Society for Immunotherapy of Cancer

FOR IMMEDIATE RELEASE
March 25, 2011

Contact:

Jimmy Balwit, MS
Society for Immunotherapy of Cancer (SITC)
Ph: 414-918-3106
jbalwit@sitcancer.org

FDA Approves Ipilimumab, Major Breakthrough in Cancer Immunotherapy

(MILWAUKEE, WI) – Today marks a major advance in the fight against cancer with the approval of ipilimumab (Yervoy) by the U.S. Food and Drug Administration (FDA) for the treatment of melanoma. In clinical studies reviewed by the FDA this monoclonal antibody (mAb) improved the survival of patients with late-stage melanoma, the leading cause of death from skin cancer.

Over the past three decades the incidence of melanoma has risen steadily, with one out of every 50 Americans at risk of developing melanoma during their lifetime. With conventional treatments, patients with advanced melanoma have a median lifespan of 6-9 months. Approval of this novel cancer immunotherapy gives physicians a powerful new tool to treat this challenging disease.

"This is a landmark advance for several reasons," said Society for Immunotherapy of Cancer (SITC) President, Thomas Gajewski, MD, PhD, University of Chicago. "First, this is a completely new way to treat cancer in the clinic, by blocking a key negative regulator of the anti-tumor immune response. Second, it is the first drug ever to show improved survival of metastatic melanoma patients. And third, we learned that clinical responses to immune therapies such as this one can take time, with patients sometimes showing disease progression prior to regression. This pattern will require significant education of the oncology community that will be utilizing these agents in the near future."

Ipilimumab (Bristol-Myers Squibb Company) targets a key physiologic factor that serves to inhibit the body's natural immune response against tumor cells. By blocking this negative regulator, this new strategy effectively takes the foot off the brake of the immune system, allowing immune cells to attack tumors more effectively. This strategy is a major breakthrough in cancer immunotherapy, and further solidifies immunotherapy as an effective cancer treatment approach to be considered along with the conventional cancer treatments of surgery, chemotherapy and radiation for patients with cancer.

Early this week, ipilimumab was reported to improve overall survival in previously untreated patients with metastatic melanoma in combination with chemotherapy compared to chemotherapy alone. Earlier results were published in the June 2010 issue of the *New England Journal of Medicine* by SITC board member F. Stephen Hodi, MD, Dana Farber Harvard Cancer Center in Boston, and colleagues. The study included 676 patients with inoperable, late-stage melanoma tumors that had already spread throughout the body. The researchers found that in patients who received ipilimumab treatment alone or in combination with an investigational cancer vaccine, 44% – 46% were alive one year after treatment, and 24% – 22% were alive two years after treatment. By comparison, with vaccine treatment alone, only 25% of patients were alive after one year, and just 14% were alive after two years. More encouragingly, a subset of patients has had apparent disappearance of their disease that has persisted for more than two years.

Patient survival with ipilimumab alone and in combination with the cancer vaccine was compared to survival of patients treated with the cancer vaccine alone (control group). Compared to the control group, ipilimumab alone significantly improved median overall survival from 6.4 months to 10.1 months. In combination with the cancer vaccine, ipilimumab provided an equivalent survival advantage, boosting median overall survival to 10.0 months, compared to the control group. One year after treatment, 46% of patients who had received ipilimumab alone were alive and 44% of patients who received ipilimumab in combination with the vaccine were alive, compared to 25% of patients who received the vaccine alone. Two years after treatment, 24% of patients treated with ipilimumab alone were still alive as were 22% of patients treated with ipilimumab plus the vaccine. By comparison, only 14% of patients were still alive two years following treatment with the vaccine alone. Additional advantages reported with this strategy included reduction in the risk of progression, and improvements in overall response rate and progression free survival. Ipilimumab is being approved along with a plan to inform health care professionals and patients about important side effects that can occur with this treatment.

CTLA-4 blockade as a strategy to boost anti-tumor immune responses was first presented at the Society's 1996 Annual Meeting in Washington D.C. shortly after being reported for the first time in *Science* that year by SITC member James Allison, PhD, Memorial Sloan-Kettering Cancer Center. This general strategy has been a major research emphasis for many of the basic scientists and clinical investigators engaged in cancer immunotherapy. As the preeminent medical association focused on cancer immunotherapy, advances in the science, clinical evaluation, and translational of CTLA-4 blockade have been extensively reported at SITC's scientific Annual Meetings and Associated Programs over the last 15 years, including most recently at the Society's 25th Annual Meeting, Hot Topic Symposium on CTLA-4 Blockade and Primer on Tumor Immunology and Biological Therapy of Cancer.

"Preclinical models have suggested that logical combinations of specific immune therapy strategies, combined with CTLA-4 blockade, can have profound synergistic activity. A major consequence of the FDA approval of ipilimumab will be the availability of this drug to clinical investigators who can systematically combine it with other therapeutic approaches with the hope of improving clinical efficacy even further, " stated Dr. Gajweski. Such combination strategies will be the focus of the 2011 SITC Workshop on Immunotherapy Combinations for cancer therapy to be held in conjunction with the Society's 26th Annual Meeting and Associated Programs in North Bethesda, November 1-6, 2011.

Through educational events and initiatives that foster scientific exchange and collaboration among basic scientists and clinical investigators form around the world, SITC is proud to advance the science and translation of immunotherapy strategies like CTLA-4 blockade that will improve the lives of patients with cancer. "FDA approval of anti-CTLA-4 further strengthens the case for cancer immunotherapy. We anticipate other novel immune therapies that will benefit patients with cancer over the coming years," said Dr. Gajewski.

Founded in 1984, the Society for Immunotherapy of Cancer (formerly the International Society for Biological Therapy of Cancer; iSBTc) is a non-profit organization of clinicians, researchers, students, post-doctoral fellows, and allied health professionals dedicated to improving cancer patient outcomes by advancing the development and application of cancer immunotherapy through interaction, innovation and leadership. For more information about SITC, please visit the Society website at www.sitcancer.org.

# # #