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Angeles Clinic Plays A Major Role in FDA Approval Of First Melanoma Drug Approved By FDA In Over A Decade

Los Angeles, California, April 21, 2011 – Recently, Bristol-Myers Squibb announced the FDA (United States Food and Drug Administration) approval of ipilimumab, called (YERVOY™), the first drug to show significant improvement in both median and long term survival in inoperable or metastatic melanoma. Metastatic melanoma is the deadliest form of skin cancer. The Angeles Clinic and Research Institute was a major contributor to the successful development of ipilimumab.

“Ipilimumab is the first in a new class of T-cell antibodies,” shares Steven J. O'Day, MD, Director of the Melanoma Program at The Angeles Clinic and Research Institute and a lead investigator of the drug. “Ipilimumab targets the person's immune system directly as opposed to the cancer.”

A T-cell is a white blood cell that is part of the immune system and protects the body against disease. Ipilimumab is directed against an antigen on the surface of T-cells. The antigen CTLA-4 (cytotoxic T-lymphocyte-associated antigen 4) acts as a “brake” on the T-cell explains Dr. O'Day. Ipilimumab turns the T-cells "on", by blocking the “brakes”, allowing the T-cells to do their work...and kill the cancer. “Ipilimumab takes time to work because you have to build an army of T-cells to then go to battle against the tumor,” shares Dr. O'Day.

“Ipilimumab is a major shift from traditional cancer therapies it terms of the timing of the anti-tumor response and durability of responses,” says Dr. O'Day. “It often takes 3-6 months to work but when it works, it works very well and frequently for years not days or months like most traditional cancer therapies. Ipilimumab is a powerful therapy that can potentially cause life-threatening side effects. Because it is very new, administering this treatment requires the skill of a highly trained medical professional. The Angeles Clinic is well-qualified to help patients with this groundbreaking protocol.”
Ipilimumab or “ipi” treatment is an outpatient treatment consisting of a 90-minute infusion, every three weeks, for a total of four doses. The vast majority of patients are only treated for a period of three months and then receive no further treatment. Ipilimumab shows a significant improvement in overall survival with increases in the one-year survival rate from 25% to 46%, and increases in the 2-year survival rate from 14% to 24%.

**Clinical Information**

The FDA approved YERVOY (ipilimumab) 3 mg/kg for the treatment of patients with unresectable (inoperable) or metastatic melanoma. YERVOY is the first therapy for unresectable or metastatic melanoma to demonstrate a significant improvement in overall survival based on results from a pivotal randomized, double-blind, placebo-controlled, international Phase III study conducted at 125 centers in 13 countries.

Findings demonstrate that patients with advanced, previously treated melanoma, who received the monoclonal antibody ipilimumab, lived 34% longer than those who received the immune-stimulating gp100 peptide vaccine.

Median overall survival was 10 months (95% CI: 8.0-13.8) for YERVOY, 6 months (95% CI: 5.5-8.7) for gp100 and 10 months (95% CI: 8.5-11.5) for YERVOY + gp100, with p-values of 0.0026 (not adjusted for multiple comparisons) for YERVOY and 0.0004 for YERVOY + gp100 vs. gp100, respectively. As published in *The New England Journal of Medicine*, the Kaplan-Meier estimated survival rate at 1 year was 46% (95% CI: 37.0, 54.1) in the YERVOY arm vs. 25% (95% CI: 18.1, 32.9) in the gp100 arm. The estimated survival rate at 2 years was 24% (95% CI: 16.0, 31.5) in the YERVOY arm vs. 14% (95% CI: 8.0, 20.0) in the gp100 arm. YERVOY, which is a recombinant, human monoclonal antibody, is the first FDA-approved cancer immunotherapy that blocks the cytotoxic T-lymphocyte antigen-4 (CTLA-4).