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Lilly Announces Phase 3 MONARCH 2 Breast Cancer Study of Abemaciclib Met Primary Endpoint of Progression-Free Survival

Abemaciclib, in combination with fulvestrant, was superior to fulvestrant plus placebo in patients with HR+, HER2- advanced breast cancer

INDIANAPOLIS, March 20, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that its MONARCH 2 trial of abemaciclib met the primary endpoint of progression-free survival (PFS). The Phase 3 study evaluated abemaciclib, a cyclin-dependent kinase (CDK) 4 and CDK 6 inhibitor, in combination with fulvestrant in women with hormone-receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), advanced breast cancer who have relapsed or progressed after endocrine therapy. The results demonstrated the addition of abemaciclib to fulvestrant resulted in a statistically significant improvement in PFS, when compared to the control arm of placebo plus fulvestrant. Detailed efficacy and safety results will be presented at an upcoming medical meeting.

"We are excited about the outcome of our first Phase 3 study for abemaciclib. These data are an important milestone in our goal of bringing abemaciclib to patients with advanced breast cancer, and we look forward to our upcoming conversations with regulators," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology. "This is another example of Lilly's commitment to delivering breakthrough treatments and improving outcomes for patients with cancer."

The global Phase 3, double-blind study was designed to evaluate the efficacy and safety of abemaciclib, in combination with fulvestrant, in patients with advanced (locoregionally recurrent or metastatic) breast cancer. The intent-to-treat population of 669 patients was randomized to receive abemaciclib or placebo orally twice a day on a continuous dosing schedule, given in combination with fulvestrant at its approved dose and schedule, until disease progression. Patients enrolled in the study had experienced disease progression on or within 12 months of receiving endocrine treatment in the neoadjuvant or adjuvant setting or while receiving first-line endocrine therapy for metastatic disease. Patients who had received chemotherapy in the metastatic setting were not eligible for the study.

The most common adverse events observed were diarrhea, neutropenia, nausea and fatigue, and were consistent with the previous studies of abemaciclib.

Lilly intends to submit a new drug application (NDA) for single-agent abemaciclib in the second quarter of 2017, based on the MONARCH 1 study, for the treatment of refractory metastatic breast cancer patients whose disease had progressed following multiple prior treatments, including endocrine therapy and one to two chemotherapy regimens in the metastatic setting. Lilly plans to submit an additional application for MONARCH 2 in the third quarter of this year.

Along with MONARCH 1 and MONARCH 2, Lilly currently has additional trials evaluating abemaciclib in breast cancer. MONARCH 3 is a Phase 3 trial of abemaciclib in combination with a nonsteroidal aromatase inhibitor in patients with HR+, HER2- advanced breast cancer. Additionally, there is a Phase 2 MONARCH trial under way: monarcHER, which is evaluating abemaciclib plus trastuzumab (with or without fulvestrant) in women with HR+, HER2+ locally advanced or metastatic breast cancer. In each of these studies, abemaciclib is administered on a continuous dosing schedule.

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 CDK 4 and CDK 6. Abemaciclib (LY2835219) is an investigational, oral cell cycle inhibitor, designed to block the growth of cancer

cells by specifically inhibiting cyclin-dependent kinases, CDK 4 and CDK 6 and was most active against Cyclin D1 and CDK 4 in cell-free enzymatic assays. In breast cancer, Cyclin D1/CDK 4 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 under way.

For more information on additional abemaciclib trials, a complete listing can be found on 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**

Fulvestrant (Faslodex®), MedImmune/AstraZeneca. MedImmune Limited/AstraZeneca provided fulvestrant for this trial.

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: March 18, 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: March 18, 2017.

[3] Metastatic Breast Cancer Network. 13 Facts about Metastatic Breast Cancer. http://www.mbcn.org/13-facts-about-metastatic-breast-cancer/. Accessed: March 18, 2017.

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