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## **Lilly Receives FDA Breakthrough Therapy Designation for Abemaciclib - a CDK 4 and 6 Inhibitor - in Advanced Breast Cancer**

### **FDA Breakthrough Therapy Designation has Potential to Expedite Development and Review**

INDIANAPOLIS, Oct. 8, 2015 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to abemaciclib, a cyclin-dependent kinase (CDK) 4 and 6 inhibitor, for patients with refractory hormone-receptor-positive (HR+) advanced or metastatic breast cancer. This designation is based on data from the breast cancer cohort expansion of the company's Phase I trial, JPBA, which studied the efficacy and safety of abemaciclib in women with advanced or metastatic breast cancer. Patients in this cohort had received a median of seven prior systemic treatments. These data were presented at the San Antonio Breast Cancer Symposium in 2014.

According to the FDA, Breakthrough Therapy Designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint.

"If caught before it spreads, patients can survive breast cancer. However, for the nearly 10 percent of patients who are initially diagnosed at stage IV,<sup>1</sup> and the nearly 30 percent of patients whose early-stage cancer will re-occur as metastatic disease,<sup>1</sup> there remains an urgent need for effective therapy options," said Richard Gaynor, M.D., senior vice president of product development and medical affairs for Lilly Oncology. "We are pleased that the FDA has designated abemaciclib as a breakthrough therapy for patients with advanced breast cancer and Lilly will work closely with the FDA in this process to expedite its development and review."

Lilly has an active clinical development program studying abemaciclib in breast cancer. MONARCH 1 is a Phase II trial evaluating the use of abemaciclib as monotherapy in women with hormone-receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) metastatic breast cancer. In addition, Lilly is evaluating abemaciclib in two Phase III clinical trials: MONARCH 2 to evaluate the combination of abemaciclib and fulvestrant in postmenopausal patients with HR+, HER2- advanced or metastatic breast cancer, and MONARCH 3 to evaluate the combination of abemaciclib and a nonsteroidal aromatase inhibitor in patients with HR+, HER2- locoregionally recurrent or metastatic breast cancer.

### **About Metastatic Breast Cancer**

Breast cancer is the most common cancer in women worldwide with nearly 1.7 million new cases diagnosed in 2012.<sup>2</sup> In the U.S. each year, nearly 232,000 new cases of invasive breast cancer will be diagnosed and about 40,000 women will die from breast cancer.<sup>3</sup> Of all diagnosed breast cancer cases in the U.S., approximately 30 percent will become metastatic, spreading to other parts of the body, with an estimated six to 10 percent of all new breast cancer cases initially being stage IV, or metastatic.<sup>1</sup> Metastatic breast cancer is considered incurable, but is generally treatable.

### **About Abemaciclib**

Cyclin-dependent kinases play a key role in regulating cell cycle progression. In many cancers, uncontrolled cell growth arises from a loss of control in regulating the cell cycle due to increased signaling from CDK 4 and 6. Lilly's abemaciclib (LY2835219) is a cell cycle inhibitor, designed to block the growth of cancer cells by specifically inhibiting CDK 4 and 6. Although abemaciclib inhibits both CDK 4 and CDK 6, the results from the cell-free enzymatic assays have shown that it was most active against Cyclin D 1 and CDK 4. Results from preclinical and early-stage clinical studies support the further evaluation of abemaciclib for the treatment of human cancers - including breast cancer and lung cancer - in which aberrant CDK 4 and 6 pathways enhance cancer cell growth. Abemaciclib has now entered into Phase III development with two trials in HR+ breast cancer patients, as well as a Phase III trial in lung cancer.

### **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](http://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](http://www.lilly.com) and [newsroom.lilly.com/social-channels](http://newsroom.lilly.com/social-channels). P-LLY

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*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 locally advanced or metastatic breast cancer and non-small cell lung 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 future study results will be consistent with the results to date or that abemaciclib will achieve its primary study endpoints or receive regulatory approvals. 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.*

<sup>1</sup> Metastatic Breast Cancer Network, "13 Facts about Metastatic Breast Cancer", <http://mbcn.org/developing-awareness/category/13-things-everyone-should-know-about-metastatic-breast-cancer>. Accessed August 18, 2015.

<sup>2</sup> World Cancer Research Fund International, "Breast Cancer", [http://www.wcrf.org/cancer\\_statistics/data\\_specific\\_cancers/breast\\_cancer\\_statistics.php](http://www.wcrf.org/cancer_statistics/data_specific_cancers/breast_cancer_statistics.php). Accessed: August 18, 2015.

<sup>3</sup> American Cancer Society, "What are the key statistics about breast cancer?", <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-key-statistics>. Accessed: August 18, 2015.

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To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/lilly-receives-fda-breakthrough-therapy-designation-for-abemaciclib--a-cdk-4-and-6-inhibitor--in-advanced-breast-cancer-300156371.html>

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