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Lilly Announces Positive Results For Ramucirumab as Single Agent in Phase III Gastric Cancer Trial

INDIANAPOLIS, Oct. 15, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the REGARD trial, a Phase III study of ramucirumab (IMC-1121B) in patients with metastatic gastric cancer, met its primary endpoint of improved overall survival and also showed prolonged progression-free survival. This trial is the first Phase III data read-out for ramucirumab.

The REGARD trial compared ramucirumab and best supportive care to placebo and best supportive care as a second-line treatment in patients with metastatic gastric and gastroesophageal junction cancers. The most frequent adverse reaction (any grade) occurring at a higher rate on the ramucirumab arm was hypertension (12%). Other adverse reactions (> 5%) occurring at a higher rate on the ramucirumab arm compared to the placebo arm were diarrhea and headache.

"We are pleased with this data of ramucirumab used as monotherapy in a second-line setting in this difficult-to-treat disease. It reinforces our confidence in the ramucirumab development program, in which we currently have six Phase III studies ongoing in five tumor types — breast, colorectal, gastric, hepatocellular and lung cancer," said Richard Gaynor, M.D., vice president, product development and medical affairs for Lilly Oncology.

REGARD is one of two ramucirumab Phase III studies in gastric cancer. RAINBOW, a Phase III trial of ramucirumab in combination with paclitaxel, completed patient enrollment last month.

Lilly plans to present data from the REGARD trial at an upcoming scientific meeting and will discuss submission plans with regulatory authorities.

Notes to Editor

About the REGARD trial

The REGARD trial is a Phase III randomized, double-blinded study of ramucirumab and best supportive care (BSC) versus placebo and BSC in the treatment of metastatic gastric or gastroesophageal junction adenocarcinoma following disease progression on first-line platinum- or fluoropyrimidine-containing combination therapy. The primary endpoint of the REGARD trial is overall survival and secondary endpoints include: progression-free survival; proportion of participants who are progression-free at week 12; proportion of participants with objective response, or objective response rate; duration of response; and safety.

About the RAINBOW trial

The RAINBOW trial is a Phase III study of ramucirumab and paclitaxel compared to placebo and paclitaxel as a second-line treatment in patients with metastatic gastric cancer (including adenocarcinomas of the gastroesophageal junction), refractory to or progressive after first-line therapy with platinum and fluoropyrimidine. The primary endpoint of the RAINBOW trial is overall survival and secondary endpoints include: progression-free survival; time to progressive disease; best overall response; objective response; and safety.

About Ramucirumab

Ramucirumab is a fully human IgG1 monoclonal antibody receptor antagonist designed to bind the extracellular domain of vascular endothelial growth factor (VEGF) receptor-2, thereby blocking the interaction of VEGF ligands (VEGF-A, VEGF-C, and VEGF-D) and inhibiting receptor activation. VEGF receptor-2 is considered a primary mediator of angiogenesis. When activated by VEGF ligands, VEGF receptor-2 promotes endothelial cell proliferation and survival, migration, and vascular permeability.

Ramucirumab, which Lilly gained through its 2008 acquisition of ImClone Systems, is being investigated in clinical trials as monotherapy and in combination with other anticancer therapies for the treatment of multiple types of cancer. It is in late-stage clinical evaluation for the treatment of breast, colorectal, gastric, hepatocellular and lung cancer.

About Gastric Cancer

Gastric cancer is fourth most common cancer in the world,¹ with approximately 989,600 new cases and 738,000 deaths annually.² Stomach cancer is much more common in less developed countries.³

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.⁴ As the stomach cancer advances, it can travel through the bloodstream and spread to organs such as the liver, lungs and bones.⁵

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.⁶ Other types include: lymphoma, gastrointestinal stromal tumor and carcinoid tumor.⁵

For more information on gastric cancer, please visit www.lillyoncologynewsroom.com.

About Lilly Oncology

For more than four 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.

¹ Globocan 2008 Cancer Fact Sheet. Stomach Cancer Incidence and Mortality Worldwide in 2008. <http://globocan.iarc.fr/factsheets/cancers/stomach.asp>. (Accessed: October 11, 2012).

² Jemal A, Bray F, Center MM, et al. Global cancer statistics. CA Cancer J Clin 2011; 61:69.

³ American Cancer Society, "Learn About Cancer: What are the Key Statistics about Stomach Cancer?" Updated: January 18, 2012; <http://www.cancer.org/Cancer/StomachCancer/DetailedGuide/stomach-cancer-key-statistics>. (Accessed: October 11, 2012).

⁴ American Cancer Society, "Learn About Cancer: Stomach Cancer," Updated: January 18, 2012; <http://www.cancer.org/Cancer/StomachCancer/index>. (Accessed: October 11, 2012).

⁵ American Cancer Society, "Learn About Cancer: What is Stomach Cancer? Topics," Updated: January 18, 2012; <http://www.cancer.org/Cancer/StomachCancer/DetailedGuide/stomach-cancer-what-is-stomach-cancer>. (Accessed: October 11, 2012).

⁶ [National Center for Biotechnology Information](http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001270/), "Gastric Cancer," Updated: December 15, 2011; <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001270/>. (Accessed: October 11, 2012).

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