Lilly's Verzenio® (abemaciclib) prolonged survival in HR+, HER2-, high-risk early breast cancer with two years of treatment

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Verzenio is the first contemporary therapy in over two decades to demonstrate a significant overall survival benefit in adjuvant HR+, HER2−, high-risk early breast cancer

Seven-year results from the Phase 3 monarchE trial also show Verzenio plus endocrine therapy demonstrated sustained benefits in invasive disease-free survival and distant relapse-free survival

These data were simultaneously published in Annals of Oncology and presented as a late-breaking oral session at the European Society for Medical Oncology (ESMO) Annual Meeting

INDIANAPOLIS, Oct. 17, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced results from the primary overall survival (OS) analysis of the Phase 3 monarchE trial showing that two years of adjuvant Verzenio plus endocrine therapy (ET) reduced the risk of death by 15.8% versus ET alone and resulted in sustained long-term improvements in invasive disease-free survival (IDFS) and distant relapse-free survival (DRFS), in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, high-risk early breast cancer.

These results were published in the *Annals of Oncology* and will be shared in a late-breaking oral presentation at the ESMO Annual Meeting today, Friday, October 17, at 2:50 PM CEST/08:50 AM ET in Berlin, Germany. These data are being submitted to regulatory health authorities globally.

"For patients, survival is what matters most — and abemaciclib plus endocrine therapy represents the first contemporary medicine in over two decades to deliver a clear improvement in overall survival in the adjuvant setting," 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 monarchE. "These results represent an important step forward in the treatment of high-risk HR+, HER2− early breast cancer."

The data presented include results from the primary OS analysis reflecting a median follow-up of 6.3 years, with more than 75% of patients having been followed for at least four years after completion of the two-year Verzenio treatment period. In the intent-to-treat (ITT) population, Verzenio plus ET reduced the risk of death by 15.8% compared to ET alone [7-year overall survival (OS) rate: 86.8% vs. 85.0%; hazard ratio (HR) 0.842; 95% CI: 0.722–0.981; 2-sided p=0.027].

In addition, treatment with Verzenio plus ET led to a sustained reduction in risk of recurrence at seven years, continuing to demonstrate the deep IDFS and DRFS benefit and carryover effect previously seen at five years in monarchE. Notably, 32% fewer patients treated with Verzenio plus ET were living with metastatic disease compared to those receiving ET alone (6.4% vs 9.4%, respectively). Continued long-term follow-up from this trial will help to determine whether this ongoing difference in patients alive with metastatic disease translates into further deepening of survival benefit with time. Results for Cohort 1 were consistent with those for the ITT population across OS, IDFS and DRFS results, and the benefit was also demonstrated across subgroups.

"These results represent an important advancement in the care of node-positive, high-risk HR+, HER2- disease by delivering meaningful reductions in recurrence and improving survival," said Jacob Van Naarden, executive vice president and president of Lilly Oncology. "These findings reinforce two years of Verzenio plus endocrine therapy as the standard of care for node-positive, high-risk disease, offering renewed hope for patients facing this diagnosis."

Safety findings were consistent with the known profile of Verzenio and prior monarchE analyses. No new safety signals or delayed toxicities were observed. Adverse events were generally managed with dose modifications, consistent with prior monarchE analyses.

"For patients facing high-risk early breast cancer, these results are meaningful," said Sue Weldon, CEO of Unite for HER. "To now have data showing a treatment helps more people live longer is a major step forward for our community. We mark this significant milestone while recognizing there's more work ahead to ensure every eligible patient has the opportunity to benefit from treatments that can change lives."

About the monarchE Study

monarchE was a global, randomized, open-label, two cohort, multicenter Phase 3 clinical trial that enrolled 5,637 adults with HR+, HER2-, node-positive EBC at high risk of recurrence. The study enrolled patients across more than 600 sites in 38 countries and is the only adjuvant study designed to investigate a CDK4/6 inhibitor specifically in a node-positive, high-risk EBC population. To be enrolled in Cohort 1 (n=5,120), which is the FDA-approved population, patients had to have 4+ positive nodes or 1-3 positive nodes and at least one of the following: tumors that were ≥5 cm or Grade 3. Patients enrolled in Cohort 2 could not have met the eligibility criteria for Cohort 1. To be enrolled in Cohort 2 (n=517), patients had to have 1-3 positive nodes and Ki-67 score ≥20%. Patients in each cohort were randomized 1:1 to receive either Verzenio 150 mg twice daily plus standard-of-care adjuvant ET (Cohort 1, n=2,555; Cohort 2, n=253) or standard-of-care adjuvant ET alone (Cohort 1, n=2,565; Cohort 2, n=264) for 2 years. ET continued for at least 5 years if deemed medically appropriate. The primary endpoint was IDFS. Consistent with expert guidelines, IDFS was defined as the length of time before breast cancer comes back, any new cancer develops, or death. OS was a key secondary endpoint in monarchE. The OS analysis plan was amended after the primary analysis of IDFS, following consultation with regulators, to increase the number of required OS events from 390 to 650 to ensure a minimum follow-up of at least 5 years and enable a more mature survival dataset.[1,2]

About Early Breast Cancer and Risk of Recurrence

It is estimated that 90% of all breast cancers are detected at an early stage.[3] Approximately 70% of all breast cancer cases are the HR+, HER2-

subtype.[4] Although the prognosis for HR+, HER2- EBC is generally favorable, high-risk patients are three times more likely than those with low risk characteristics to experience recurrence – with the majority being incurable metastatic disease.[5] These patients have an increased risk of recurrence during the first two years of endocrine therapy.

Factors associated with high-risk of recurrence in HR+, HER2- early breast cancer include: positive nodal status, the number of positive nodes, large tumor size (≥5 cm), and high tumor grade (Grade 3). Node-positive means that cancer cells from the tumor in the breast have been found in the lymph nodes near the breast. Although breast cancer is removed through surgery, the presence of cancer cells in the lymph nodes signifies that there is a higher chance of developing recurrence and distant metastatic disease.

About Breast Cancer
Breast cancer is the second most commonly diagnosed cancer worldwide (following lung cancer), according to GLOBOCAN. The estimated 2.3 million new cases indicate that close to 1 in every 4 cancers diagnosed in 2022 is breast cancer. With approximately 666,000 deaths in 2022, breast cancer is the fourth-leading cause of cancer death worldwide.[6] In the U.S., it is estimated that there will be more than 310,000 new cases of breast cancer diagnosed in 2024. Breast cancer is the second leading cause of cancer death in women in the U.S.[7]

About Verzenio® (abemaciclib)
Verzenio® (abemaciclib) is approved to treat people with certain HR+, HER2- breast cancers in the adjuvant and advanced or metastatic setting. Verzenio is the first CDK4/6 inhibitor approved to treat node-positive, high-risk early breast cancer (EBC) patients.[8] For HR+, HER2- breast cancer, The National Comprehensive Cancer Network® (NCCN®) recommends consideration of two years of abemaciclib (Verzenio) added to endocrine therapy as a Category 1 treatment option in the adjuvant setting.[9] NCCN® also includes Verzenio plus endocrine therapy as a preferred treatment option for HR+, HER2- metastatic breast cancer.[9]

The collective results of Lilly's clinical development program continue to differentiate Verzenio as a CDK4/6 inhibitor. In high-risk EBC, Verzenio has shown a persistent and deepening benefit beyond the two-year treatment period in the monarchE trial, an adjuvant study designed specifically to investigate a CDK4/6 inhibitor in a node-positive, high-risk EBC population.[10] In metastatic breast cancer, Verzenio has demonstrated statistically significant OS in the Phase 3 MONARCH 2 study.[11] Verzenio has shown a consistent and generally manageable safety profile across clinical trials.

Verzenio is an oral tablet taken twice daily and available in strengths of 50 mg, 100 mg, 150 mg, and 200 mg. Discovered and developed by Lilly researchers, Verzenio was first approved in 2017 and is currently authorized for use in more than 90 counties around the world. For full details on indicated uses of Verzenio in HR+, HER2- breast cancer, please see full Prescribing Information, available at www.Verzenio.com.

INDICATIONS FOR VERZENIO®
VERZENIO® is a kinase inhibitor indicated:

- in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence.
- in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
- in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy 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 forVerzenio 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%; 0.5% vs <0.1%), 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 and Patient Information for Verzenio.

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About Lilly
Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help tens of millions of 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/news, or follow us on Facebook, Instagram, and LinkedIn. P-LLY

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 as a treatment for people with certain types of breast cancer 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 Verzenio will be commercially successful. 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.

Endnotes and References

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