



Staff Contact: Jimmy Balwit
International Society for Biological Therapy of Cancer
555 E. Wells St., Suite 1100, Milwaukee, WI 53202
Phone: 414-271-2456 - Fax: 414-276-3349
Email: jbalwit@isbtc.org - Website: www.isbtc.org

CANCER IMMUNOTHERAPIES COMING OF AGE

Breadth of Promising Biological Cancer Treatments Presented at ASCO

(MILWAUKEE, WI - June 8, 2010) - Advances in cancer immunotherapies were in the spotlight at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago this week. Members of the International Society for Biological Therapy of Cancer (iSBTc), the preeminent medical association focused on cancer immunotherapy, announced important advances that are giving doctors new options to fight cancer. These new options, called immunotherapies or biological treatment, use a patient's own immune system to recognize and destroy cancer cells. Clinical studies show promising results in the biological treatment of a wide range of cancers, from advanced melanoma to prostate and breast cancer. As more studies emerge and immunotherapies move from the lab bench to the bedside, it is becoming increasingly clear that these biological treatment approaches are coming of age as a promising option for cancer patients. Some of the recent studies on cancer immunotherapies that were presented at ASCO are summarized below.

Positive results of a phase III randomized trial of anti-CTLA-4 blockade in patients with advanced melanoma demonstrated that treatment with ipilimumab, alone or in combination with cancer vaccine gp100, provided a significant overall survival advantage compared to treatment with gp100 vaccine alone. As reported by iSBTc member Dr. Steven O'Day and published June 5th in the *New England Journal of Medicine* by iSBTc Board Member Dr. F. Stephen Hodi et al, treatment with ipilimumab was associated with a median overall survival of 10.0-10.1 months compared to 6.4 months with gp100 alone. At year one 44-46% of the patients treated with ipilimumab were alive, compared to 25% of patients treated only with gp100. At year two 22-24% of the ipilimumab-treated patients were alive, compared to 14% of the patients in the control group who received only gp100. (See iSBTc June 6, 2010 Press Release for more information on this study <http://www.isbtc.org/UserFiles/file/IpiReleaseforweb.pdf>).

In addition to the exciting results from the ipilimumab clinical trial on melanoma, phase II results presented at ASCO on interleukin-21 (IL-21) treatment of melanoma showed promise for this cytokine-based approach. In an ASCO session on melanoma co-chaired by iSBTc Vice President Dr. Thomas F. Gajewski, investigator Dr. Teresa M. Petrella reported a 24% overall response rate (ORR) to IL-21 for first-line treatment of metastatic melanoma, with a median response duration of 5 months. The ORR was not dependent on the dose, expression of the IL-21 receptor or status of BRAF mutation. Median progression free survival reported in the study was 5.19 months (95% C.I. [2.17, 5.95]). The investigators are planning a randomized phase II trial of IL-21 to confirm these results.

Dr. Gajewski noted the potential importance of this IL-21 study, "This was a remarkably high clinical response rate for a new immunoregulatory cytokine, and the toxicity profile seems quite favorable compared to that seen with other cytokines currently in clinical use. These results are also in keeping with the activity in renal cell cancer presented at the 2008 iSBTc annual meeting, in that case combined with Sorafenib."

(continued)



Staff Contact: Jimmy Balwit
International Society for Biological Therapy of Cancer
555 E. Wells St., Suite 1100, Milwaukee, WI 53202
Phone: 414-271-2456 ~ Fax: 414-276-3349
Email: jbalwit@isbtc.org ~ Website: www.isbtc.org

CANCER IMMUNOTHERAPIES COMING OF AGE (continued)

In addition to these exciting results for biological treatment of melanoma, other studies reported at the ASCO meeting pointed to additional encouraging advances in immunotherapy for other cancers. Among these were positive reports on the recently approved therapeutic prostate cancer vaccine PROVENGE® (Dendreon Corp.) and an antibody directed at another distinct suppressor of anti-tumor immunity, PD-1.

Interleukin-2 administration was reported by iSBTc member Dr. David McDermott and the Cytokine Working Group to mediate a 30% response rate in 115 patients with conventional renal cell carcinoma (RCC) in the Select Trial. Dr. Uday B. Dandamudi also reported for the Cytokine Working Group that combination of IL-2 with bevacizumab was feasible and associated with a 9 month progression free survival in RCC patients, even in an era of targeted therapeutics. These promising studies, and other important results that will be presented in October 2010 at the iSBTc Annual Meeting, demonstrate that immunotherapies and biologic treatments of cancer are coming of age and represent a growing therapeutic option in the treatment of cancer.

#

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.