Lilly to highlight progress across key programs in early and advanced hormone receptor-positive breast cancer at the 2025 San Antonio Breast Cancer Symposium

November 24, 2025

Updated results from the Phase 3 EMBER-3 trial for Inluriyo™ (imlunestrant) alone and in combination with Verzenio® (abemaciclib) in ER+, HER2– metastatic breast cancer to be presented as a late-breaking oral presentation

Updated safety and efficacy data to be presented from PIKALO-1, the Phase 1/2 trial of Lilly's pan-mutant-selective PI3Kα inhibitor, which will be advanced into the Phase 3 PIKALO-2 study

New subgroup analysis from the Phase 3 monarchE trial that explores outcomes by nodal status for Verzenio plus endocrine therapy in HR+, HER2– high-risk early breast cancer

INDIANAPOLIS, Nov. 24, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that new data from across its breast oncology portfolio and pipeline will be featured at the San Antonio Breast Cancer Symposium (SABCS), taking place December 9–12 in San Antonio, Texas. These updates reflect Lilly's continued progress across key pathways in hormone receptor–positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) breast cancer, the most common form of breast cancer.[1]

Presentation Highlights

Inluriyo (imlunestrant; estrogen receptor antagonist)
In a late-breaking oral presentation, Lilly will share updated results from the Phase 3 EMBER-3 trial evaluating Inluriyo (imlunestrant) alone and in combination with Verzenio (abemaciclib), in patients with ER+, HER2– advanced or metastatic breast cancer. The presentation will feature a pre-specified interim overall survival (OS) analysis, with updates on progression-free survival (PFS) and time to chemotherapy (TTC). In addition, a poster presentation will provide results of an exploratory analysis of early changes in circulating tumor DNA (ctDNA) and correlation to clinical outcomes.

Verzenio (abemaciclib; CDK4/6 inhibitor)
In a poster presentation, Lilly will share results from a subgroup analysis of the Phase 3 monarchE trial, evaluating adjuvant abemaciclib plus endocrine therapy by nodal status in patients with HR+, HER2– high-risk early breast cancer. These data expand on recent results at ESMO 2025, which showed that adjuvant abemaciclib plus endocrine therapy prolonged overall survival and sustained long-term improvements in invasive disease-free survival (IDFS) and distant relapse-free survival (DRFS).

LY4064809 / STX-478 (investigational pan-mutant-selective PI3Kα inhibitor)
In a poster presentation, Lilly will share findings from PIKALO-1, the ongoing Phase 1/2 study evaluating LY4064809 alone and in combination with endocrine therapy and CDK4/6 inhibitors in patients with PIK3CA-mutant HR+, HER2– advanced breast cancer, including updated data on safety, efficacy, biomarkers, and analyses across pre-diabetic, diabetic, and non-diabetic subgroups. LY4064809 is planned to advance into the Phase 3 PIKALO-2 study (NCT07174336), for which a dose optimization lead-in is ongoing.

"At SABCS 2025, we're proud to showcase new data across our portfolio of investigational and approved breast cancer medicines, addressing the three most important biologic targets in HR+ breast cancer: CDK4/6, the estrogen receptor, and PI3K," said Jacob Van Naarden, executive vice president and president of Lilly Oncology. "Together, these presentations reflect the continued momentum of Lilly's breast oncology portfolio and our commitment to translating biologic conviction into meaningful progress for people living with breast cancer."

A full list of abstract titles and viewing details are listed below:

Abstract Title	Author	Presentation Type/#	Session Title	Presentation Date/Time (CST)
Inluriyo (imlunestrant)				
Imlunestrant with or without abemaciclib in advanced breast cancer (ABC): Updated efficacy results from the phase 3 EMBER-3 trial	Komal Jhaveri	Oral Presentation #GS3-08	General Session 3	Friday, December 12 10:45-11:00 a.m. CST
Real-world ESR1 mutation (ESR1m) testing and positivity rates in patients with ER+/HER2- metastatic breast cancer (MBC)	Lindsay Williams	Poster #PS1-12-08	Poster Session 1	Wednesday, December 10 12:30-2:00 p.m. CST

Patient Experience with Intramuscular vs. Oral Endocrine Therapy in Metastatic Breast Cancer	Erica Fortune	Poster #PS1-03-03	Poster Session 1	Wednesday, December 10 12:30-2:00 p.m. CST
Circulating Tumour DNA (ctDNA) Dynamics From Patients With ER+, HER2- Advanced Breast Cancer in the Phase 3 EMBER-3 Trial	Francois Clement Bidard	Poster #PD5-08	Poster Spotlight 5: Liquid Biomarkers in Breast Cancer-Driving Precision Medicine	Thursday, December 11 8:03-8:06 a.m. CST
Verzenio® (abemaciclib)				
MonarchE: subgroup analysis of adjuvant abemaciclib + endocrine therapy for HR+, HER2-, high-risk early breast cancer by nodal status	Javier Cortes	Poster #PS1-08-08	Poster Session 1	Wednesday, December 10, 2025 12:30-2:00 p.m. CST
Abemaciclib plus endocrine therapy in HR+/HER2- advanced breast cancer: insights from an Italian retrospective observational study	Elisabetta Munzone	Poster #PS5-04-08	Poster Session 5	Friday, December 12 12:30-2:00 p.m. CST
Treatment Persistence and Dosing Patterns in US Patients with HR+/HER2-, Node-Positive Early Breast Cancer Treated with Adjuvant Abemaciclib	Hatem Soliman	Poster #PS5-05-09	Poster Session 5	Friday, December 12 12:30-2:00 p.m. CST
LY4064809 (STX-478)				
A phase 1/2 trial of LY4064809 (STX-478), a pan-mutant-selective PI3Kα inhibitor in HR+, HER2- advanced breast cancer (ABC), Updated results from PIKALO-1	Komal Jhaveri	Poster #PS1-08-24	Poster Session 1	Wednesday, December 10, 2025 12:30-2:00 p.m. CST

For more information on Lilly's Oncology pipeline click here.

About Inluriyo™ (imlunestrant)
Inluriyo (imlunestrant) is an oral estrogen receptor antagonist that delivers continuous ER inhibition, including in *ESR1*-mutant cancers. The estrogen receptor (ER) is the key therapeutic target for patients with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2–) breast cancer. Inluriyo is a U.S. FDA approved oral prescription medicine. Inluriyo is also currently being studied in combination with abemaciclib for advanced breast cancer and as an adjuvant treatment in early breast cancer, including: NCT04975308, NCT05514054 and NCT04188548.

INDICATION FOR INLURIYO (imlunestrant)

INLURIYO is indicated for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

IMPORTANT SAFETY INFORMATION FOR INLURIYO

Warnings and Precautions — Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, Inluriyo can cause fetal harm when administered to a pregnant woman. In an animal reproduction study, oral administration of imlunestrant to pregnant rats during the period of organogenesis led to embryo-fetal mortality and structural abnormalities at maternal exposures that were below the human exposure at the recommended dose based on area under the curve (AUC). Avoid the use of imlunestrant in pregnant women. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Inluriyo and for 1 week after the last dose.

Serious and Fatal Adverse Reactions

Serious adverse reactions occurred in 10% of patients who received Inluriyo. Serious adverse reactions in >1% of patients included pleural effusion (1.2%). **Fatal adverse reactions** occurred in 1.8% of patients who received Inluriyo, including cardiac arrest, acute myocardial infarction, right ventricular failure, hypovolemic shock, and upper gastrointestinal hemorrhage (each 0.3%).

Most Common Adverse Reactions

The **most common adverse reactions** (incidence ≥10%), including laboratory abnormalities, in patients who received Inluriyo were: hemoglobin decreased (30%), musculoskeletal pain (30%), calcium decreased (26%), neutrophils decreased (26%), AST increased (25%), fatigue (23%), diarrhea

(22%), ALT increased (21%), triglycerides increased (21%), nausea (17%), platelets decreased (16%), constipation (10%), cholesterol increased (10%), and abdominal pain (10%).

Drug Interactions

Imlunestrant is a CYP3A substrate. Avoid concomitant use of Inluriyo with **strong CYP3A inhibitors**. If concomitant use cannot be avoided, reduce the dosage of Inluriyo. Avoid concomitant use of Inluriyo with **strong CYP3A inducers**. If concomitant use cannot be avoided, increase the dosage of Inluriyo.

Imlunestrant inhibits both **P-gp** and **BCRP**. Avoid concomitant use unless otherwise recommended in the Prescribing Information for P-gp or BCRP substrates where minimal concentration changes may lead to serious adverse reactions.

Use in Specific Populations — Lactation

Because of the potential for serious adverse reactions in the breastfed child, **advise lactating women to not breastfeed during treatment with Inluriyo and for 1 week after the last dose**.

Use in Specific Populations — Hepatic Impairment

Reduce the dose of Inluriyo for patients with moderate (**Child-Pugh B**) or severe (**Child-Pugh C**) hepatic impairment. No dosage adjustment is recommended for patients with mild hepatic impairment (**Child-Pugh A**).

Inluriyo (imlunestrant) is available as 200 mg tablets.

Please click to access Prescribing Information for Inluriyo.

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About Verzenio (abemaciclib)
Verzenio (abemaciclib) is approved to treat people with certain HR+, HER2- breast cancers in the adjuvant and advanced or metastatic settings.

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 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 and Patient Information for Verzenio.

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About LY4064809
LY4064809 (STX-478) is an investigational, oral, next-generation inhibitor phosphoinositide 3-kinase alpha (PI3Kα) inhibitor designed to selectively target tumors with *PIK3CA* mutations while sparing wild-type PI3Kα. Activating mutations in the *PIK3CA* gene (which encodes PI3Kα enzyme) are oncogenic drivers present in approximately 40% of hormone receptor positive (HR+)/HER2-negative breast cancers and occur at lower frequencies in many other cancers.[3,4] LY4064809 is currently being studied in patients with HR+ breast cancer and other solid tumors with *PIK3CA* mutations, **NCT05768139** and is planned to advance into the Phase 3 PIKALO-2 study, NCT07174336.

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 (abemaciclib) as a potential treatment for people with certain types of early breast cancer, Inluriyo (imlunestrant) as a treatment for people with certain types of breast cancer, LY4064809 (STX-478) as a potential treatment for people with PIK3CA-mutated advanced solid tumors, 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 any of these therapies will prove to be a safe and effective treatment or receive regulatory approval, 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.

References & Endnotes

1. American Cancer Society. (2023). *Breast cancer facts & figures 2023–2024*. American Cancer Society, Inc.

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SOURCE Eli Lilly and Company