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Lilly Announces Ramucirumab Phase III Lung Cancer Trial Meets Primary Endpoint of Overall Survival

-- Ramucirumab Improved Survival in Second-Line Study of Patients with Non-Small Cell Lung Cancer --

INDIANAPOLIS, Feb. 19, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the REVEL trial, a global Phase III study of ramucirumab in combination with chemotherapy in patients with second-line non-small cell lung cancer (NSCLC), showed a statistically significant improvement in the primary endpoint of overall survival in the ramucirumab-plus-docetaxel arm compared to the control arm of placebo plus docetaxel. REVEL also showed a statistically significant improvement in progression-free survival in the ramucirumab arm compared to the control arm.

The global, randomized, double-blind REVEL trial compared ramucirumab and docetaxel to placebo and docetaxel in NSCLC patients whose disease has progressed after failure of prior platinum-based chemotherapy for locally advanced or metastatic disease. The study included nonsquamous and squamous NSCLC patients. The most common (> 5% incidence) Grade $\geq$ 3 adverse events occurring at a higher rate on the ramucirumab-plus-docetaxel arm compared to the control arm were decreased white blood cell count (neutropenia/leukopenia), febrile neutropenia, fatigue/asthenia and hypertension.

"We are pleased with these Phase III data of ramucirumab in non-small cell lung cancer, which accounts for most cases of lung cancer - the leading cause of cancer-related mortality worldwide. Despite currently available therapies, there continues to be a need for new second-line treatment options for patients with lung cancer," said Richard Gaynor, M.D., senior vice president, product development and medical affairs for Lilly Oncology. "REVEL is the first positive Phase III study of a biologic in combination with chemotherapy to demonstrate improved overall survival compared to chemotherapy alone in second-line non-small cell lung cancer."

Lilly plans to present data from the REVEL trial at an upcoming scientific meeting and intends to submit the first application of these data to regulatory authorities in 2014.

Dr. Gaynor added, "These data reinforce our confidence in the overall ramucirumab development program, in which we have several Phase III and earlier-phase studies in multiple tumor types, both as a single agent and in combination with other therapies. Moreover, these data underscore Lilly's continued leadership in thoracic oncology."

Notes to Editor

About the REVEL trial

REVEL is a global, double-blind, placebo-controlled Phase III study of ramucirumab and docetaxel compared to placebo and docetaxel in NSCLC patients whose disease has progressed after failure of prior platinum-based chemotherapy for locally advanced or metastatic disease. Initiated in 2010, the global study enrolled more than 1,200 patients across 26 countries. The primary endpoint of the REVEL trial is overall survival and secondary endpoints include: progression-free survival; objective response rate; quality of life; and safety. The study included nonsquamous and squamous NSCLC patients.

About Lung Cancer

Lung cancer is the leading cause of cancer death in the U.S. and most other countries, killing nearly 1.6 million people worldwide each year.[i] In the U.S., lung cancer is responsible for nearly 30 percent of all cancer deaths, more than those from breast, colon and prostate cancers combined.[ii] Stage IV NSCLC is a very difficult-to-treat cancer and the prognosis for patients with NSCLC is poor when locally advanced or metastatic.[iii] NSCLC is much more common than other types of lung cancer, and accounts for 85 percent of all lung cancer cases. Patients with squamous cell carcinoma represent about 30 percent of all patients affected by NSCLC, while non-squamous patients represent about 70 percent.[iv]

About Ramucirumab

Ramucirumab (IMC-1121B) 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 tumor types. The REVEL lung cancer trial is the third positive Phase III study of ramucirumab; all three of those studies demonstrated improved overall survival and progression-free survival. The first, which studied ramucirumab in gastric cancer as a single agent, is the basis for regulatory submissions in the U.S. and EU; the second, which studied ramucirumab in gastric cancer in combination with paclitaxel, is a planned regulatory submission in 2014. Top-line results for Phase III trials of ramucirumab in hepatocellular (liver) and colorectal cancer are expected in 2014.

About Lilly Oncology

For more than fifty years, Lilly has been dedicated to delivering life-changing medicines and support to people living with cancer and those who care for them. Lilly is determined to build on this heritage and continue making life better for all those affected by cancer around the world. To learn more about Lilly's commitment to people with cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and http://newsroom.lilly.com/social-channels.

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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.

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

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[i] International Agency for Research on Cancer. GLOBOCAN 2012. Lung Cancer Estimated Incidence, Mortality and Prevalence Worldwide in 2012. http://globocan.iarc.fr. Accessed February 18, 2014.

[ii] American Cancer Society, *Cancer Facts & Figures 2012*, http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-031941.pdf. Accessed February 18, 2014.

[iii] National Cancer Institute. *General information about non-small cell lung cancer.* May 30, 2013. http://www.cancer.gov/cancertopics/pdq/treatment/non-small-cell-lung/healthprofessional/page1. Accessed February 18, 2014.

[iv] American Cancer Society, *What is non-small cell lung cancer?* http://www.cancer.org/cancer/lungcancer-non-smallcell/detailedguide/non-small-cell-lung-cancer-what-is-non-small-cell-lung-cancer. Accessed February 18, 2014.

SOURCE Eli Lilly and Company