Lilly Announces Details of Presentations at 2022 San Antonio Breast Cancer Symposium

November 21, 2022

INDIANAPOLIS, Nov. 21, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that study investigators will present data from its breast cancer portfolio and pipeline at the 2022 San Antonio Breast Cancer Symposium (SABCS), to be held December 6-10, 2022, in San Antonio, Texas, and virtually. These presentations include new results from studies of Verzenio® (abemaciclib; a CDK4/6 inhibitor), imlunestrant (an investigational oral selective estrogen receptor degrader [SERD]), and LOXO-783 (an investigational mutant-selective allosteric PI3Kα H1047R inhibitor).

The Verzenio oral and poster presentations will provide updated clinical data from ongoing studies in early and advanced forms of hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer. An oral presentation will provide results from a pre-planned overall survival (OS) analysis from the Phase 3 monarchE study in HR+, HER2-, node-positive, high risk early breast cancer, including four-year efficacy outcomes. Updated results at the final OS from the Phase 3 MONARCH 2 trial of Verzenio plus fulvestrant in patients with HR+, HER2- advanced breast cancer will be presented in a spotlight poster discussion. Additional analyses include real-world evidence in early breast cancer with a high risk of recurrence.

In a spotlight poster discussion, combination therapy results with imlunestrant will be presented from the Phase 1 EMBER trial of imlunestrant in combination with Verzenio, with or without an aromatase inhibitor, in patients with estrogen receptor positive (ER+), HER2- advanced breast cancer. In addition, pharmacodynamic data from the preoperative EMBER-2 trial evaluating imlunestrant in ER+, HER2- early breast cancer will be provided. Preclinical data with LOXO-783 in combination with standard-of-care breast cancer agents will also be presented at the meeting.

A list of the presentations, along with their viewing details, is shared below.

Presentation Title	**Details**
Verzenio (abemaciclib)	
Abemaciclib plus endocrine therapy for HR+, HER2-, node-positive, high-risk early breast cancer: Results from a pre-planned monarchE overall survival interim analysis, including 4-year efficacy outcomes	Presentation #GS1-09 General Session #1 Date: Tuesday, December 6, 2022 Presentation Time: 4:00 – 4:15 PM CT Location: Hall 3 Presenter: Johnston S
Final overall survival analysis of Monarch 2: A phase 3 trial of abemaciclib plus fulvestrant in patients with hormone receptor-positive, HER2-negative advanced breast cancer	Presentation #PD13-11 Spotlight Poster Discussion Session #13: Therapeutic Approaches for HR+/Her2- Breast Cancer Date: Thursday, December 8, 2022 Presentation Time: 5:00 – 6:15 PM CT Location: Stars at Night Ballroom 1&2 Presenter: Llombart-Cussac A
Persistence with adjuvant endocrine therapy in patients with early breast cancer at high risk of recurrence: a US-based real-world study	Presentation #P4-03-01 Poster Session 4: Epidemiology, Risk, and Prevention: Epidemiology - Population Studies Date: Thursday, December 8, 2022 Presentation Time: 7:00 – 8:15 PM CT Location: Hall 1 Presenter: Vikto AS
Association of neutrophil-to-lymphocyte ratio and absolute lymphocyte count with clinical outcomes for patients with advanced breast cancer in the MONARCH 2 trial	Presentation #P5-02-23 Poster Session 5: Prognostic and Predictive Factors: Biomarkers Predicting Tx Response: For Targeted Therapies Date: Thursday, December 8, 2022 Presentation Time: 5:00 – 6:15 PM CT Location: Hall 1 Presenter: Tokunaga E
Costs of breast cancer recurrence after initial treatment for high risk early breast cancer using SEER-Medicare linked data	Presentation #P6-07-01 Poster Session 6: Psychosocial, QOL, and Educational Aspects: Social and Education Issues - Cost-Effectiveness Date: Friday, December 9, 2022 Presentation Time: 7:00 – 8:15 AM CT Location: Hall 1 Presenter: Vitko AS
Imlunestrant	

Imlunestrant, an oral selective estrogen receptor degrader, in combination with abemaciclib with or without an aromatase inhibitor, in estrogen receptor-positive advanced breast cancer: Results from the phase 1a/b EMBER study	Presentation #PD13-12 Spotlight Poster Session 13: Therapeutic Approaches for HR+/HER2- Breast Cancer Date: Thursday, December 8, 2022 Presentation Time: 5:00 – 6:15 PM CT Location: Stars at Night Ballroom 1&2 Presenter: Jhaveri K
A preoperative window-of-opportunity study of imlunestrant in estrogen receptor-positive, HER2-negative early breast cancer: Results from the EMBER-2 study	Presentation #P6-10-06 Poster Session 6: Treatment: Therapeutic Strategies - Novel Targets and Targeted Agents Date: Friday, December 9, 2022 Presentation Time: 7:00 – 8:15 AM CT Location: Hall 1 Presenter: Neven P
LOXO-783	
A potent, highly mutant selective and brain-penetrant allosteric PI3Kα H1047R inhibitor in combination with standard of care (SOC) treatments in preclinical PI3Kα H1047R-mutant breast cancer models	Presentation #P4-08-02 Poster Session 4: Tumor Cell and Molecular Biology: Novel/Emerging Therapeutic Targets Date: Thursday, December 8, 2022 Presentation Time: 7:00 – 8:15 AM CT Location: Hall 1 Presenter: Puca L

About Verzenio® (abemaciclib)

Verzenio® (abemaciclib) is a targeted treatment known as a CDK4/6 inhibitor. Verzenio is a nonchemotherapy oral tablet.

Verzenio works inside the cell to block CDK4/6 activity and help stop the growth of cancer cells so that they may eventually die (based on preclinical studies). Cyclin-dependent kinases (CDK)4/6 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. 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.

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.

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

About Imlunestrant

Imlunestrant (LY3484356) is an investigational, oral selective estrogen receptor degrader (SERD) with pure antagonistic properties. The estrogen receptor (ER) is the key therapeutic target for patients with ER+/HER2- breast cancer. Novel degraders of ER may overcome endocrine therapy resistance while providing consistent oral pharmacology and convenience of administration. Imlunestrant was specifically designed to deliver continuous estrogen receptor target inhibition throughout the dosing period and regardless of ESR1 mutational status. Imlunestrant is currently being studied in several clinical studies.

For information about imlunestrant clinical trials, please refer to www.clinicaltrials.gov. Interested patients and physicians can contact the Loxo@Lilly clinical trial team by e-mailing clinicaltrials@loxooncology.com.

About LOXO-783

LOXO-783 is an investigational potent, highly mutant-selective and brain-penetrant allosteric PI3Kα H1047R inhibitor that is designed to spare wild-type PI3Kα, other PI3K isoforms, and other kinases. Phosphoinositide 3-kinase alpha (PI3Kα) H1047R mutations are activating oncogenic events that occur in approximately 15 percent of breast cancers and less commonly in other cancers. LOXO-783 has shown preclinical activity without on-target wild-type PI3Kα mediated toxicity. LOXO-783 is being investigated in an open-label, multicenter, Phase 1a/1b study in patients with PIK3CA

H1047R-mutant advanced breast cancer and other solid tumors.

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, imlunestrant, and LOXO-783 as potential treatments for people with various types of cancer and the timeline for future readouts, presentations, and other milestones relating to Verzenio, imlunestrant, and LOXO-783 and their 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, imlunestrant, and LOXO-783 will prove to be safe and effective treatments for certain types of cancer, that Verzenio will receive additional regulatory approvals, that imlunestrant or LOXO-783 will receive 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.

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