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Lilly Announces Phase 3 MONARCH 3 Breast Cancer Study of Abemaciclib Demonstrated Superior Progression-Free Survival at Interim Analysis

The Phase 3 study compared abemaciclib in combination with an aromatase inhibitor versus an aromatase inhibitor alone in patients with HR+, HER2- advanced breast cancer

INDIANAPOLIS, April 24, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that following a pre-planned interim analysis for MONARCH 3, the trial met its primary endpoint of demonstrating statistically significant improvement in progression-free survival (PFS). In addition, improvement was shown in a key secondary endpoint of objective response rate (ORR). The Phase 3 study evaluated abemaciclib, a cyclin-dependent kinase (CDK)4 and CDK6 inhibitor, in combination with an aromatase inhibitor (letrozole or anastrozole) compared to treatment with an aromatase inhibitor alone in women with hormone-receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer. Detailed efficacy and safety results will be presented at a medical meeting in the second half of the year.

"Today marks another important milestone in our clinical development program for abemaciclib, a drug we believe has the potential to be best in class," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology. "We are very excited about the results seen in patients with breast cancer, from single-agent activity to clinically meaningful benefit when used in combination with fulvestrant or aromatase inhibitors. Along with additional abemaciclib clinical trials in other tumor types, these data underscore Lilly's commitment to delivering life-changing medicines to treat and cure people living with cancer around the world."

The global Phase 3, double-blind, placebo-controlled study was designed to evaluate the efficacy and safety of abemaciclib in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with advanced (locoregionally recurrent or metastatic) breast cancer who have had no prior systemic treatment for advanced disease. A total of 493 patients were randomized to receive 150 mg of abemaciclib or placebo orally twice a day without interruption, given in combination with either 1 mg of anastrozole or 2.5 mg of letrozole once daily until disease progression or unacceptable toxicity. The primary endpoint of the study was PFS, with key secondary endpoints of ORR, overall survival and safety. The adverse events were generally consistent with previous studies of abemaciclib, with the most common adverse events being diarrhea, neutropenia, fatigue, and nausea.

Following this MONARCH 3 interim analysis, Lilly intends to begin global submissions of these results in the third quarter of 2017. In addition, Lilly intends to initiate MONARCH 1 and MONARCH 2 submissions beginning in the second quarter of 2017.

Other MONARCH trials currently underway include: monarchHER, which is evaluating abemaciclib plus trastuzumab (with or without fulvestrant) in women with HR+, HER2+ locally advanced or metastatic breast cancer, and MONARCH plus, a Phase 3 study of abemaciclib in combination with endocrine therapies to support registration in China. In addition, Lilly has an ongoing Phase 3 trial evaluating abemaciclib in lung cancer. Lilly is also evaluating abemaciclib in patients with brain metastases, as well as in patients with pancreatic cancer.

Notes to Editor

About Metastatic Breast Cancer

Breast cancer is the most common cancer in women worldwide with nearly 1.7 million new cases diagnosed in 2012.¹ In the U.S. this year, approximately 252,710 new cases of invasive breast cancer will be diagnosed and about 40,610 people will die from breast cancer.² Of all early stage breast cancer cases diagnosed in the U.S., approximately 30 percent will become metastatic, spreading to other parts of the body. In addition, an estimated six to 10 percent of all new breast cancer cases are initially diagnosed as being stage IV, or metastatic.³ Metastatic breast cancer is considered incurable, but is generally treatable.

About Abemaciclib

In many cancers, uncontrolled cell growth arises from a loss of cell cycle regulation due to increased signaling from CDK4

and CDK6. Abemaciclib (LY2835219) is an investigational, oral cell cycle inhibitor, designed to block the growth of cancer cells by specifically inhibiting cyclin-dependent kinases, CDK4 and CDK6 and was most active against Cyclin D1 and CDK4 in cell-free enzymatic assays. In breast cancer, Cyclin D1/CDK4 has been shown to promote phosphorylation of the retinoblastoma protein (Rb), cell proliferation and tumor growth. In hormone receptor-positive breast cancer cell lines, sustained target inhibition by abemaciclib reduced phosphorylation of Rb, inducing cell cycle arrest.

In 2015, the U.S. Food and Drug Administration granted abemaciclib Breakthrough Therapy Designation based on data from the breast cancer cohort expansion of the company's Phase 1 trial, JPBA, which studied the efficacy and safety of abemaciclib in women with advanced or metastatic breast cancer. In addition to its current MONARCH clinical trials evaluating abemaciclib in breast cancer, a Phase 3 trial of abemaciclib in lung cancer is also underway.

For more information on additional abemaciclib trials, a complete listing can be found on [ClinicalTrials.gov](https://clinicaltrials.gov) (in the search box on the home page, type in "abemaciclib").

About Lilly Oncology

For more than 50 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 www.lilly.com/newsroom/social-channels. P-LLY

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Lilly Forward-Looking Statement

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about abemaciclib as a potential treatment for patients with breast cancer 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. Among other things, there can be no guarantee that abemaciclib will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

¹ World Cancer Research Fund International. Breast Cancer.

http://www.wcrf.org/cancer_statistics/data_specific_cancers/breast_cancer_statistics.php. Accessed: April 23, 2017.

² American Cancer Society. What are the key statistics about breast cancer?

<http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-key-statistics>. Accessed: April 23, 2017.

³ Metastatic Breast Cancer Network. 13 Facts about Metastatic Breast Cancer. <http://www.mbcn.org/13-facts-about-metastatic-breast-cancer/>. Accessed: April 23, 2017.

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