Society for Immunotherapy of Cancer

June 2, 2014

More Promising Cancer Immunotherapy Data Released at ASCO for the Treatment of Patients with Melanoma and Cervical Cancer

CHICAGO – More promising news from the immunotherapy field in the treatment of melanoma was the highlight in Monday's afternoon sessions at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago.

Data presented today by several SITC members showed that the immune-checkpoint inhibitor, Ipilimumab, can be effective when given at a higher dose in an adjuvant setting for earlier stage melanoma than had been discovered before. In 2011, Ipilimumab was approved for use in inoperable stage IV metastatic melanoma, but with these new presented results, this immunotherapy is showing promise in treating a new cohort of patients. The data presented also showed that the use of Ipilimumab after surgery in patients with high risk stage II melanoma reduced the relative risk for recurrence by approximately 25 percent, compared to those on a placebo.

The PD-1 antibody, MK-3475 appeared again today in data presented from a phase I clinical trial, this time in the treatment of patients with advanced melanoma. The trial was lead by SITC member Antoni Ribas and involved a total of 411 patients, of which 211 had already received treatment with Ipilimumab. Thirty-four percent of total patients involved responded to MK-3475, but there was an even higher response rate of approximately 40 percent of patients who had not been treated with Ipilimumab prior, compared to those who had received the drug.

"The emerging data evaluating anti-PD1 antibodies in melanoma continue to be impressive with growing response rates for patients involved in these clinical trials," said Thomas F. Gajewski, MD, PhD, immediate past president of SITC. "While more data is needed, this is extremely encouraging and argues that immunotherapies really will be capable of improving the long-term outcome of our patients.

More research results making headlines at ASCO come as a follow up to data presented at last year's meeting, but this time the new data is showing longer-term results for the combination of Ipilimumab with Nivolumab for advanced melanoma. Presented results by SITC member, Mario Sznol, show that the combination of the two immunotherapies produced a median survival of 40 months for patients involved in the same study as last year. This is almost double the survival time of the previously reported results, when the drugs were used alone rather than in combination.

Monday melanoma-focused session ended with even more promising data presented by SITC vice president, Howard L. Kaufman, MD, FACS. The research he presented comes from the first-ever, randomized phase III clinical trial of a new oncolytic virus in patients with cancer. The trial consisted of 436 patients with advanced melanoma who were

treated with a genetically-modified form of the herpesvirus, known as Talimogene Laherpaepvec (T-VEC), whose native form causes the common cold sore.

Results released last year showed that T-VEC improved durable response rates, which included at least 50% tumor shrinkage in both injected and un-injected tumors lasting six months or longer. Of the patients who had an objective overall response, approximately 40% were complete responses, which included regression of both injected and in-injected lesions. Data presented today showed a trend towards improved overall survival in patients treated with T-VEC with a 21% reduction in the risk of dying and patients treated with T-VEC had a 4.4 month improved survival compared to patients treated with recombinant GM-CSF. Findings also demonstrated that patients with stage IIIB/C and IVM1a melanoma as well as patients receiving T-VEC as first line treatment had a more pronounced overall survival benefit. Results of the trial also showed that this treatment had a very tolerable safety profile demonstrating this form of treatment is safe and can result in durable clinical responses with a trend toward improved survival.

This data is very exciting because it's another platform of technology that can advance the field of cancer immunotherapy and improve outcomes for patients with melanoma," Bernard A. Fox, PhD, past president of SITC said. "Further studies of T-VEC in combination with Ipilimumab have begun and preliminary data from Phase I trials have demonstrated a 56% response rate with the combination treatment in melanoma, improving from the 11% response rate observed with Ipilimumab alone."

Cancer immunotherapy data from a cervical cancer clinical trial was also presented and gain attention at the ASCO Annual Meeting on Monday as well. The trial involved a novel approach to the treatment of cervical cancer, using a human papillomavirus (HPV)-targeted adoptive T-cell therapy. Although this approach is experimental, early results from the small study show that two women with widespread metastatic disease had complete remissions after a single treatment and are still cancer free a year later.

"The data presented on T cell therapy for the treatment of cervical cancer are particularly intriguing due to the ability to target a viral antigen (HPV)," Howard L. Kaufman, MD, FACS, SITC Vice President, said. "Although the numbers are small, the data suggests that metastatic cervical cancer may be amenable to treatment with immunotherapy and this is a disease that has historically been resistant to most forms of therapy."

About SITC
Founded in 1984, Society for Immunotherapy of Cancer (SITC) is a non-profit medical society dedicated to improving cancer patient outcomes by advancing the development, science and application of cancer immunotherapy through the core values of interaction, innovation and leadership. For more information on SITC, visit the Society website at: www.sitcancer.org.