October 23, 2013

FDA Grants Lilly's Ramucirumab Priority Review as a Potential Single-Agent Treatment for Advanced Gastric Cancer

INDIANAPOLIS, Oct. 23, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has assigned Priority Review to the regulatory submission for ramucirumab (IMC-1121B) as a single-agent treatment for advanced gastric cancer following disease progression after initial chemotherapy.

"We are very pleased that the FDA has granted Priority Review to ramucirumab in advanced gastric cancer, as patients with this difficult-to-treat disease typically have a poor prognosis and limited treatment options," said Richard Gaynor, M.D., vice president, product development and medical affairs for Lilly Oncology. "If approved, ramucirumab will be the first FDA-approved therapy for patients in this setting. Overall, stomach cancer is the second leading cause of cancer death globally and remains an area of high unmet need."

Priority Review status for a biologics license application, or BLA, means that the FDA's goal is to take action within eight months of a completed filing. Therefore, Lilly anticipates agency action on this application in the second quarter of 2014. The priority designation aims to expedite the review of applications for drugs that, if approved, would represent a significant advance in treatment.

This BLA for ramucirumab was based on data from REGARD, a global, randomized, double-blind Phase III study of ramucirumab plus best supportive care compared to placebo plus best supportive care as a treatment in patients with advanced gastric cancer (including adenocarcinomas of the gastro-esophageal junction) following progression after initial chemotherapy. A registration dossier is also under regulatory review by the European Medicines Agency (EMA) for a Marketing Authorization Application.

Lilly also studied ramucirumab in combination with paclitaxel for the treatment of advanced gastric cancer in its Phase III RAINBOW trial. The combination-therapy ramucirumab data from that trial will be the basis for separate regulatory applications. Lilly expects top-line results from three additional Phase III trials of ramucirumab — one each in colorectal, hepatocellular (liver) and lung cancer — in 2014.

About Ramucirumab
Ramucirumab is designed to directly inhibit angiogenesis, a process by which blood vessels supply blood to tumors. Ramucirumab is a human, receptor-targeted antibody that specifically blocks the vascular endothelial growth factor (VEGF) receptor 2 and inhibits downstream signaling involved in the formation and maintenance of aberrant blood vessels that supply blood to tumors.

Ramucirumab, which Lilly gained through its 2008 acquisition of ImClone Systems, is being investigated in clinical trials as a single agent and in combination with other anticancer therapies for the treatment of multiple types of cancer. Beyond gastric cancer, results from three Phase III trials — one each in colorectal, hepatocellular (liver) and lung cancer — are expected in 2014.

About Lilly Oncology
For more than five decades, Lilly Oncology has been dedicated to delivering innovative solutions that improve the care of people living with cancer. Lilly Oncology is committed to delivering life-extending and life-enhancing medicines to patients. To learn more about Lilly's commitment to cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company
Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

P-LLY

This press release contains forward-looking statements about the potential of ramucirumab as a treatment of various cancers and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in

the process of development and commercialization. There is no guarantee that future studies will be positive or that ramucirumab will receive regulatory approvals or prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

Contact:	Tracy Henrikson (Lilly Oncology)	Neil Hochman (TogoRun)
	908-243-9945 (office)	212-453-2067 (office)
	609-240-3902 (mobile)	516-784-9089 (mobile)
	Email: tracy.henrikson@imclone.com	Email: n.hochman@togorun.com

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

SOURCE Eli Lilly and Company