Merck Announces Generic Name for MK-3475, Merck’s Investigational anti-PD-1 Antibody: Pembrolizumab

Merck (NYSE: MRK), known as MSD outside the United States and Canada, today said that the nonproprietary name for MK-3475, Merck’s investigational anti-PD-1 antibody, is pembrolizumab. This follows the review of pembrolizumab by both the United States Adopted Names Council and the International Nonproprietary Names Programme of the World Health Organization. Pembrolizumab replaces the previously proposed name, lambrolizumab.

About Pembrolizumab

Pembrolizumab is an investigational selective, humanized monoclonal anti-PD-1 antibody designed to block the interaction of PD-1 on T-cells with its ligands, PD-L1 and PD-L2, to reactivate anti-tumor immunity. Pembrolizumab exerts dual ligand blockade of PD-1 pathway.

Today, pembrolizumab is being evaluated across more than 30 types of cancers, as monotherapy and in combination. It is anticipated that by the end of 2014, the pembrolizumab 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 new Phase 3 studies. For information about Merck’s oncology clinical studies, please visit www.merck.com/clinical-trials.

The Biologics License Application (BLA) for pembrolizumab is under priority review with the U.S. Food and Drug Administration (FDA) for the proposed indication for the treatment of patients with advanced melanoma previously-treated with ipilimumab; the PDUFA date is October 28, 2014. Pembrolizumab has been granted FDA’s Breakthrough Therapy designation for advanced melanoma. If approved by the FDA, pembrolizumab has the potential to be the first PD-1 immune checkpoint modulator approved in this class. The company plans to file a Marketing Authorization Application in Europe for pembrolizumab for advanced melanoma in 2014.

About Merck Oncology: A Focus on Immuno-Oncology

At Merck Oncology, our goal is to translate breakthrough science into biomedical innovations to help people with cancer worldwide. Harnessing immune mechanisms to fight cancer is the priority focus of our oncology research and development program. The Company is advancing a pipeline of immunotherapy candidates and combination regimens. Cancer is one of the world’s most urgent unmet medical needs. Helping to empower people to fight cancer is our passion. For information about Merck’s commitment to Oncology visit the Merck Oncology Information Center at http://www.mercknewsroom.com/oncology-infocenter.

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.

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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