



News Release

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Merck Initiates Rolling Submission of U.S. Biologics License Application for MK-3475, an Investigational Anti-PD-1 Immunotherapy, in Patients with Advanced Melanoma

Expects to Complete Application in First Half of 2014

WHITEHOUSE STATION, N.J., January 13, 2014 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, said today it has started a rolling submission to the U.S. Food and Drug Administration (FDA) of a Biologics License Application for MK-3475, the company's investigational anti-PD-1 immunotherapy, for patients with advanced melanoma who have been previously treated with ipilimumab. A rolling submission allows completed portions of the application to be submitted and reviewed by the FDA on an ongoing basis. The company expects to complete the application in the first half of 2014.

“Our MK-3475 is a novel immunomodulatory molecule that holds promise for patients with advanced malignancy who now have limited treatment options,” said Roger M. Perlmutter, M.D., Ph.D., president, Merck Research Laboratories. “Initiation of this rolling submission represents an important milestone in the MK-3475 clinical development program for patients suffering from malignant melanoma.”

Clinical Development of MK-3475 in Advanced Melanoma

MK-3475 is currently being studied in three clinical trials for advanced melanoma including a Phase III trial of MK-3475 versus ipilimumab in ipilimumab-naïve advanced melanoma patients (PN 006). Enrollment is complete in the advanced melanoma cohorts in the company's Phase 1B trial (PN 001) and the Phase II trial (PN 002) comparing two doses of MK-3475 versus chemotherapy in patients with advanced melanoma who have progressed after

prior therapy. In April 2013, Merck announced that MK-3475 received a Breakthrough Therapy Designation for advanced melanoma from the FDA.

About MK-3475

Many tumors are able to evade the immune system through a mechanism that exploits the PD-1 inhibitory checkpoint protein. MK-3475 is an investigational, highly selective anti-PD-1 immunotherapy designed to restore the natural ability of the immune system to recognize and target cancer cells by selectively achieving dual ligand blockade (PD-L1 and PD-L2) of the PD-1 protein. By blocking PD-1, MK-3475 enables activation of the immune system's T-cells that target cancer by essentially releasing a brake on the immune system.

MK-3475 is currently being studied in 10 clinical trials estimated to enroll more than 4,000 patients across a broad range of cancer types including: bladder, colorectal, gastric, head and neck, melanoma, non-small cell lung, renal, triple negative breast and hematological malignancies. Additional trials, both as monotherapy and in combination with other cancer therapies, are planned. For information on Merck's clinical trials please visit <http://www.merck.com/clinical-trials/>.

About Advanced Melanoma

Melanoma is the most dangerous type of skin cancer. While it accounts for only 5 percent of all cases, melanoma is the cause of 75 percent of skin cancer deaths. According to the American Cancer Society, an estimated 9,180 people in the U.S. died from advanced melanoma in 2012.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#).

Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These

statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2012 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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