



NEWS RELEASE

Jan7Merck Announces FDA Acceptance for Review of MK-3475 Biologics License Application for Advanced Melanoma

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Priority Review Designation for MK-3475 BLA for Proposed Indication of Unresectable or Metastatic Melanoma in Patients Who Have Been Previously Treated with Ipilimumab

Advancing New Phase 3 Studies with MK-3475 in Adjuvant Melanoma, Previously-Untreated Non-Small Cell Lung Cancer, Advanced Head & Neck and Bladder Cancers

Data from Studies in Three Different Cancer Types to be presented at 2014 ASCO Annual Meeting

Initiating Phase 1 Study with Investigational Anti-GITR Antibody (MK-4166)

BOSTON--(**BUSINESS WIRE**)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for MK-3475, Merck's investigational anti-PD-1 antibody, for the treatment of unresectable or metastatic melanoma in patients who have been previously treated with ipilimumab. The FDA granted Priority Review designation with a PDUFA date of October 28, 2014, and the MK-3475 BLA will be reviewed under the FDA's Accelerated Approval program. The FDA previously granted MK-3475 Breakthrough Therapy designation for advanced melanoma, the most dangerous type of skin cancer. If approved by the FDA, MK-3475 has the potential to be the first anti-PD-1 antibody in a new class of immune checkpoint modulators.

Merck also announced it plans to file a Marketing Authorization Application for MK-3475 in Europe for advanced melanoma by the end of 2014.

“Patients with advanced melanoma have few therapeutic options and often fail to respond to all available treatments,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “We are hopeful that the FDA, through their priority review of our application, will agree to make MK-3475 available to patients with advanced melanoma who have no other therapeutic options.”

MK-3475 Development Ongoing in 30 Tumors, as Monotherapy and in Combination

Today, Merck highlighted progress on the advancement of the MK-3475 development program – currently ongoing in 30 tumor types as monotherapy and in combination. It is anticipated that by the end of 2014, the MK-3475 development program will grow to more than 24 clinical trials across 30 different tumor types, enrolling an estimated 6,000 patients at nearly 300 clinical trial sites worldwide, including four new Phase 3 studies. Ongoing and planned late-stage monotherapy and combination studies include:

- Seven Phase 3 registrational trials spanning advanced melanoma (adjuvant, ipilimumab-naïve, and ipilimumab-refractory), advanced non-small cell lung cancer (NSCLC) (previously-treated and previously-untreated), advanced head & neck cancer and advanced bladder cancer; and,
- Ten combination studies, including advanced melanoma, advanced NSCLC, advanced renal cell carcinoma, HER2+ breast cancer and other solid tumors.

Merck also said today that based on encouraging preclinical data, it plans to initiate a Phase 1 dose-ranging study with its investigational anti-GITR agonistic antibody, MK-4166, in patients with advanced malignances. GITR (glucocorticoid-induced TNFR receptor) is an activating immune checkpoint receptor, which is believed to stimulate immune activity against cancer cells. This will be the second investigational immune checkpoint antibody within Merck’s immuno-oncology discovery program to enter clinical development.

Dr. Perlmutter added, “Our priority is advancing breakthrough immunomodulatory molecules that reveal the ability of the immune system to eliminate cancer cells. While MK-3475 provides a firm foundation for Merck’s research and development strategy in oncology, we are also advancing a broad pipeline of immune checkpoint agonists and antagonists.”

MK-3475 Presentations at 2014 ASCO Annual Meeting

At the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting, Merck will have more than 15 company-sponsored abstracts on MK-3475, including six oral presentations. Clinical data will be presented from studies in advanced melanoma, advanced NSCLC, as well as advanced head & neck cancer, which is the first time data for MK-

3475 will be presented in this cancer type.

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 2013 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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