Lilly Announces Updated Data from the Verzenio® (abemaciclib) Phase 3 monarchE Trial Presented at SABCS and Simultaneously Published in The Lancet Oncology

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The benefit of adjuvant Verzenio in combination with endocrine therapy continues to deepen with additional follow-up, now demonstrating an absolute improvement in invasive disease-free survival (IDFS) and distance relapse-free survival (DRFS) rates of 6.4% and 5.9% at four years, respectively, in patients with HR+, HER2-, node-positive, high risk early breast cancer

INDIANAPOLIS, Dec. 6, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced updated results from the pivotal Phase 3 monarchE trial of adjuvant Verzenio® (abemaciclib) in combination with standard endocrine therapy (ET) for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, high risk early breast cancer (EBC). These data, which include results for investigational uses in the intent-to-treat (ITT) and Cohort 1 populations, were presented today as an oral presentation at the 2022 San Antonio Breast Cancer Symposium (SABCS) and simultaneously published in *The Lancet Oncology*.

Data include updated results from a prespecified analysis reflecting a median follow-up of 3.5 years, with all patients having now discontinued or completed the two-year Verzenio treatment period. The absolute increase in invasive disease-free survival (IDFS) and distance relapse-free survival (DRFS) continued to deepen in magnitude at four years, to 6.4% and 5.9%, respectively, reflecting improvements from the two- and three-year rates. This IDFS and DRFS benefit was seen across all prespecified subgroups, regardless of Ki-67 score. While overall survival (OS) data remain immature at this time, fewer deaths were observed in the Verzenio-plus-ET arm compared to the ET monotherapy arm (HR=0.929, 95% CI: 0.748, 1.153). There were no new safety findings, and overall results are consistent with the well-established safety profile for Verzenio.

"These results from the monarchE trial provide further evidence of the clinically meaningful benefit that adjuvant Verzenio adds to standard endocrine therapy in patients with high risk early breast cancer, a population with an urgent need to intensify therapy. Moreover, this benefit continues to deepen at four years, well beyond the two-year treatment course with adjuvant Verzenio," said Stephen Johnston, M.D., Ph.D., Professor of Breast Cancer Medicine and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust (London, U.K.) and lead investigator for the monarchE trial.

The monarchE trial (N=5,637) included women and men with HR+, HER2-, node-positive EBC with a high risk of disease recurrence. The ITT population included patients enrolled to both Cohort 1 and Cohort 2, with Cohort 1 (N=5,120) representing 91% of all enrolled patients. Cohort 1 enrolled patients based on high risk clinical pathological factors (≥4 positive axillary lymph nodes [ALN], or 1-3 positive ALN and either Grade 3 disease or tumor size ≥5 cm). Cohort 2 enrolled patients with 1-3 positive ALN and centrally determined Ki-67 score of ≥20% (defined in the study as "Ki-67 high"). Ki-67 is a marker of cellular proliferation. Ki-67 score was also determined centrally in Cohort 1 patients with a suitable sample, but Ki-67 determination was not required for enrollment in this cohort.

At the July 1, 2022 data cutoff, in the ITT population, the risk of developing invasive disease was reduced by 33.6% (HR=0.664, 95% CI: 0.578, 0.762; nominal p<0.0001). The four-year IDFS rate was 85.8% for patients treated with Verzenio plus ET compared to 79.4% for patients treated with ET alone, reflecting an absolute difference of 6.4% (compared to 2.8% at two years). The majority of the IDFS events were distant metastatic disease. Adjuvant Verzenio also reduced the risk of developing metastatic disease by 34.1% (HR=0.659, 95% CI: 0.567, 0.767; nominal p<0.0001). The four-year DRFS rate was 88.4% for patients treated with Verzenio plus ET compared to 82.5% for patients treated with ET alone, an absolute difference of 5.9% (compared to 2.5% at two years). Consistent with the findings of previous analyses, a high Ki-67 score correlated with increased risk of recurrence, but IDFS and DRFS results showed a similar benefit regardless of Ki-67 status. Data presented at SABCS also included efficacy outcomes in the FDA-approved population, as well as the Cohort 1 population.

OS data remain immature. Fewer deaths were observed in the Verzenio-plus-ET arm (157 [5.6%] of 2,808 patients) compared to the ET monotherapy arm (173 [6.1%] of 2,829 patients) (HR=0.929, 95% CI: 0.748, 1.153; p = 0.50). Fewer deaths due to breast cancer occurred in the Verzenio-plus-ET arm compared to the ET alone arm (117 [4.2%] of 2,791 patients vs. 138 [4.9%] of 2,800 patients). Nearly twice as many patients in the control arm have developed and are living with metastatic disease compared to those receiving Verzenio. Continued follow-up is ongoing until final assessment of OS.

The most frequent adverse events (AEs) were diarrhea, neutropenia, and fatigue in the Verzenio arm, and arthralgia, hot flush, and fatigue in the control arm; the most common Grade 3-4 AEs were neutropenia, leucopenia, and diarrhea in the Verzenio arm and arthralgia, neutropenia, and ALT increased in the ET alone arm.

"The continued strengthening of the adjuvant Verzenio benefit seen at four years further underscores the potential importance of these data for women and men with HR+, HER2-, node-positive, high risk early breast cancer," said David Hyman, M.D., chief medical officer, Loxo@Lilly. "We are pleased with these results and have submitted an application with the FDA to expand our adjuvant indication in the U.S. based on these data."

As previously published in the *Journal of Clinical Oncology*,[1] and subsequently updated in the *Annals of Oncology*,[2] monarchE met its primary endpoint of a statistically significant improvement in IDFS in the ITT population for patients treated with adjuvant Verzenio plus ET compared to those treated with ET alone. Consistent with expert guidelines, IDFS was defined as the length of time before breast cancer comes back, any new cancer develops, or death. On October 12, 2021, the FDA approved Verzenio in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with HR+, HER2-, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score of ≥20% as determined by an FDA-approved test.[3]

About the monarchE Study

monarchE is a global, randomized, open-label, two cohort, multicenter Phase 3 study in adult women and men with HR+, HER2-, node-positive

resected EBC with clinical and pathological features consistent with a high risk of disease recurrence. A total of 5,637 patients were randomized (1:1) to receive two years of Verzenio 150 mg twice daily plus physician's choice of standard endocrine therapy, or standard endocrine therapy alone. Patients in both treatment arms were instructed to continue to receive adjuvant endocrine therapy for up to 5-10 years as recommended by their clinician. Cohort 1 enrolled patients with ≥4 positive axillary lymph nodes (ALN), or 1-3 positive ALN and either Grade 3 disease or tumor size ≥5 cm. Cohort 2 enrolled patients with 1-3 positive ALN and centrally determined Ki-67 score of ≥20%. The primary endpoint was IDFS in the ITT population (Cohorts 1 & 2). Consistent with expert guidelines, IDFS was defined as the length of time before breast cancer comes back, any new cancer develops, or death. Secondary endpoints were IDFS in patients with high Ki-67 score (in the ITT population and in the Cohort 1 population), DRFS, overall survival, and safety.[2,3]

About Early Breast Cancer and Risk of Recurrence
It is estimated that 90 percent of all breast cancers are detected at an early stage. Although the prognosis for HR+, HER2- EBC is generally positive, 20 percent of patients will experience recurrence potentially to incurable metastatic disease.[4] Risk of recurrence is greatest within the initial two to three years post-diagnosis, particularly in patients with node-positive, high risk EBC.[5] Factors associated with high risk of recurrence include: positive nodal status, large tumor size (≥5 cm), high tumor grade (Grade 3), and high rate of cellular proliferation [Ki-67 score (≥20%)].[3]

Node-positive means that cancer cells from the tumor in the breast have been found in the lymph nodes in the armpit area. Although the breast cancer is removed through surgery, the presence of cancer cells in the lymph nodes signifies that there is a higher chance of the cancer returning and spreading.

About Breast Cancer
Breast cancer has now surpassed lung cancer as the most commonly diagnosed cancer worldwide, according to GLOBOCAN. The estimated 2.3 million new cases indicate that 1 in every 8 cancers diagnosed in 2020 is breast cancer. With approximately 685,000 deaths in 2020, breast cancer is the fifth-leading cause of cancer death worldwide.[6] In the U.S., it is estimated that there will be 290,560 new cases of breast cancer in 2022.[7]

Approximately 70 percent of all breast cancers are of the HR+, HER2- subtype.[8]

INDICATIONS FOR VERZENIO®
Verzenio® (abemaciclib) in combination with endocrine therapy (ET) is indicated for the adjuvant treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, early breast cancer (EBC) at high risk of recurrence and a Ki-67 score of ≥20%, as determined by a U.S. Food and Drug Administration (FDA)-approved test.

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

- In combination with ET (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with HR+, HER2-, node-positive, EBC at high risk of recurrence and a Ki-67 score ≥20% as determined by an FDA-approved test
- In combination with an aromatase inhibitor as initial ET for the treatment of postmenopausal women, and men, with HR+, HER2- advanced or metastatic breast cancer
- In combination with fulvestrant for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following ET
- As monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following ET and prior chemotherapy in the metastatic setting

IMPORTANT SAFETY INFORMATION FOR VERZENIO (abemaciclib)
Severe **diarrhea** associated with dehydration and infection occurred in patients treated with Verzenio. Across four clinical trials in 3691 patients, diarrhea occurred in 81 to 90% of patients who received Verzenio. Grade 3 diarrhea occurred in 8 to 20% of patients receiving Verzenio. Most patients experienced diarrhea during the first month of Verzenio treatment. The median time to onset of the first diarrhea event ranged from 6 to 8 days; and the median duration of Grade 2 and Grade 3 diarrhea ranged from 6 to 11 days and 5 to 8 days, respectively. Across trials, 19 to 26% of patients with diarrhea required a Verzenio dose interruption and 13 to 23% required a dose reduction.

Instruct patients to start antidiarrheal therapy, such as loperamide, at the first sign of loose stools, 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, including febrile neutropenia and fatal neutropenic sepsis, occurred in patients treated with Verzenio. Across four clinical trials in 3691 patients, neutropenia occurred in 37 to 46% of patients receiving Verzenio. A Grade ≥3 decrease in neutrophil count (based on laboratory findings) occurred in 19 to 32% of patients receiving Verzenio. Across trials, the median time to first episode of Grade ≥3 neutropenia ranged from 29 to 33 days, and the median duration of Grade ≥3 neutropenia ranged from 11 to 16 days. Febrile neutropenia has been reported in <1% of patients exposed to Verzenio across trials. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider.

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.

Severe, life-threatening, or fatal **interstitial lung disease (ILD) or pneumonitis** can occur in patients treated with Verzenio and other CDK4/6 inhibitors. In Verzenio-treated patients in EBC (monarchE), 3% of patients experienced ILD or pneumonitis of any grade: 0.4% were Grade 3 or 4 and there was one fatality (0.1%). In Verzenio-treated patients in MBC (MONARCH 1, MONARCH 2, MONARCH 3), 3.3% of Verzenio-treated patients had ILD or pneumonitis of any grade: 0.6% had Grade 3 or 4, and 0.4% had fatal outcomes. Additional cases of ILD or pneumonitis have been observed in the postmarketing setting, with fatalities reported.

Monitor patients for pulmonary symptoms indicative of ILD or pneumonitis. Symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on

radiologic exams. Infectious, neoplastic, and other causes for such symptoms should be excluded by means of appropriate investigations. Dose interruption or dose reduction is recommended in patients who develop persistent or recurrent Grade 2 ILD or pneumonitis. Permanently discontinue Verzenio in all patients with Grade 3 or 4 ILD or pneumonitis.

Grade ≥3 increases in alanine aminotransferase (ALT) (2 to 6%) and **aspartate aminotransferase (AST)** (2 to 3%) were reported in patients receiving Verzenio. Across three clinical trials in 3559 patients (monarchE, MONARCH 2, MONARCH 3), the median time to onset of Grade ≥3 ALT increases ranged from 57 to 87 days and the median time to resolution to Grade <3 was 13 to 14 days. The median time to onset of Grade ≥3 AST increases ranged from 71 to 185 days and the median time to resolution to Grade <3 ranged from 11 to 15 days.

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 any Grade 3 or 4 hepatic transaminase elevation.

Venous thromboembolic events (VTE) were reported in 2 to 5% of patients across three clinical trials in 3559 patients treated with Verzenio (monarchE, MONARCH 2, MONARCH 3). VTE included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis. In clinical trials, deaths due to VTE have been reported in patients treated with Verzenio.

Verzenio has not been studied in patients with early breast cancer who had a history of VTE. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate. Dose interruption is recommended for EBC patients with any grade VTE and for MBC patients with a Grade 3 or 4 VTE.

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 3 weeks after the last dose. Based on findings in animals, Verzenio may impair fertility in males of reproductive potential. 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.

The **most common adverse reactions (all grades, ≥10%)** observed in **monarchE for Verzenio plus tamoxifen or an aromatase inhibitor vs tamoxifen or an aromatase inhibitor, with a difference between arms of ≥2%,** were diarrhea (84% vs 9%), infections (51% vs 39%), neutropenia (46% vs 6%), fatigue (41% vs 18%), leukopenia (38% vs 7%), nausea (30% vs 9%), anemia (24% vs 4%), headache (20% vs 15%), vomiting (18% vs 4.6%), stomatitis (14% vs 5%), lymphopenia (14% vs 3%), thrombocytopenia (13% vs 2%), decreased appetite (12% vs 2.4%), ALT increased (12% vs 6%), AST increased (12% vs 5%), dizziness (11% vs 7%), rash (11% vs 4.5%), and alopecia (11% vs 2.7 %).

The **most frequently reported ≥5% Grade 3 or 4 adverse reaction** that occurred in the Verzenio arm vs the tamoxifen or an aromatase inhibitor arm of monarchE were neutropenia (19.6% vs 1%), leukopenia (11% vs <1%), diarrhea (8% vs 0.2%), and lymphopenia (5% vs <1%).

Lab abnormalities (all grades; Grade 3 or 4) for **monarchE in ≥10% for Verzenio plus tamoxifen or an aromatase inhibitor with a difference between arms of ≥2%** were increased serum creatinine (99% vs 91%; .5% vs <.1%), decreased white blood cells (89% vs 28%; 19.1% vs 1.1%), decreased neutrophil count (84% vs 23%; 18.7% vs 1.9%), anemia (68% vs 17%; 1% vs .1%), decreased lymphocyte count (59% vs 24%; 13.2 % vs 2.5%), decreased platelet count (37% vs 10%; .9% vs .2%), increased ALT (37% vs 24%; 2.6% vs 1.2%), increased AST (31% vs 18%; 1.6% vs .9%), and hypokalemia (11% vs 3.8%; 1.3% vs 0.2%).

The **most common adverse reactions (all grades, ≥10%)** observed in **MONARCH 3 for Verzenio plus anastrozole or letrozole vs anastrozole or letrozole, with a difference between arms of ≥2%,** were diarrhea (81% vs 30%), fatigue (40% vs 32%), neutropenia (41% vs 2%), 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 3.1%), influenza-like illness (10% vs 8%), and thrombocytopenia (10% vs 2%).

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 1%), diarrhea (9% vs 1.2%), leukopenia (7% vs <1%)), increased ALT (6% vs 2%), and anemia (6% vs 1%).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 3 in ≥10% for Verzenio plus anastrozole or letrozole with a difference between arms of ≥2%** were increased serum creatinine (98% vs 84%; 2.2% vs 0%), decreased white blood cells (82% vs 27%; 13% vs 0.6%), anemia (82% vs 28%; 1.6% vs 0%), decreased neutrophil count (80% vs 21%; 21.9% vs 2.6%), decreased lymphocyte count (53% vs 26%; 7.6% vs 1.9%), decreased platelet count (36% vs 12%; 1.9% vs 0.6%), increased ALT (48% vs 25%; 6.6% vs 1.9%), and increased AST (37% vs 23%; 3.8% vs 0.6%).

The **most common adverse reactions (all grades, ≥10%)** observed in **MONARCH 2 for Verzenio plus fulvestrant vs fulvestrant, with a difference between arms of ≥2%,** 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 2.7%), thrombocytopenia (16% vs 3%), alopecia (16% vs 1.8%), 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 4.5%), pyrexia (11% vs 6%), and weight decreased (10% vs 2.2%).

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 (25% vs 1%), diarrhea (13% vs 0.4%), leukopenia (9% vs 0%), anemia (7% vs 1%), and infections (5.7% vs 3.5%).

Lab abnormalities (all grades; Grade 3 or 4) for **MONARCH 2 in ≥10% for Verzenio plus fulvestrant with a difference between arms of ≥2%** were increased serum creatinine (98% vs 74%; 1.2% vs 0%), decreased white blood cells (90% vs 33%; 23.7% vs .9%), decreased neutrophil count (87% vs 30%; 32.5% vs 4.2%), anemia (84% vs 34%; 2.6% vs .5%), decreased lymphocyte count (63% vs 32%; 12.2% vs 1.8%), decreased platelet count (53% vs 15%; 2.1% vs 0%), increased ALT (41% vs 32%; 4.6% vs 1.4%), and increased AST (37% vs 25%; 3.9% vs 4.2%).

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%), constipation (17%), leukopenia (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** from **MONARCH 1** with Verzenio were diarrhea (20%), neutropenia (24%), fatigue (13%), and leukopenia (5%).

Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 1 with Verzenio were increased serum creatinine (99%; .8%), decreased white blood cells (91%; 28%), decreased neutrophil count (88%; 26.6%), anemia (69%; 0%), decreased lymphocyte count (42%; 13.8%), decreased platelet count (41%; 2.3%), increased ALT (31%; 3.1%), and increased AST (30%; 3.8%).

Strong and moderate 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 strong CYP3A inhibitors other than ketoconazole. 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 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 inhibitor. With concomitant use of moderate CYP3A inhibitors, monitor for adverse reactions and consider reducing the Verzenio dose in 50 mg decrements. Patients should avoid grapefruit products.

Avoid concomitant use of strong or moderate CYP3A inducers and consider alternative agents. Coadministration of strong or moderate CYP3A inducers decreased the plasma concentrations of abemaciclib plus its active metabolites and may lead to reduced activity.

With severe hepatic impairment (Child-Pugh 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
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram and LinkedIn. P-LLY

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Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Verzenio (abemaciclib) as a treatment for people with early breast cancer and the timeline for future readouts, presentations, and other milestones relating to Verzenio its clinical trials, and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with study results to date, that Verzenio will receive additional regulatory approvals, or that Lilly will execute its strategy as expected. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's 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] Johnston SRD, Harbeck N, Hegg R, et al; monarchE Committee Members and Investigators. Abemaciclib combined with endocrine therapy for the adjuvant treatment of HR+, HER2-, node-positive, high-risk, early breast cancer (monarchE) [published online ahead of print, September 20, 2020]. *J Clin Oncol*. doi:10.1200/JCO.20.02514.

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