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**SINGLE-AGENT RAMUCIRUMAB SIGNIFICANTLY IMPROVES OVERALL
SURVIVAL IN ADVANCED GASTRIC CANCER PATIENTS**

-- REGARD data published in *The Lancet* --

INDIANAPOLIS, October 3, 2013 – Eli Lilly and Company (NYSE: LLY) today announced that results from the Phase III REGARD trial of ramucirumab (IMC-1121B) as a single agent in patients with advanced gastric cancer who have had disease progression after initial chemotherapy were published today in *The Lancet*. REGARD is the first Phase III study with either a single-agent biologic or an anti-angiogenic therapy to show improved overall survival and progression-free survival in advanced gastric cancer patients.

REGARD is a global, randomized, double-blind Phase III study of ramucirumab and best supportive care compared to placebo and best supportive care as treatment in patients with advanced gastric cancer following progression after initial chemotherapy. Patients (n=355) were randomly assigned in a 2:1 ratio, to receive best supportive care plus either ramucirumab 8 mg/kg or placebo, intravenously once every two weeks. Median duration of treatment was eight weeks in the ramucirumab group and six weeks in the placebo group.

Patients treated with single-agent ramucirumab (n=238) achieved a median overall survival of 5.2 months compared to 3.8 months for patients on the placebo arm (n=117), representing a 37 percent increase. The overall survival hazard ratio was 0.776 (95% CI, 0.603-0.998; p=0.0473), which corresponds to a 22 percent reduction in risk of death. Patients on the ramucirumab arm achieved a median progression-free survival of 2.1 months compared to 1.3 months for those on the placebo arm. The progression-free survival hazard ratio was 0.483 (95% CI, 0.376-0.620; p<0.0001).

In the REGARD analysis reported in *The Lancet*, the following adverse events occurred at a higher rate (for Grade 3 or higher) on the ramucirumab arm: hypertension (8% on ramucirumab vs 3% on placebo) and abdominal pain (6% vs 3%). No Grade 4 hypertension was observed on the ramucirumab arm. Adverse events of special interest occurring on the ramucirumab arm at a higher rate for Grade 3 or higher were bleeding or hemorrhage (3.4% vs 2.6%), arterial thromboembolic events (1% vs 0%) and proteinuria (0.4% vs 0%). Additional adverse events (>5% any grade) that have been previously reported for REGARD and occurring at a higher rate (for Grade 3 or higher) on the ramucirumab arm included hyponatremia (3.4% vs 0.9%) and hypokalemia (2.1% vs 0.9%), and those with a higher rate (any grade) on the ramucirumab arm included headache (9.3% vs 3.5%) and diarrhea (14.4% vs 8.7%). Five (2%) deaths in the ramucirumab group and two (2%) deaths in the placebo group (2:1 randomization) were reported by the investigator to be related to treatment.

“We are pleased with this data of ramucirumab as a single agent in advanced gastric cancer, a devastating disease where the prognosis for patients is poor. There are no agents specifically approved in the U.S. or EU for advanced gastric cancer patients in this setting,” said Richard Gaynor, M.D., vice president, product development and medical affairs for Lilly Oncology. “Gastric cancer is the fourth most common cancer in the world and the second-leading cause of cancer-related death – this is a major global health issue.”

“What we found is that the patients who received ramucirumab had a significant improvement in their survival as well as reducing the rate of cancer progression. The side effects associated with ramucirumab, except for hypertension, were mostly similar to what patients receiving placebo experienced,” said Charles S. Fuchs, M.D., MPH, director of the Gastrointestinal Cancer Center at Dana-Farber Cancer Institute. “The results are very encouraging for patients with stomach cancer.”

REGARD is one of two ramucirumab Phase III studies in gastric cancer. RAINBOW, a global Phase III study of ramucirumab in combination with paclitaxel in patients with advanced gastric cancer, met its primary endpoint of improved overall survival and a secondary endpoint of improved progression-free survival, Lilly announced last week.

The REGARD single-agent ramucirumab data are the basis for current U.S. and EU regulatory submissions. The RAINBOW combination-therapy ramucirumab data will be the basis for separate regulatory applications.

Notes to Editor

About the REGARD trial

REGARD is a global, randomized, double-blind, placebo-controlled Phase III study of ramucirumab and best supportive care compared to placebo and best supportive care as treatment in patients with advanced gastric cancer (including adenocarcinomas of the gastro-esophageal junction) following progression after initial chemotherapy. In total, 355 patients were randomized in 29 countries. Patients enrolled in this study in general had poor prognostic factors; 36 percent were age 65 or older, 31 percent had peritoneal metastases, and 67 percent had disease progression within six months after initiation of their previous therapy. The adverse events in *The Lancet* reported selected events that occurred at a rate of 10 percent or higher (any grade) and 2 percent or higher (Grade 3 or higher), as well as adverse events of special interest that were evaluated due to the mechanism of action of drug.

About the RAINBOW trial

RAINBOW is a global, randomized, double-blind, placebo-controlled Phase III study of ramucirumab and paclitaxel compared to placebo and paclitaxel in patients with advanced (locally advanced, unresectable or metastatic) gastric cancer (including adenocarcinomas of the gastro-esophageal junction) refractory to or progressive after initial chemotherapy containing platinum and fluoropyrimidine. Initiated in 2010, the global study randomized a total of 665 patients across 27 countries in North America, South America, Europe, Australia and Asia.

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 Gastric Cancer

Gastric cancer is the fourth most common cancer in the world and the second-leading cause of cancer-related death.ⁱ There were approximately one million new cases of stomach cancer worldwide in 2008 (640,000 men, 348,000 women), with approximately 736,000 deaths

(463,000 men, 273,000 women), making it the third-leading cause of cancer death globally in men and the fifth in women.ⁱⁱ Stomach cancer is more prevalent in countries outside the U.S. and EU.ⁱⁱⁱ

Gastric cancer is a disease in which cancer cells form in the lining of the stomach. It develops slowly, usually over many years and often goes undetected.^{iv} As the stomach cancer advances, it can travel through the bloodstream and spread to organs such as the liver, lungs and bones.^v

The most common type of stomach cancer is called adenocarcinoma, which starts from one of the common cell types found in the lining of the stomach.^{vi} Other types include: lymphoma, gastrointestinal stromal tumor and carcinoid tumor.^v

About Lilly Oncology

For more than five decades, Lilly Oncology, a division of Eli Lilly and Company, has been dedicated to delivering innovative solutions that improve the care of people living with cancer. Because no two cancer patients are alike, Lilly Oncology is committed to developing novel treatment approaches. 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.

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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.

ⁱ Globocan 2008 Cancer Fact Sheet. Stomach Cancer Incidence and Mortality Worldwide in 2008. <http://globocan.iarc.fr/factsheets/cancers/stomach.asp>. (Accessed: September 25, 2013).

ⁱⁱ Jemal A, Bray F, Center MM, et al. Global cancer statistics. *CA Cancer J Clin* 2011; 61:69.

ⁱⁱⁱ American Cancer Society, "Learn About Cancer: What are the Key Statistics about Stomach Cancer?" Updated: February 22, 2013; <http://www.cancer.org/Cancer/StomachCancer/DetailedGuide/stomach-cancer-key-statistics>, (Accessed: September 25, 2013).

^{iv} American Cancer Society, "Learn About Cancer: Stomach Cancer," Updated: February 22, 2013; <http://www.cancer.org/Cancer/StomachCancer/index>, (Accessed: September 25, 2013).

^v American Cancer Society, "Learn About Cancer: What is Stomach Cancer? Topics," Updated: February 22, 2013; <http://www.cancer.org/Cancer/StomachCancer/DetailedGuide/stomach-cancer-what-is-stomach-cancer>, (Accessed: September 25, 2013).

^{vi} National Center for Biotechnology Information, "Gastric Cancer," Updated: December 15, 2011; <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001270/>, (Accessed: September 25, 2013).