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IMMUNOTHERAPY BREAKTHROUGH FOR CANCER PATIENT TREATMENT

(CHICAGO – June 6, 2010) - Immunotherapy, a growing therapeutic option in the fight against cancer, made a giant leap forward this weekend with the release of clinical trial results of Bristol-Myers Squibb Company's ipilimumab. The results, reported by Dr. Steven O'Day at the 2010 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago and published June 5th in the New England Journal of Medicine, indicate that ipilimumab significantly improved the survival of patients with late stage melanoma, either as the only cancer-fighting agent, or in combination with a cancer vaccine.

Ipilimumab is a human monoclonal antibody that targets a key negative regulator (CTLA-4) of the body's immune response against tumor cells. By relieving negative regulation, this antibody effectively takes a foot off the brake of the immune system, allowing immune cells to attack tumors more effectively. As such, ipilimumab represents a new class of promising immunotherapeutic agents and may offer hope to patients with a variety of advanced cancers, including melanoma and possibly other tumors, including lung, ovarian and prostate cancer.

The study, a phase III, randomized, double-blind, multi-center clinical trial, evaluated the safety and efficacy of ipilimumab alone and in combination with a therapeutic cancer vaccine consisting of the gp100 antigen. The study included 676 previously treated patients with inoperable, late stage melanoma tumors that had already spread through the body.

Survival of patients treated with ipilimumab alone (137 patients) and ipilimumab in combination with the cancer vaccine (403 patients) was compared to survival of patients who were treated with the cancer vaccine alone (136 patients). Compared to this control group, treatment with ipilimumab alone improved median overall survival from 6.4 months to 10.1 months (hazard ratio for death compared to gp100 alone, 0.66; p=0.003). The combination of gp100 cancer vaccine with ipilimumab provided an equivalent survival advantage to treatment with ipilimumab alone, boosting median overall patient survival to 10.0 months, compared to the control group (hazard ratio for death compared to gp100 alone, 0.68; p<0.001). After one year, 46% of patients who received ipilimumab alone were alive and 44% of patients who received ipilimumab in combination with gp100 were alive, compared to 25% of patients who received gp100 vaccine alone. Twenty-four percent (24%) of patients treated with ipilimumab alone were alive after two years as were 22% of patients treated with ipilimumab plus gp100. By comparison, 14% of patients treated with gp100 vaccine alone were alive at two years.

Additional advantages with ipilimumab were also reported for secondary outcome measures evaluated in the study, including reduction in the risk of progression, best overall response rate, and progression-free survival.

Addressng a global audience of cancer researchers and clinical oncologists at the ASCO meeting, Dr. O'Day emphasized, "For the first time, a significant improvements in overall survival has been demostrated in previously-treated advanced

melanoma patients in a large, randomized Phase 3 study."

“We have been excited to follow and advance the science of CTLA-4 blockade as a means of boosting anti-tumor immune responses since this model was presented by Dr. James Allison at our Society's 1996 Annual Meeting in Washington, D.C., shortly after being reported for the first time in Science that year” stated Dr. Bernard Fox, President of the International Society for Biological Therapy of Cancer (iSBTc), the preeminent medical association focused on cancer immunotherapy. “This current ipilimumab clinical trial is a major landmark in cancer immunotherapy and suggests opportunities to explore additional therapeutic combinations with anti-CTLA-4 to treat other cancers. We are eager to see this strategy translated into broader clinical use and look forward to improvements in cancer outcomes with this approach.”

iSBTc member, Dr. Steven O'Day continued, "Results from this ipilimumab study are exciting and show the potentials of harnessing the immune system to treat cancers like metastatic melanoma."

In addition to these and other exciting results for cancer treatment with ipilimumab, a number of other studies reported at the ASCO meeting pointed to additional encouraging advances in cancer immunotherapy. Among these are positive reports on the recently approved therapeutic prostate cancer vaccine Provenge® (Dendreon Corp.), interleukin-2, interleukin-21, and an antibody directed at another distinct suppressor of anti-tumor immunity, PD-1. These reports, and other important results to be presented in October 2010 at the iSBTc Annual Meeting, indicate that immunotherapies and biologic treatments of cancer are delivering on their promise to offer clinicians and patients a strategy to harness the body’s own defense system in the treatment of cancer.

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Founded in 1984, 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 biological therapy/immunotherapy through interaction, innovation and leadership. For more information about iSBTc, please visit the Society website at www.isbtc.org.

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