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SITC Reacts to FDA Approval of First PD-1 Blocking Drug for Melanoma

MILWAUKEE, WI – The Society for Immunotherapy of Cancer (SITC) is delighted with the news that the U.S. Food and Drug Administration (FDA) has granted accelerated approval to Keytruda (pembrolizumab) for the treatment of metastatic melanoma.

"This is a very exciting announcement for patients with melanoma," explained SITC Vice President Howard Kaufman, MD. "Melanoma is a potentially devastating disease, and pembrolizumab represents a significant advance for immunotherapy because the drug can lead to durable responses and also has a favorable safety profile." He stressed that "FDA approval of pembrolizumab offers physicians and their patients another option for treating melanoma."

According to Dr. Kaufman, "the incidence of melanoma is increasing more rapidly than other types of cancer. Historically, once the tumor spreads, melanoma survival rates were typically less than one year. With the approval of immunotherapy agents, such as pembrolizumab, we can anticipate longer life expectancies."

There have been five FDA approvals for melanoma since 2011, but Keytruda is the first treatment of its kind. Specifically, it is the first FDA approved drug that blocks a cellular pathway called PD-1, which prevents exhaustion of T cells. Investigators have known for many years that T cells, which are part of the white blood cells, can recognize and destroy melanoma cells. While many of the previous immunotherapy drugs have targeted T cells by stimulating their activity, Keytruda works by preventing tumors from inhibiting T cell activity. Pembrolizumab is intended to be used in patients who have not responded to other standard agents already approved for the treatment of melanoma.

An FDA press release (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm412802.htm) stated that it "granted Keytruda breakthrough therapy designation because the sponsor demonstrated through preliminary clinical evidence that the drug may offer a substantial improvement over available therapies."

SITC has taken a lead in the field by sponsoring the first clinical immunotherapy guidelines for the treatment of melanoma. Based on the approval of pembrolizumanb, the guidelines will be updated shortly to provide expert recommendations for patients and treating physicians.

Additional information on cancer immunotherapy (http://www.sitcancer.org/about-sitc/newsroom/media-resources) is available at the SITC website.

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.