4	Melanoma	Drug: cyclophosphamide; Procedure: CD8+ T Cells; Drug: interleukin-2; Drug: ipilimumab	TX	NCT02027935
Immunotherapy Study for Patients With Stage IV Melanoma	Stage IV Melanoma; Metastatic Melanoma	Drug: HyperAcute-Melanoma (HAM) immunotherapy; Drug: ipilimumab	NC; TN	NCT02054520
T Cell Receptor Immunotherapy Targeting NY-ESO-1 for Patients With NY-ESO-1 Expressing Melanoma	Metastatic Cancer; Metastatic Melanoma	Biological: Anti-NY ESO-1 TCR CD62L+ cells; Drug: aldesleukin; Drug: cyclophosphamide; Drug: fludarabine	MD	NCT02062359
Study of IDO Inhibitor in Combination With Ipilimumab for Adult Patients With Metastatic Melanoma	Metastatic Melanoma; Stage III Melanoma; Stage IV Melanoma	Drug: indoximod; Drug: ipilimumab	GA; NC; NH; VA	NCT02073123
A Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With GD2+ Solid Tumors	Sarcoma; Osteosarcoma; Rhabdomyosarcoma; Neuroblastoma; Melanoma	Biological: Anti-GD2-CAR engineered T cells; Drug: AP1903; Drug: cyclophosphamide	MD	NCT02107963
Immunotherapy Using 41BB Selected Tumor Infiltrating Lymphocytes for Patients With Metastatic Melanoma	Melanoma; Skin Cancer	Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide; Biological: 4-1BB selected TIL	MD	NCT02111863
Treatment of Advanced Melanoma With MK-3475 and Peginterferon	Melanoma	Drug: MK-3475; Drug: peginterferon alfa-2b	PA	NCT02112032
CDX-1401 and Poly-ICLC Vaccine Therapy With or Without CDX-301in Treating Patients With Stage IIB-IV Melanoma	Multiple Cancer Types	Biological: DEC-205/NY-ESO-1 fusion protein CDX-1401; Other: Laboratory biomarker analysis; Biological: Neoantigen-based melanoma-poly-ICLC vaccine; Other: Pharmacological study; Biological: Recombinant Flt3 ligand	NH; NY	NCT02129075

MELANOMA (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
A Study of the Safety and Efficacy of Pembrolizumab (MK-3475) in Combination With Trametinib and Dabrafenib in Participants With Advanced Melanoma (MK-3475-022/ KEYNOTE-022)	Melanoma	Biological: pembrolizumab; Drug: dabrafenib; Drug: trametinib	CA; MD	NCT02130466
T Cell Receptor Immunotherapy Targeting MAGE-A3 for Patients With Metastatic Cancer Who Are HLA-A*01-Positive	Metastatic Cancer; Metastatic Melanoma	Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide; Biological: Anti-MAGE-A3 HLAA 01-restricted TCR	MD	NCT02153905
Expanded Access Program With Nivolumab (BMS-936558) in Combination With Ipilimumab (Yervoy) in Anti-CTLA-4 Treatment-Naive Subjects With Unresectable or Metastatic Melanoma (CheckMate 218)	Malignant Melanoma	Drug: nivolumab; Drug: ipilimumab	CA; CT; GA; MA; MD; MI; NY; PA; TN; WA	NCT02186249
Adoptive Therapy Using Antigen-Specific CD4 T Cells	Melanoma; Sarcoma	Drug: ipilimumab; Drug: cyclophosphamide; Biological: CD4+ T cells	TX	NCT02210104
Dabrafenib and Trametinib Followed by Ipilimumab and Nivolumab or Ipilimumab and Nivolumab Followed by Dabrafenib and Trametinib in Treating Patients With Stage III-IV BRAFV600 Melanoma	Recurrent Melanoma; Stage IIIA Skin Melanoma; Stage IIIB Skin Melanoma; Stage IIIC Skin Melanoma; Stage IV Skin Melanoma	Drug: dabrafenib; Biological: ipilimumab; Other: Laboratory biomarker analysis; Biological: nivolumab; Other: Quality-of-life assessment; Drug: trametinib	PA	NCT02224781
RTA 408 Capsules in Patients With Melanoma - REVEAL	Melanoma; Unresectable (Stage III) Melanoma; Metastatic (Stage IV) Melanoma	Drug: RTA 408 Capsules (2.5 mg/capsule); Drug: ipilimumab (3 mg/kg)	AL; AR; CA; DE; FL; MA; NC; NJ; OH; TX	NCT02259231
Neoadjuvant Pembrolizumab for Unresectable Stage III and Unresectable Stage IV Melanoma	Unresectable Malignant Neoplasm; Melanoma; Metastatic Melanoma; Stage IV Melanoma; Stage III Melanoma	Drug: pembrolizumab	MO	NCT02306850
Ex Vivo-Activated Lymph Node Lymphocytes in Treating Patients With Stage IIIC-IV Melanoma	Stage IIIC Skin Melanoma; Stage IV Melanoma	Procedure: Lymph node; Biological: X-ACT	OH	NCT02327390
A Study of Pembrolizumab (MK-3475) in Pediatric Participants With Advanced Melanoma or Advanced, Relapsed, or Refractory PD-L1-Positive Solid Tumors or Lymphoma (MK-3475-051/KEYNOTE-051)	Melanoma; Lymphoma; Solid Tumor	Biological: pembrolizumab	TN; WA	NCT02332668
A Comparison of Matured Dendritic Cells and Montanide in Study Subjects With High Risk of Melanoma Recurrence	Melanoma	Biological: DC vaccine; Biological: montanide vaccine; Biological: Poly-ICLC	NY	NCT02334735
Efficacy Study of Nivolumab Compared to Ipilimumab in Prevention of Recurrence of Melanoma After Complete Resection of Stage IIIB/C or Stage IV Melanoma (CheckMate 238)	Melanoma	Drug: ipilimumab; Drug: nivolumab; Other: Placebo matching ipilimumab; Other: Placebo matching nivolumab	AR; CA; CO; CT; DC; FL; GA; IL; MA; MI; MN; MO; NC; NJ; NY; OH; OR; PA; SC; TN; TX; VA; WA	NCT02388906
In Situ, Autologous Therapeutic Vaccination Against Solid Cancers With Intratumoral Hiltonol	Melanoma; Head and Neck Cancer; Sarcoma; Non-Melanoma Skin Cancers	Biological: Hiltonol	GA; MD; NY; PA; SC	NCT02423863
Trial of Vemurafenib and Cobimetinib in Patients With Advanced BRAFV600 Mutant Melanoma	Melanoma	Drug: cobimetinib; Drug: vemurafenib	MD	NCT02427893
A Pilot Study to Evaluate PBR PET in Brain Tumor Patients Treated With Chemoradiation or Immunotherapy	Intracranial Tumors; Glioblastoma; Melanoma	Other: PBR PET; Biological: Cancer Immunotherapy; Radiation: Radiation and chemotherapy	MA	NCT02431572

MISCELLANEOUS

Title	Cancer Type	Treatment	Location	NCT Number
Study of Cytokines in Children With Opsoclonus-Myoclonus Syndrome	Opsoclonus-myoclonus Syndrome		IL	NCT00806182
Hybrid Immunotherapy for Hemophagocytic Lymphohistiocytosis	Hemophagocytic Lymphohistiocytosis	Drug: ATG, rabbit; Drug: etoposide; Drug: Intrathecal methotrexate; Drug: hydrocortisone	AZ; CA; FL; LA; MA; OH; PA; TX	NCT01104025
Natural History Study of SCID Disorders	SCID; Leaky SCID; Omenn Syndrome; Reticular Dysgenesis; ADA Deficiency; XSCID		AL; CA; CO; DC; FL; GA; IL; LA; MA; MD; MI; MN; MO; NC; NJ; NY; OH; OR; PA; TX; UT; WA; WI	NCT01186913
Study to Evaluate the Safety and Tolerability of IV Doses of BMS-906024 in Subjects With Advanced or Metastatic Solid Tumors	Cancer	Drug: BMS-906024	CA; GA; MI; TN; TX	NCT01292655
Patients Treated for SCID (1968-2010)	SCID; ADA-SCID; XSCID; Leaky SCID; Omenn Syndrome; Reticular Dysgenesis		AL; CA; CO; DC; FL; GA; IL; LA; MA; MD; MI; MN; MO; NC; NJ; NY; OH; OR; PA; TX; UT; WA; WI	NCT01346150
A Phase I Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Patients With Locally Advanced or Metastatic Solid Tumors	Solid Cancers	Drug: MPDL3280A	AZ; CA; CT; FL; MA; MD; NC; NV; NY; TN; VA	NCT01375842

MISCELLANEOUS (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Human Placental-Derived Stem Cell Transplantation	Mucopolysaccharidosis I; Mucopolysaccharidosis VI; Adrenoleukodystrophy; Niemann-Pick Disease; Metachromatic Leukodystrophy; Wolman Disease; Krabbe's Disease; Gaucher's Disease; Fucosidosis; Batten Disease; Severe Aplastic Anemia; Diamond-Blackfan Anemia; Amegakaryocytic Thrombocytopenia; Myelodysplastic Syndrome; Acute Myelogenous Leukemia; Acute Lymphocytic Leukemia	Drug: Human placental-derived stem cell	NY; UT	NCT01586455
A Phase IB Study of MPDL3280A (an Engineered Anti-PDL1 Antibody) in Combination With Avastin (Bevacizumab) and/or With Chemotherapy in Patients With Locally Advanced or Metastatic Solid Tumors	Neoplasms	Drug: FOLFOX; Drug: MPDL3280A; Drug: MPDL3280A; Drug: bevacizumab (Avastin); Drug: bevacizumab (Avastin); Drug: carboplatin; Drug: nab-paclitaxel; Drug: paclitaxel; Drug: pemetrexed	CO; CT; DC; MA; NC; NY; TN	NCT01633970
A Phase I Study of an Anti-KIR Antibody in Combination With an Anti-PD1 Antibody in Patients With Advanced Solid Tumors	Cancer, Not Specified	Drug: lirilumab; Drug: nivolumab	IL; MA; MD; NY; OR	NCT01714739
Efficacy and Safety Study of Abatacept to Treat Lupus Nephritis	Lupus Nephritis	Biological: BMS-188667; Drug: mycophenolate mofetil; Drug: prednisone; Biological: Placebo matching with BMS-188667	AL; CA; FL; GA; LA; MA; NC; NJ; NY; OH; TN; TX; UT; VA	NCT01714817
Ipilimumab and Imatinib Mesylate in Advanced Cancer	Advanced Cancers	Drug: ipilimumab; Drug: imatinib mesylate	TX	NCT01738139
Immunotherapy for Recurrent Ependymomas in Children Treatment for Recurrent Ependymomas Using HLA-A2 Restricted Tumor Antigen Peptides in Combination With Imiquimod	Ependymoma	Biological: HLA-A2 restricted synthetic tumor antigen; Drug: imiquimod; Other: enzyme-linked immunosorbent assay; Other: flow cytometry; Other: immunohistochemistry staining method; Other: Laboratory biomarker analysis	PA	NCT01795313
Safety Study of Intratumoral Injection of Clostridium Novyi-NT Spores to Treat Patients With Solid Tumors That Have Not Responded to Standard Therapies	Solid Tumor Malignancies	Biological: Clostridium novyi-NT spores	IL; MD; MI; MO; NY; OH; TX	NCT01924689
T Cell Receptor Immunotherapy Targeting NY-ESO-1 for Patients With NY-ESO-1 Expressing Cancer	Metastatic Cancers Other Than Melanoma That Express ESO Antigen	Biological: Anti-NY ESO-1 mTCR PBL; Drug: cyclophosphamide; Drug: fludarabine; Biological: aldesleukin	MD	NCT01967823
Safety Study of Anti-LAG-3 With and Without Anti-PD-1 in the Treatment of Solid Tumors	Neoplasms by Site	Biological: BMS-986016; Biological: BMS-936558	IL; MA; MD; NY; OR; PA; TX; WA	NCT01968109
Tocilizumab and Hemophagocytic Lymphohistiocytosis (HLH)	Hemophagocytic Lymphohistiocytosis	Drug: tocilizumab	PA	NCT02007239
Patients Treated for Chronic Granulomatous Disease (CGD) Since 1995	Granulomatous Disease, Chronic		CA; DC; FL; GA; LA; MA; MD; MI; MO; NC; NJ; NY; OH; OR; PA; TX; UT; WA; WI	NCT02082353
T Cell Receptor Immunotherapy Targeting MAGE-A3 for Patients With Metastatic Cancer Who Are HLA-DP0401-Positive	Metastatic Cancer That Express the MAGE-A3-DP4 Antigen	Biological: Anti-MAGE-A3-DP4 TCR; Drug: cyclophosphamide; Drug: fludarabine; Drug: aldesleukin	MD	NCT02111850
Immunotherapy in Subjects With HPV6 (Human Papillomavirus) Associated Aerodigestive Malignancies	Aerodigestive Malignancies (e.g Squamous Cell Carcinoma)	Biological: INO-3106, INO-9012	PA	NCT02241369
Pembrolizumab in Treating Patients With Relapsed or Refractory Stage IB-IVB Mycosis Fungoides or Sézary Syndrome	Recurrent Mycosis Fungoides and Sézary Syndrome; Stage IB Mycosis Fungoides and Sézary Syndrome; Stage IIA Mycosis Fungoides and Sézary Syndrome; Stage IIB Mycosis Fungoides and Sézary Syndrome; Stage IIIA Mycosis Fungoides and Sézary Syndrome; Stage IIIB Mycosis Fungoides and Sézary Syndrome; Stage IVA Mycosis Fungoides and Sézary Syndrome; Stage IVB Mycosis Fungoides and Sézary Syndrome	Other: Laboratory biomarker analysis; Biological: pembrolizumab	CA; CT; FL; NY; OH; PA	NCT02243579
A Study Of PF-04518600 In Patients With Select Advanced Solid Tumors	Neoplasms	Drug: PF-04518600; Drug: PF-04518600	CA; WA	NCT02315066
A Phase I Study of MEDI0562 in Adult Subjects With Selected Solid Tumors	Solid Tumors	Biological: MEDI0562	CA; NY; OR	NCT02318394
Study of the Kinetics, Dosimetry and Safety of [18F]F-AraG, a Positron Emission Tomography Imaging Tracer	Cancer	Drug: [18F]F-AraG	CA	NCT02323893
A Phase I/IIA Study of BMS-986148 in Subjects With Select Advanced Solid Tumors	Advanced Cancer	Drug: BMS-986148	CA; NC	NCT02341625
Adoptive Immunotherapy With Activated Marrow Infiltrating Lymphocytes and Cyclophosphamide Graft-Versus-Host Disease Prophylaxis in Patients With Relapse of Hematologic Malignancies After Allogeneic Hematopoietic Cell Transplantation	Hematologic Malignancies; Graft-Versus-Host Disease	Biological: Activated PTCy-MILs	MD	NCT02342613

MISCELLANEOUS (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Safety Study of SEA-CD40 in Cancer Patients	Cancer; Carcinoma; Neoplasms; Neoplasm Metastasis	Drug: SEA-CD40	IL; MI; OR; WA	NCT02376699
A Trial of GI-6301 Vs. Placebo in Combination With Radiotherapy in Locally Advanced, Unresectable Chordoma	Chordoma	Biological: GI-6301	MD	NCT02383498
Study of BMS-986158 in Subjects With Select Advanced Solid Tumors	Multiple Indications Cancer	Drug: BMS-986158; Drug: paclitaxel	CA; SC	NCT02419417
Safety Study of AMG 228 to Treat Solid Tumors	Advanced Malignancy; Advanced Solid Tumors; Cancer; Oncology; Oncology Patients; Tumors; Melanoma; Non-Small Cell Lung Cancer; Squamous Cell Carcinoma of the Head and Neck; Transitional Cell Carinoma of Bladder; Colorectal Cancer	Drug: AMG 228	NY	NCT02437916

NEUROENDOCRINE TUMORS

Title	Cancer Type	Treatment	Location	NCT Number
Isotretinoin With or Without Dinutuximab, Aldesleukin, and Sargramostim Following Stem Cell Transplant in Treating Patients With Neuroblastoma	Localized Resectable Neuroblastoma; Localized Unresectable Neuroblastoma; Regional Neuroblastoma; Stage IV Neuroblastoma; Stage IVS Neuroblastoma	Biological: aldesleukin; Biological: dinutuximab; Drug: isotretinoin; Other: Laboratory biomarker analysis; Other: Pharmacological study; Other: Quality-of-life assessment; Biological: sargramostim	AL; AR; AZ; CA; CO; CT; DC; DE; FL; GA; HI; IA; IL; IN; KY; LA; MA; MD; ME; MI; MN; MO; MS; NC; ND; NE; NH; NJ; NM; NV; NY; OH; OK; OR; PA; RI; SC; SD; TN; TX; UT; VA; VT; WA; WI; WV	NCT00026312
Viral Oncoprotein Targeted Autologous T Cell Therapy for Merkel Cell Carcinoma	Recurrent Merkel Cell Carcinoma; Stage IV Merkel Cell Carcinoma	Radiation: Radiation therapy; Biological: Recombinant interferon beta; Biological: MCPyV TAg-specific polyclonal autologous CD8+ T cells; Biological: aldesleukin; Other: Laboratory biomarker analysis	WA	NCT01758458
3rd Generation GD-2 Chimeric Antigen Receptor and iCaspase Suicide Safety Switch, Neuroblastoma, GRAIN	Neuroblastoma	Genetic: iC9-GD2 T Cell Lymphocytes-frozen cells; Genetic: iC9-GD2 T cell lymphocytes-fresh cells; Drug: cyclophosphamide; Drug: fludarabine; Drug: pembrolizumab; Genetic: iC9-GD2 T cell lymphocytes-fresh cells	TX	NCT01822652
NK White Blood Cells and Interleukin in Children and Young Adults With Advanced Solid Tumors	Solid Tumors; Brain Tumors; Sarcoma; Pediatric Cancers; Neuroblastoma	Biological: Recombinant human interleukin-15 (rhIL-15); Biological: NK cell infusion	MD	NCT01875601
Phase II STIR Trial: Haploidentical Transplant and Donor Natural Killer Cells for Solid Tumors	Ewing Sarcoma; Neuroblastoma; Rhabdomyosarcoma	Procedure: Allogeneic HCT; Drug: Donor NK cell infusion	WI	NCT02100891
Anti-GD2 3F8 Monoclonal Antibody and GM-CSF for High-Risk Neuroblastoma	Neuroblastoma	Biological: Anti-GD2 3F8 monoclonal antibody; Drug: GM-CSF (granulocyte-macrophage colony-stimulating factor); Drug: Oral isotretinoin	NY	NCT02100930
A Phase I Trial of T Cells Expressing an Anti-GD2 Chimeric Antigen Receptor in Children and Young Adults With GD2+ Solid Tumors	Sarcoma; Osteosarcoma; Rhabdomyosarcoma; Neuroblastoma; Melanoma	Biological: Anti-GD2-CAR engineered T cells; Drug: AP1903; Drug: cyclophosphamide	MD	NCT02107963
A Pilot Study of Immunotherapy Including Haploidentical NK Cell Infusion Following CD133+ Positively-Selected Autologous Hematopoietic Stem Cells in Children With High-Risk Solid Tumors or Lymphomas	Neuroblastoma; Lymphoma; High-risk Tumor	Device: CD133+ selected autologous stem cell infusion; Biological: IL-2; Biological: hu14.18K322A; Drug: busulfan; Drug: melphalan; Biological: GM-CSF; Drug: bendamustine; Drug: etoposide; Drug: cytarabine; Drug: carboplatin; Device: Haploidentical natural killer cell infusion; Biological: G-CSF; Drug: etoposide phosphate	TN	NCT02130869
Activated T Cells Armed With GD2 Bispecific Antibody in Children and Young Adults With Neuroblastoma and Osteosarcoma	Desmoplastic Small Round Cell Tumor; Disseminated Neuroblastoma; Metastatic Childhood Soft Tissue Sarcoma; Metastatic Ewing Sarcoma/PNET; Metastatic Osteosarcoma; Recurrent Adult Soft Tissue Sarcoma; Recurrent Childhood Soft Tissue Sarcoma; Recurrent Ewing Sarcoma/PNET; Recurrent Melanoma; Recurrent Neuroblastoma; Recurrent Osteosarcoma	Biological: IL-2; Biological: GD2Bi-aATC; Biological: GM-CSF; Other: Laboratory evaluations of immune responses	MI; NY	NCT02173093
Pembrolizumab in Treating Patients With Advanced Merkel Cell Cancer	Recurrent Merkel Cell Carcinoma; Stage IIIA Merkel Cell Carcinoma; Stage IIIB Merkel Cell Carcinoma; Stage IV Merkel Cell Carcinoma	Other: Laboratory biomarker analysis; Biological: pembrolizumab	CA; CT; GA; MD; NY; OH; WA	NCT02267603

NEUROENDOCRINE TUMORS (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Engineered Neuroblastoma Cellular Immunotherapy (ENCIT)-01	Neuroblastoma; Ganglioneuroblastoma	Biological: Patient derived CD171 specific CAR T cells expressing EGFRt; Biological: Patient derived CD171 specific CAR T cells expressing EGFRt	WA	NCT02311621

OVARIAN

Title	Cancer Type	Treatment	Location	NCT Number
CAR T Cell Receptor Immunotherapy Targeting Mesothelin for Patients With Metastatic Cancer	Metastatic Cancer; Pancreatic Cancer; Mesothelioma; Ovarian Cancer	Drug: fludarabine; Biological: Anti-mesothelin CAR; Drug: cyclophosphamide; Drug: aldesleukin	MD	NCT01583686
Intrapleural AdV-tk Therapy in Patients With Malignant Pleural Effusion	Malignant Pleural Effusion; Lung Cancer; Mesothelioma; Breast Cancer; Ovarian Cancer	Biological: AdV-tk plus valacyclovir	PA	NCT01997190
Autologous Dendritic Cell-Tumor Cell Immunotherapy for Advanced Epithelial Ovarian Carcinomas	Stage III Ovarian Carcinoma; Stage IV Ovarian Carcinoma; Fallopian Tube Carcinoma; Primary Peritoneal Carcinoma	Biological: ovapuldencel-T; Biological: MC: Autologous PBMCs in GM-CSF	CA	NCT02033616
INCB024360 Before Surgery in Treating Patients With Newly Diagnosed Stage III-IV Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Stage IIIA Fallopian Tube Cancer; Stage IIIA Ovarian Cancer; Stage IIIA Primary Peritoneal Cancer; Stage IIIB Fallopian Tube Cancer; Stage IIIB Ovarian Cancer; Stage IIIB Primary Peritoneal Cancer; Stage IIIC Fallopian Tube Cancer; Stage IIIC Ovarian Cancer; Stage IIIC Primary Peritoneal Cancer; Stage IV Fallopian Tube Cancer; Stage IV Ovarian Cancer; Stage IV Primary Peritoneal Cancer	Drug: IDO1 inhibitor INCB024360; Other: Laboratory biomarker analysis; Procedure: Therapeutic conventional surgery	MN; NY	NCT02042430
Phase III Trial of Maintenance FANG for High-Risk Stage III/IV Ovarian Cancer	Ovarian Cancer; Ovarian Neoplasms	Biological: FANG autologous tumor cell immunotherapy; Biological: Placebo	CA; MI; MT; NH; PA; TX; WA	NCT02346747
A Phase I/II Study of Motolimod (VTX-2337) and MEDI4736 in Subjects With Recurrent, Platinum-Resistant Ovarian Cancer for Whom Pegylated Liposomal Doxorubicin (PLD) is Indicated	Ovarian Cancer	Drug: motolimod; Drug: MEDI4736; Drug: pegylated liposomal doxorubicin	AZ; NY; OH; RI; TX	NCT02431559

PANCREATIC

Title	Cancer Type	Treatment	Location	NCT Number
A Trial of Boost Vaccinations of Pancreatic Tumor Cell Vaccine	Pancreatic Cancer	Biological: PANC 10.05 pcDNA-1/GM-Neo and PANC 6.03 pcDNA-1 neo vaccine	MD	NCT01088789
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Cancer	Metastatic Colorectal Cancer; Metastatic Gastric Cancer; Metastatic Pancreatic Cancer; Metastatic Hepatocellular Carcinoma; Metastatic Cholangiocarcinoma	Biological: Young TIL; Drug: aldesleukin; Drug: cyclophosphamide; Drug: fludarabine	MD	NCT01174121
CAR T Cell Receptor Immunotherapy Targeting Mesothelin for Patients With Metastatic Cancer	Metastatic Cancer; Pancreatic Cancer; Mesothelioma; Ovarian Cancer	Drug: fludarabine; Biological: Anti-mesothelin CAR; Drug: cyclophosphamide; Drug: aldesleukin	MD	NCT01583686
Immunotherapy Study in Borderline Resectable or Locally Advanced Unresectable Pancreatic Cancer	Pancreatic Cancer; Pancreatic Carcinoma Non-Resectable; Locally Advanced Malignant Neoplasm	Drug: FOLFIRINOX; Biological: algenpantucel-L Immunotherapy; Radiation: 5-FU chemoradiation; Drug: gemcitabine; Drug: capecitabine; Drug: nab-paclitaxel	AZ; CA; CT; FL; IL; IN; KS; MI; MN; NC; NY; OH; OK; OR; PA; TN; TX; WA; WI	NCT01836432
A Phase II, Multicenter Study of FOLFIRINOX Followed by Ipilimumab With Allogenic GM-CSF Transfected Pancreatic Tumor Vaccine in the Treatment of Metastatic Pancreatic Cancer	Metastatic Pancreatic Adenocarcinoma	Drug: ipilimumab; Biological: Vaccine; Drug: FOLFIRINOX	MD	NCT01896869
Combination Chemotherapy With or Without Oregovomab Followed by Stereotactic Body Radiation Therapy and Nelfinavir Mesylate in Treating Patients With Locally Advanced Pancreatic Cancer	Pancreatic Adenocarcinoma; Resectable Pancreatic Cancer; Stage IA Pancreatic Cancer; Stage IB Pancreatic Cancer; Stage IIA Pancreatic Cancer; Stage IIB Pancreatic Cancer; Stage III Pancreatic Cancer	Procedure: 4-dimensional computed tomography; Drug: fluorouracil; Drug: gemcitabine hydrochloride; Other: Laboratory biomarker analysis; Drug: leucovorin calcium; Drug: nelfinavir mesylate; Biological: oregovomab; Radiation: Stereotactic body radiation therapy; Procedure: Therapeutic conventional surgery	NE	NCT01959672
Safety and Efficacy of Combination Listeria/GVAX Pancreas Vaccine in the Pancreatic Cancer Setting	2nd-line, 3rd-line and Greater Metastatic Pancreatic Cancer	Biological: GVAX pancreas vaccine; Biological: CRS-207; Drug: gemcitabine, capecitabine, 5-FU, irinotecan or erlotinib; Drug: cyclophosphamide	AZ; CA; CO; FL; IL; MD; MO; NC; NY; OR; PA; TN; VA; WA	NCT02004262
Safety and Immunological Effect of Pembrolizumab in Resectable or Borderline Resectable Pancreatic Cancer	Pancreatic Cancer	Drug: pembrolizumab; Radiation: Neoadjuvant chemoradiation	VA	NCT02305186
Inovio TRT-001: Telomerase DNA Immunotherapy in Breast, Lung, and Pancreatic Cancers	Breast Cancer; Lung Cancer; Pancreatic Cancer	Biological: INO-1400; Biological: INO-9012	PA	NCT02327468
Immunotherapy and SBRT Study in Borderline Resectable Pancreatic Cancer	Pancreatic Cancer; Pancreatic Carcinoma Non-Resectable	Drug: mFOLFIRINOX; Biological: algenpantucel-L Immunotherapy; Radiation: SBRT; Drug: gemcitabine	KY; MA	NCT02405585

PANCREATIC (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Neoadjuvant GMCI Plus mFOLFIRINOX and Chemoradiation for Non-Metastatic Pancreatic Adenocarcinoma	Pancreatic Adenocarcinoma	Biological: GMCI; Drug: mFOLFIRINOX; Drug: gemcitabine; Radiation: Radiation; Procedure: Surgery	OH	NCT02446093
Pilot Study of Autologous T Cells in Patients With Metastatic Pancreatic Cancer	Pancreatic Cancer	Biological: CART-meso-19 T cells; Drug: cyclophosphamide	CA	NCT02465983

PENILE

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Human Papillomavirus-Associated Cancers	Cervical Cancer; Oropharyngeal Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: Young TIL; Drug: aldesleukin	MD	NCT01585428
T Cell Receptor Immunotherapy Targeting HPV-16 E6 for HPV-Associated Cancers	Vaginal Cancer; Cervical Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: E6 TCR; Drug: aldesleukin	MD	NCT02280811

PROSTATE

Title	Cancer Type	Treatment	Location	NCT Number
Phase II Study of Adenovirus/PSA Vaccine in Men With Recurrent Prostate Cancer After Local Therapy APP21	Recurrent Prostate Cancer	Biological: Adenovirus/PSA vaccine	IA	NCT00583752
Adoptive Transfer of Autologous T Cells Targeted to Prostate Specific Membrane Antigen (PSMA) for the Treatment of Castrate Metastatic Prostate Cancer (CMPC)	Prostate Cancer	Biological: Engineered autologous T cells; Drug: cyclophosphamide	NY	NCT01140373
Efficacy Trial of the Implantation of Mouse Renal Adenocarcinoma Macrobeads in Subjects With Castration-Resistant Prostate Cancer Resistant to Taxanes (Docetaxel, Cabazitaxel) and Evidence of Disease Progression on Androgen-axis Inhibition and/or Immunotherapy in the Form of Sipuleucel-T	Prostate Cancer	Biological: Cancer macrobead placement in abdominal cavity	NY	NCT01174368
Sipuleucel-T, CT-011, and Cyclophosphamide for Advanced Prostate Cancer	Prostatic Neoplasms	Drug: CT-011 (Anti-PD1 Antibody); Other: sipuleucel-T (Provenge); Drug: cyclophosphamide	GA	NCT01420965
Phase III Study of ProstAtak Immunotherapy With Standard Radiation Therapy for Localized Prostate Cancer	Prostate Cancer	Biological: ProstAtak(AdV-tk) plus valacyclovir; Biological: Placebo plus valacyclovir	AZ; CO; MA; MD; NM; NY; PA; TX	NCT01436968
C11-Sodium Acetate PET/CT Imaging for Metastatic Disease in Intermediate- to High-Risk Prostate Adenocarcinoma	Prostate Cancer; Prostate Adenocarcinoma	Drug: C11-sodium acetate	AZ	NCT01530269
Ipilimumab and GMCSF Immunotherapy for Prostate Cancer	Prostate Cancer	Drug: ipilimumab; Drug: GM-CSF	CA	NCT01530984
Combining Ipilimumab With Abiraterone Acetate Plus Prednisone in Chemotherapy and Immunotherapy-naive Patients With Progressive Metastatic Castration-Resistant Prostate Cancer	Prostate Cancer	Drug: ipilimumab	IL; NY; OR	NCT01688492
Monitoring Anti-Prostate Cancer Immunity Following Stereotactic Body Radiotherapy (SBRT)	Oligometastatic Prostate Cancer		MN	NCT01777802
A Randomized Phase II Trial of Combining Sipuleucel-T With Immediate vs. Delayed CTLA-4 Blockade for Prostate Cancer	Prostate Cancer	Drug: sipuleucel-T; Drug: ipilimumab	CA; TX	NCT01804465
Sipuleucel-T With or Without Radiation Therapy in Treating Patients With Hormone-Resistant Metastatic Prostate Cancer	Adenocarcinoma of the Prostate; Bone Metastases; Hormone-Resistant Prostate Cancer; Recurrent Prostate Cancer; Soft Tissue Metastases; Stage IV Prostate Cancer	Biological: sipuleucel-T; Radiation: External beam radiation therapy; Other: Laboratory biomarker analysis	CA; UT	NCT01807065
Sipuleucel-T and Stereotactic Ablative Body Radiation (SABR) for Metastatic Castrate-Resistant Prostate Cancer (mCRPC)	Metastatic Castration-Resistant Prostate Cancer; mCRPC	Drug: sipuleucel-T; Radiation: Stereotactic ablative body radiation	TX	NCT01818986
Enzalutamide With or Without Vaccine Therapy for Advanced Prostate Cancer	Prostate Cancer	Biological: PROSTVAC-F/TRICOM; Biological: PROSTVAC-V/TRICOM; Drug: enzalutamide (Xtandi)	MD	NCT01867333
Enzalutamide in Combination With PSA-TRICOM in Patients With Non-Metastatic Castration Sensitive Prostate Cancer	Prostate Cancer	Biological: PROSTVAC-F/TRICOM; Biological: PROSTVAC-V/TRICOM; Drug: enzalutamide (Xtandi)	MD	NCT01875250
CYT107 With or Without Vaccine Therapy in Treating Patients With Metastatic Hormone-Resistant Prostate Cancer	Hormone-Resistant Prostate Cancer; Recurrent Prostate Cancer; Stage IV Prostate Cancer	Biological: glycosylated recombinant human interleukin-7; Other: Laboratory biomarker analysis	CA; GA; NH; NY; WA	NCT01881867

PROSTATE (CONTINUED)

Title	Cancer Type	Treatment	Location	NCT Number
Combining Ipilimumab, Degarelix, and Radical Prostatectomy in Men With Newly Diagnosed Metastatic Castration-Sensitive Prostate Cancer or Ipilimumab and Degarelix in Men With Biochemically Recurrent Castration-Sensitive Prostate Cancer After Radical Prostatectomy	Metastatic Castration-Sensitive Prostate Cancer	Drug: degarelix; Drug: ipilimumab; Procedure: Radical prostatectomy	NY	NCT02020070
Dendreon Lymph Node Biopsy in Metastatic Castrate-Resistant Prostate Cancer	Prostate Cancer	Drug: sipuleucel-T; Procedure: Lymph node biopsy	NC	NCT02036918
PET/MR Assessment of Sipuleucel T Treatment for Metastatic Castration Resistant Prostate Cancer	Prostate Cancer	Device: PET/CT; Device: PET/MRI	NY	NCT02042053
Phase III Study of DCVAC Added to Standard Chemotherapy for Men With Metastatic Castration-Resistant Prostate Cancer	Metastatic Castration-Resistant Prostate Cancer	Biological: DCVAC; Biological: Placebo; Drug: docetaxel; Drug: Taxotere	AL; AZ; CA; CO; CT; FL; KS; LA; MD; MI; MN; NC; NE; NJ; NV; NY; OR; PA; SC; TN; TX; VA; WA	NCT02111577
A Multicenter Trial Enrolling Men With Advanced Prostate Cancer Who Are to Receive Combination Radiation and Sipuleucel-T	Castration-Refractory Metastatic Prostate Cancer (mCRPC)	Drug: Provenge	AZ	NCT02232230
Pilot Study of DRibble Vaccine for Prostate Cancer Patients	Adenocarcinoma of the Prostate	Drug: cyclophosphamide; Biological: DRibble vaccine; Biological: HPV vaccinations; Drug: imiquimod	OR	NCT02234921
Phase II Study of Sipuleucel-T W/ or W/O Radium-223 in Men With Asymptomatic or Minimally Symptomatic Bone-MCRPC	Prostate Cancer	Drug: radium-223; Biological: sipuleucel-T	MD	NCT02463799

SARCOMA

Title	Cancer Type	Treatment	Location	NCT Number
Her2 Chimeric Antigen Receptor Expressing T Cells in Advanced Sarcoma	Sarcoma	Genetic: Autologous HER2-specific T cells; Drug: fludarabine; Drug: cyclophosphamide	TX	NCT00902044

THYROID

Title	Cancer Type	Treatment	Location	NCT Number
Administering Peripheral Blood Lymphocytes Transduced With a Murine T Cell Receptor Recognizing Human Thyroglobulin to People With Thyroglobulin-Expressing Thyroid Cancer	Metastatic Thyroid Cancer	Drug: aldesleukin; Drug: fludarabine; Drug: cyclophosphamide; Biological: Anti-thyroglobulin mTCR PBL	MD	NCT02390739

UROTHELIAL

Title	Cancer Type	Treatment	Location	NCT Number
A Study of Pembrolizumab (MK-3475) Versus Paclitaxel, Docetaxel, or Vinflunine for Participants With Advanced Urothelial Cancer (MK-3475-045/KEYNOTE-045)	Urothelial Cancer	Biological: pembrolizumab; Drug: paclitaxel; Drug: vinflunine; Drug: docetaxel	AL; CA; CT; FL; IL; NC; NV; NY; OH; PA; TN	NCT02256436
Study of Pembrolizumab (MK-3475) in Participants With Advanced Urothelial Cancer (MK-3475-052/KEYNOTE-52)	Urothelial Cancer	Biological: pembrolizumab	IL; IN; NY; OR	NCT02335424

VAGINAL

Title	Cancer Type	Treatment	Location	NCT Number
Immunotherapy Using Tumor-Infiltrating Lymphocytes for Patients With Metastatic Human Papillomavirus-Associated Cancers	Cervical Cancer; Oropharyngeal Cancer; Vaginal Cancer; Anal Cancer; Penile Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: Young TIL; Drug: aldesleukin	MD	NCT01585428
T Cell Receptor Immunotherapy Targeting HPV-16 E6 for HPV-Associated Cancers	Vaginal Cancer; Cervical Cancer; Anal Cancer; Penile Cancer; Oropharyngeal Cancer	Drug: fludarabine; Drug: cyclophosphamide; Biological: E6 TCR; Drug: aldesleukin	MD	NCT02280811

ADVOCACY & FINANCIAL RESOURCES

CLINICAL TRIALS

CenterWatch www.centerwatch.com

Coalition of Cancer Cooperative Groups www.cancertrialshelp.org

LIVESTRONG Foundation www.livestrong.org/we-can-help/planning-medical-care/considering-clinical-trials

MolecularMatch www.molecularmatch.com

My Clinical Trial Locator http://myclinicaltriallocator.com

PearlPoint Cancer Support www.pearlpoint.org

FINANCIAL ASSISTANCE

BenefitsCheckUp www.benefitscheckup.org

Bringing Hope Home www.bringinghopehome.org

Cancer*Care* www.cancercare.org/financial

Cancer Financial Assistance Coalition www.cancerfac.org

The CHAIN Fund www.thechainfund.com

HealthWell Foundation www.healthwellfoundation.org

NeedyMeds www.needymeds.com

Partnership for Prescription Assistance www.pparx.org

Patient Access Network Foundation www.panfoundation.org

Patient Advocate Foundation www.patientadvocate.org

Patient Services Inc. www.patientservicesinc.org

The Pins for Pauly Foundation Inc. www.pinsforpauly.org

RxAssist www.rxassist.org

The Social Security and Disability Resource Center www.ssdrc.com

State Health Insurance Assistance Programs www.shiptacenter.org

PATIENT ADVOCACY

Dream Foundation www.dreamfoundation.org

Foundation for Health Coverage Education www.coverageforall.org

Friend for Life Cancer Support Network www.friend4life.org

Health Connections Network www.healthconnectionsnetwork.org

LIVESTRONG Foundation www.livestrong.org

Living Well Cancer Resource Center http://livingwellcrc.org

Research Advocacy Network www.researchadvocacy.org

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