Lilly Receives Additional FDA Approval for VerzenioTM (abemaciclib), as Initial Treatment for Advanced Breast Cancer

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- New indication based on MONARCH 3 trial can help more women living with HR+, HER2- advanced breast cancer
- Verzenio is the only CDK4 & 6 inhibitor approved across HR+, HER2- metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant and as a single agent, and is the only CDK4 & 6 inhibitor approved with a continuous dosing schedule

INDIANAPOLIS, Feb. 26, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. Food and Drug Administration (FDA) has approved Verzenio™ (abemaciclib) in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer. This additional FDA approval marks the third indication for Verzenio within five months. In September 2017, Verzenio became the first and only cyclin-dependent kinase (CDK)4 & 6 inhibitor approved in combination and as a single agent in metastatic breast cancer. Specifically, Verzenio was approved for use in combination with fulvestrant for the treatment of women with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy, and as monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

The recommended dose of Verzenio in combination with an AI is 150 mg orally twice daily, continued until disease progression or unacceptable toxicity. Verzenio is available in four tablet strengths (200 mg, 150 mg, 100 mg, and 50 mg).

This approval of Verzenio as initial therapy in combination with an AI is based on the efficacy and safety demonstrated in the pivotal MONARCH 3 clinical trial. MONARCH 3 is a Phase 3, randomized, double-blind, placebo-controlled trial evaluating Verzenio in combination with an AI as initial endocrine-based therapy that enrolled 493 postmenopausal women with HR+, HER2- advanced breast cancer who had no prior systemic treatment for advanced disease. In patients who received neoadjuvant/adjuvant endocrine therapy, a disease-free interval of more than 12 months since completion of endocrine therapy was required. This Verzenio new drug application was given Priority Review as part of the FDA's Expedited Programs for Serious Conditions, a program used for therapies that address an unmet medical need in the treatment of serious or life-threatening conditions, such as metastatic breast cancer. Verzenio was also granted Breakthrough Therapy Designation in 2015 based on the Phase 1 JPBA trial.

In MONARCH 3, Verzenio dosed orally at 150 mg twice daily on a continuous schedule with an AI demonstrated a greater than 28-month median progression-free survival (PFS) in patients who received initial endocrine-based therapy for metastatic disease (28.2 months [95% CI: 23.5-NR] vs 14.8 months [95% CI: 11.2-19.2] with placebo plus an AI [HR: 0.54; 95% CI: 0.418-0.698, *P* <0.0001]). In patients with measurable disease who received Verzenio plus an AI (n=267), an objective response rate of 55.4 percent was achieved (ORR; defined as complete response plus partial response [CR + PR], and based upon confirmed responses; PR defined as ≥30% reduction in target lesions)[1] (n=148; 95% CI: 49.5-61.4), with 52.1 percent of patients having achieved a PR (n=139) and 3.4 percent having achieved a CR (n=9).[2] In comparison, in the placebo-plus-AI group of patients with measurable disease (n=132), ORR was 40.2 percent (n=53; 95% CI: 31.8-48.5), with all women being partial responders. Median duration of response (DoR) was 27.4 months with Verzenio plus an AI (95% CI: 25.7-NR) versus 17.5 months with placebo plus an AI (95% CI: 11.2-22.2).[3,4]

"This approval is an important milestone, as it shows that Verzenio plus an aromatase inhibitor substantially reduced tumor size and delayed disease progression in women with HR+, HER2- metastatic breast cancer. Notably, the MONARCH 3 trial included patients with certain concerning clinical characteristics, such as a pattern of disease that spread to the liver," said Joyce O'Shaughnessy, M.D., Celebrating Women Chair in Breast Cancer Research and chair, Breast Cancer Research Program, Baylor University Medical Center, Texas Oncology and U.S. Oncology, Dallas, TX. "This information will help inform treatment decisions for each patient, which can be complicated in advanced breast cancer."

The labeling for Verzenio contains warnings and precautions for diarrhea, neutropenia, hepatotoxicity, venous thromboembolism, and embryofetal toxicity. Instruct patients at the first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their healthcare provider. Perform complete blood counts and liver function tests prior to the start of Verzenio treatment, every two weeks for the first two months, monthly for the next two months, and as clinically indicated. Based on results, Verzenio may require dose modification. Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate. Advise patients of potential risk to a fetus and to use effective contraception. See full **Prescribing Information** for further management instructions. The most common adverse reactions in the MONARCH 1, 2, and 3 trials (all grades, ≥20%) were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia.

"The speed with which our team has been able to work with the FDA to gain approval for this additional Verzenio indication underscores Lilly's commitment to delivering meaningful medicines that can help more people living with advanced breast cancer," said Sue Mahony, Ph.D., senior vice president and president of Lilly Oncology. "Verzenio has now been developed, studied and clinically proven in three key trials to be effective for women with HR+, HER2- metastatic breast cancer – helping to ensure we are providing support to those who need it most."

"For those facing a diagnosis of metastatic breast cancer or learning that their disease has spread further, each new indication and clinical development is critical," said Marc Hurlbert, Ph.D., chairman, Metastatic Breast Cancer Alliance. "Today's news represents continued progress towards helping more people living with this devastating disease."

About MONARCH 3
MONARCH 3 is a Phase 3, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of Verzenio (abemaciclib), a CDK4 & 6 inhibitor, in combination with an AI (anastrozole or letrozole), as initial endocrine-based therapy for postmenopausal women with HR+, HER2- advanced (locoregionally recurrent or metastatic) breast cancer who have had no prior systemic treatment for advanced disease. If neoadjuvant/adjuvant endocrine therapy was administered, a disease-free interval of more than 12 months since completion of endocrine therapy was required. A total of 493 patients were randomized 2:1 to receive 150 mg of Verzenio 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, DoR, overall survival and safety.

About Advanced Breast Cancer

Breast cancer is the most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012.[5] An estimated 266,120 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S. in 2018.[6] Advanced breast cancer includes metastatic breast cancer, meaning cancer that has spread from the breast tissue to other parts of the body, and locally or regionally advanced breast cancer, meaning the cancer has grown outside the organ where it started but has not yet spread to other parts of the body.[7] Of all early stage breast cancer cases diagnosed in the U.S., approximately 30 percent will become metastatic and an estimated six to 10 percent of all new breast cancer cases are initially diagnosed as being metastatic.[8] Survival is lower among women with a more advanced stage at diagnosis: 5-year relative survival is 99 percent for localized disease, 85 percent for regional disease, and 26 percent for metastatic disease. Other factors, such as tumor size, also impact 5-year survival estimates.[9]

About Verzenio™ (abemaciclib)
Verzenio (abemaciclib) is an inhibitor of cyclin-dependent kinases (CDK)4 & 6, which are activated by binding to D-cyclins. In estrogen receptor-positive (ER+) breast cancer cell lines, cyclin D1 and CDK4 & 6 promote phosphorylation of the retinoblastoma protein (Rb), cell cycle progression, and cell proliferation.

In vitro, continuous exposure to Verzenio inhibited Rb phosphorylation and blocked progression from G1 to S phase of the cell cycle, resulting in senescence and apoptosis (cell death). Preclinically, Verzenio dosed daily without interruption resulted in reduction of tumor size. Inhibiting CDK4 & 6 in healthy cells can result in side effects, some of which may be serious.[3] Clinical evidence also suggests that Verzenio crosses the blood-brain barrier. In patients with advanced cancer, including breast cancer, concentrations of Verzenio and its active metabolites (M2 and M20) in cerebrospinal fluid are comparable to unbound plasma concentrations.[3,10]

Verzenio is Lilly's first solid oral dosage form to be made using a faster, more efficient process known as continuous manufacturing. Continuous manufacturing is a new and advanced type of manufacturing within the pharmaceutical industry, and Lilly is one of the first companies to use this technology.

INDICATION

Verzenio is indicated for the treatment of HR+, HER2- advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor for postmenopausal women as initial endocrine-based therapy
- in combination with fulvestrant for women with disease progression following endocrine therapy
- as a single agent for adult patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

IMPORTANT SAFETY INFORMATION

Diarrhea occurred in 81% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 20% of patients receiving Verzenio alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

Diarrhea incidence was greatest during the first month of Verzenio dosing. In MONARCH 3, the median time to onset of the first diarrhea event was 8 days, and the median duration of diarrhea for Grades 2 and 3 were 11 and 8 days, respectively. In MONARCH 2, the median time to onset of the first diarrhea event was 6 days, and the median duration of diarrhea for Grades 2 and 3 were 9 days and 6 days, respectively. In MONARCH 3, 19% of patients with diarrhea required a dose omission and 13% required a dose reduction. In MONARCH 2, 22% of patients with diarrhea required a dose omission and 22% required a dose reduction. The time to onset and resolution for diarrhea were similar across MONARCH 3, MONARCH 2, and MONARCH 1.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow-up. For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue Verzenio until toxicity resolves to ≤Grade 1, and then resume Verzenio at the next lower dose.

Neutropenia occurred in 41% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 46% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 37% of patients receiving Verzenio alone in MONARCH 1. A Grade ≥3 decrease in neutrophil count (based on laboratory findings) occurred in 22% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 32% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 27% of patients receiving Verzenio alone in MONARCH 1. In MONARCH 3, the median time to first episode of Grade ≥3 neutropenia was 33 days, and in MONARCH 2 and MONARCH 1, was 29 days. In MONARCH 3, median duration of Grade ≥3 neutropenia was 11 days, and for MONARCH 2 and MONARCH 1 was 15 days.

Monitor complete blood counts prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Febrile neutropenia has been reported in <1% of patients exposed to Verzenio in the MONARCH studies. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider.

Grade ≥3 increases in **alanine aminotransferase (ALT)** (6% versus 2%) and **aspartate aminotransferase (AST)** (3% versus 1%) were reported in the Verzenio and placebo arms, respectively, in MONARCH 3. Grade ≥3 increases in ALT (4% versus 2%) and AST (2% versus 3%) were reported in the Verzenio and placebo arms respectively, in MONARCH 2.

In MONARCH 3, for patients receiving Verzenio plus an aromatase inhibitor with Grade ≥3 increases in ALT or AST, median time to onset was 61 and 71 days, respectively, and median time to resolution to Grade <3 was 14 and 15 days, respectively. In MONARCH 2, for patients receiving Verzenio plus fulvestrant with Grade ≥3 increases in ALT or AST, median time to onset was 57 and 185 days, respectively, and median time to resolution to Grade <3 was 14 and 13 days, respectively.

For assessment of potential **hepatotoxicity**, monitor liver function tests (LFTs) prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, dose discontinuation, or delay in starting treatment cycles is recommended for patients who develop persistent or recurrent Grade 2, or Grade 3 or 4, hepatic transaminase elevation.

Venous thromboembolic events were reported in 5% of patients treated with Verzenio plus an aromatase inhibitor as compared to 0.6% of patients treated with an aromatase inhibitor plus placebo in MONARCH 3. Venous thromboembolic events were reported in 5% of patients treated with Verzenio plus fulvestrant in MONARCH 2 as compared to 0.9% of patients treated with fulvestrant plus placebo. Venous thromboembolic events included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis. Across the clinical development program, deaths due to venous thromboembolism have been reported. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate.

Verzenio can cause **fetal harm** when administered to a pregnant woman based on findings from animal studies and the mechanism of action. In animal reproduction studies, administration of abemaciclib to pregnant rats during the period of organogenesis caused teratogenicity and decreased fetal weight at maternal exposures that were similar to the human clinical exposure based on area under the curve (AUC) at the maximum recommended human dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with Verzenio and for at least 3 weeks after the last dose. There are no data on the presence of Verzenio in human milk or its effects on the breastfed child or on milk production. Advise lactating women not to breastfeed during Verzenio treatment and for at least 3 weeks after the last dose because of the potential for serious adverse reactions in breastfed infants. Based on findings in animals, Verzenio may impair fertility in males of reproductive potential.

The most common adverse reactions (all grades, ≥10%) observed in **MONARCH 3 for Verzenio plus anastrozole or letrozole and ≥2% higher than placebo plus anastrozole or letrozole vs placebo plus anastrozole or letrozole** were diarrhea (81% vs 30%), neutropenia (41% vs 2%), fatigue (40% vs 32%), infections (39% vs 29%), nausea (39% vs 20%), abdominal pain (29% vs 12%), vomiting (28% vs 12%), anemia (28% vs 5%), alopecia (27% vs 11%), decreased appetite (24% vs 9%), leukopenia (21% vs 2%), creatinine increased (19% vs 4%), constipation (16% vs 12%), ALT increased (16% vs 7%), AST increased (15% vs 7%), rash (14% vs 5%), pruritus (13% vs 9%), cough (13% vs 9%), dyspnea (12% vs 6%), dizziness (11% vs 9%), weight decreased (10% vs 3%), influenza-like illness (10% vs 8%), and thrombocytopenia (10% vs 2%).

The most common adverse reactions (all grades, ≥10%) observed in **MONARCH 2 for Verzenio plus fulvestrant and ≥2% higher than placebo plus fulvestrant vs placebo plus fulvestrant** were diarrhea (86% vs 25%), neutropenia (46% vs 4%), fatigue (46% vs 32%), nausea (45% vs 23%), infections (43% vs 25%), abdominal pain (35% vs 16%), anemia (29% vs 4%), leukopenia (28% vs 2%), decreased appetite (27% vs 12%), vomiting (26% vs 10%), headache (20% vs 15%), dysgeusia (18% vs 3%), thrombocytopenia (16% vs 3%), alopecia (16% vs 2%), stomatitis (15% vs 10%), ALT increased (13% vs 5%), pruritus (13% vs 6%), cough (13% vs 11%), dizziness (12% vs 6%), AST increased (12% vs 7%), peripheral edema (12% vs 7%), creatinine increased (12% vs <1%), rash (11% vs 4%), pyrexia (11% vs 6%), and weight decreased (10% vs 2%).

The most common adverse reactions (all grades, ≥10%) observed in **MONARCH 1** with Verzenio were diarrhea (90%), fatigue (65%), nausea (64%), decreased appetite (45%), abdominal pain (39%), neutropenia (37%), vomiting (35%), infections (31%), anemia (25%), thrombocytopenia (20%), headache (20%), cough (19%), leukopenia (17%), constipation (17%), arthralgia (15%), dry mouth (14%), weight decreased (14%), stomatitis (14%), creatinine increased (13%), alopecia (12%), dysgeusia (12%), pyrexia (11%), dizziness (11%), and dehydration (10%).

The most frequently reported ≥5% Grade 3 or 4 adverse reactions that occurred in the Verzenio arm vs the placebo arm of **MONARCH 3** were neutropenia (22% vs 2%), diarrhea (9% vs 1%), leukopenia (8% vs <1%), ALT increased (7% vs 2%), and anemia (6% vs 1%).

The most frequently reported ≥5% Grade 3 or 4 adverse reactions that occurred in the Verzenio arm vs the placebo arm of **MONARCH 2** were neutropenia (27% vs 2%), diarrhea (13% vs <1%), leukopenia (9% vs 0%), anemia (7% vs 1%), and infections (6% vs 3%).

The most frequently reported ≥5% Grade 3 or 4 adverse reactions from **MONARCH 1** with Verzenio were neutropenia (24%), diarrhea (20%), fatigue (13%), infections (7%), leukopenia (6%), anemia (5%), and nausea (5%).

Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 3 in ≥10% for Verzenio plus anastrozole or letrozole and ≥2% higher than placebo plus anastrozole or letrozolevs placebo plus anastrozole or letrozole were increased serum creatinine (98% vs 84%; 2% vs 0%), decreased white blood cells (82% vs 27%; 13% vs <1%), anemia (82% vs 28%; 2% vs 0%), decreased neutrophil count (80% vs 21%; 22% vs 3%), decreased lymphocyte count (53% vs 26%; 8% vs 2%), decreased platelet count (36% vs 12%; 2% vs <1%), increased ALT (48% vs 25%; 7% vs 2%), and increased AST (37% vs 23%; 4% vs <1%).

Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 2 in ≥10% for Verzenio plus fulvestrant and ≥2% higher than placebo plus fulvestrant vs placebo plus fulvestrant were increased serum creatinine (98% vs 74%; 1% vs 0%), decreased white blood cells (90% vs 33%; 23% vs 1%), decreased neutrophil count (87% vs 30%; 33% vs 4%), anemia (84% vs 33%; 3% vs <1%), decreased lymphocyte count (63% vs 32%; 12% vs 2%), decreased platelet count (53% vs 15%; 2% vs 0%), increased ALT (41% vs 32%; 5% vs 1%), and increased AST (37% vs 25%; 4% vs 4%).

Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 1 with Verzenio were increased serum creatinine (98%; <1%), decreased white blood cells (91%; 28%), decreased neutrophil count (88%; 27%), anemia (68%; 0%), decreased lymphocyte count (42%; 14%), decreased platelet count (41%; 2%), increased ALT (31%; 3%), and increased AST (30%; 4%).

Strong CYP3A inhibitors increased the exposure of abemaciclib plus its active metabolites to a clinically meaningful extent and may lead to increased toxicity. Avoid concomitant use of ketoconazole. Ketoconazole is predicted to increase the AUC of abemaciclib by up to 16-fold. In patients with recommended starting doses of 200 mg twice daily or 150 mg twice daily, reduce the Verzenio dose to 100 mg twice daily with concomitant use of other strong CYP3A inhibitors. In patients who have had a dose reduction to 100 mg twice daily due to adverse reactions, further reduce the Verzenio dose to 50 mg twice daily with concomitant use of other strong CYP3A inhibitors. If a patient taking Verzenio discontinues a strong CYP3A inhibitor, increase the Verzenio dose (after 3 to 5 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor. Patients should avoid grapefruit products.

Avoid concomitant use of strong CYP3A inducers and consider alternative agents. Coadministration of Verzenio with rifampin, a strong CYP3A inducer, decreased the plasma concentrations of abemaciclib plus its active metabolites and may lead to reduced activity.

With severe hepatic impairment (Child-Pugh Class C), reduce the Verzenio dosing frequency to once daily. The pharmacokinetics of Verzenio in patients with **severe renal impairment** (CLcr <30 mL/min), end stage renal disease, or in patients on dialysis is **unknown.** No dosage adjustments are necessary in patients with mild or moderate hepatic (Child-Pugh A or B) and/or renal impairment (CLcr ≥30-89 mL/min).

Please see full **Prescribing Information** for Verzenio.

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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 newsroom.lilly.com/social-channels.

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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 additional 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.

Refer to: Tracy Henrikson; tracy.henrikson@lilly.com; 609-240-3902 (media)
Kevin Hern; hern_kevin_r@lilly.com; 317-277-1838 (investors)

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