Lilly highlights strength of breast cancer portfolio with new data across validated drivers of hormone receptor-positive disease at the 2026 San Antonio Breast Cancer Symposium

November 23, 2026

Phase 3 EMBER-3 data with longer follow-up, including final overall survival for Inluriyo versus standard endocrine therapy, to be featured in a late-breaking oral presentation

New biomarker analysis from Phase 3 monarchE trial exploring the role of tumor subtypes in HR+, HER2– high-risk early breast cancer, to be featured in an oral presentation

Updated Phase 1/2 data on tersolisib, an investigational pan-mutant-selective PI3Kα inhibitor, to be featured in a poster presentation

INDIANAPOLIS, Nov. 23, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that new data from across its breast cancer portfolio, spanning early to advanced hormone receptor-positive (HR+) breast cancer, will be featured at the San Antonio Breast Cancer Symposium (SABCS), taking place December 8–11 in San Antonio, Texas. Lilly's presence marks the progress in a portfolio built around the biology of HR+ breast cancer, targeting three clinically validated drivers of the disease: the estrogen receptor, CDK4/6 and PI3Kα.

Key Presentation Highlights:

Inluriyo (imlunestrant; estrogen receptor antagonist/oral SERD): In a late-breaking oral presentation, Lilly will share updated results from the Phase 3 EMBER-3 trial, including final overall survival for Inluriyo monotherapy in patients with ER+, HER2–, *ESR1*-mutated advanced breast cancer, along with updated efficacy of Inluriyo in combination with Verzenio. EMBER-3 data have supported approvals in this setting, as well as the evidence-based practice of changing endocrine therapy (ET) and CDK4/6 inhibitor at progression.

Verzenio (abemaciclib; CDK4/6 inhibitor): In an oral presentation, Lilly will share results from the largest exploratory biomarker analysis of untreated tumors in people with HR+, HER2–, node-positive, high-risk early breast cancer from the Phase 3 monarchE trial. These data add to the body of evidence supporting abemaciclib as standard of care in this setting.

Tersolisib (investigational pan-mutant-selective PI3Kα inhibitor): In a poster presentation, Lilly will share updated results from PIKALO-1, evaluating investigational tersolisib in combination with ET plus a CDK4/6 inhibitor in people with HR+, HER2– *PIK3CA*-mutated advanced breast cancer, including pre-diabetic or diabetic populations. These data support the ongoing Phase 3 PIKALO-2 study of tersolisib in first-line disease, which began dosing patients earlier this year.

Real-World Evidence: An analysis of more than 40,000 people with early breast cancer looks at how long people stay on ET over ten years, how that relates to outcomes, and whether changing standard ET affects the risk of recurrence. The group studied closely resembles patients in the Phase 3 EMBER-4 trial, Lilly's largest-ever oncology trial, evaluating imlunestrant in ER+, HER2– early breast cancer.

Jacob Van Naarden, Executive Vice President and President of Lilly Oncology: "Our deep experience and sustained commitment in HR+ breast cancer have built one of the fastest-growing portfolios in the industry, targeting key drivers of the disease. At SABCS, we're showing how our HR+ breast cancer portfolio fits together. We're sharing new insight into what drives recurrence in high-risk disease, updated data for tersolisib, our PI3Kα inhibitor now in Phase 3, and EMBER-3, the Phase 3 trial behind an approved all-oral combination of Inluriyo and Verzenio. Together, they move us toward one simple ambition: better outcomes for every person living with HR+ breast cancer, through a medicine matched to the biology of their cancer."

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

Abstract Title	**Author**	**Presentation Type/#**	**Session Title**	**Session Date/Time (CST)**
Inluriyo (imlunestrant; estrogen receptor antagonist/oral SERD)				
Final overall survival of imlunestrant versus standard of care in *ESR1*-mutated advanced breast cancer: updated efficacy from the phase 3 EMBER-3 trial	Komal L. Jhaveri	Oral Presentation #GS3-1	General Session 3	Friday, December 11, 9:15-11:45 a.m.
preEMBER: A phase 2, open-label study evaluating imlunestrant in premenopausal women with estrogen receptor-positive (ER+), HER2-negative (HER2−) early breast cancer (EBC)	Oleg Gluz	Poster #P1-1-11	Poster Session 1	Wednesday, December 9, 12:30-2:00 p.m.
Verzenio (abemaciclib; CDK4/6 inhibitor)				

Characterization of clinical outcomes in monarchE by histologic, molecular, and genomic subtypes: updated baseline tumor analysis of patients with HR+, HER2–, node-positive, high-risk early breast cancer	Nick Turner	Oral Presentation #GS3-4	General Session 3	Friday, December 11, 9:15-11:45 a.m.
Long-term persistence and dose modifications with adjuvant abemaciclib in HR+, HER2–, node-positive early breast cancer	Susan F. Dent	Poster #P2-7-03	Poster Session 2	Wednesday, December 9, 5:00-6:30 p.m.
Tersolisib (investigational pan-mutant-selective PI3Kα inhibitor)				
A Phase 1/2 trial of tersolisib (LY4064809/STX-478), a pan-mutant-selective PI3Kα inhibitor in *PIK3CA*-mutant HR+, HER2– advanced breast cancer: updated triplet cohort results from PIKALO-1	Maxime Brunet	Poster #P5-10-15	Poster Session 5	Friday, December 11, 12:30-2:00 p.m.
PIKALO-2: A randomized phase 3 trial of tersolisib or placebo plus a CDK4/6 inhibitor and endocrine therapy as first-line treatment for *PIK3CA*-mutated, HR+, HER2– advanced breast cancer	Komal L. Jhaveri	Poster #P2-2-28	Poster Session 2	Wednesday, December 9, 5:00-6:30 p.m.
Real-World Evidence				
Endocrine therapy persistence declines progressively over ten years and non-persistence is associated with worse outcomes in real-world patients with ER+, HER2− early breast cancer at increased risk of recurrence	Seth Wander	Poster #P2-4-18	Poster Session 2	Wednesday, December 9, 5:00-6:30 p.m.
A real-world analysis of education during treatment and abemaciclib persistence in HR+, HER2− breast cancer	Sara Nunnery	Poster #P2-4-11	Poster Session 2	Wednesday, December 9, 5:00-6:30 p.m.
Real-world tolerability and dose modification with adjuvant abemaciclib in HR+, HER2–, node-positive early breast cancer in the US	Caleb Paydar	Poster #P2-5-25	Poster Session 2	Wednesday, December 9, 5:00-6:30 p.m.
First-line real-world outcomes in *PIK3CA*-mutant HR+, HER2– advanced breast cancer in the US	Hope S. Rugo	Poster #P2-4-15	Poster Session 2	Wednesday, December 9, 5:00-6:30 p.m.
Therapeutic area research				
Prevalence of diabetes mellitus and pre-diabetes in US patients diagnosed with breast cancer	Virginia G. Kaklamani	Poster #P5-5-16	Poster Session 5	Friday, December 11, 12:30-2:00 p.m.

About Inluriyo (imlunestrant)
Inluriyo (imlunestrant) (pronounced en-loo-ree-yoh) 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 ER+, HER2– breast cancer. Inluriyo is a U.S. FDA approved oral prescription medicine, 200 mg tablets taken as a once-daily dose of 400 mg taken on an empty stomach, at least 2 hours before food or 1 hour after food. Inluriyo is also currently being studied as an adjuvant treatment in early breast cancer in the Phase 3 EMBER-4 trial (NCT05514054).

For full details on indicated uses of Inluriyo in ER+, HER2– *ESR1*m metastatic breast cancer, please see full Prescribing Information, available at www.inluriyo.lilly.com.

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 authorized for use in more than 90 countries 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.lilly.com.

INDICATIONS FOR INLURIYO

Inluriyo (imlunestrant) is an estrogen receptor antagonist indicated[1,2]:

- as monotherapy for the treatment of adults with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast

cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.
- in combination with abemaciclib for the treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.

IMPORTANT SAFETY INFORMATION FOR INLURIYO (imlunestrant) AS MONOTHERAPY AND IN COMBINATION WITH VERZENIO (abemaciclib)

Diarrhea: Severe diarrhea associated with dehydration and infection occurred in patients treated with Verzenio. Instruct patients at the first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their healthcare provider. In EMBER-3, diarrhea occurred in 86% of patients who received Inluriyo in combination with Verzenio; Grade 3 or 4 diarrhea occurred in 9%. Follow specific dose modification and management instructions located in the Prescribing Information for each drug.

Neutropenia: Neutropenia, including febrile neutropenia and fatal neutropenic sepsis, occurred in patients treated with Verzenio. In EMBER-3, neutrophil count decreased in 86% of patients who received Inluriyo in combination with Verzenio; Grade 3 or 4 decreases occurred in 21%. 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. Follow specific dose modification and management instructions located in the Prescribing Information for each drug.

Interstitial Lung Disease (ILD)/Pneumonitis: Severe, life-threatening, or fatal interstitial lung disease (ILD) or pneumonitis can occur in patients treated with Verzenio and other CDK4/6 inhibitors. In EMBER-3, ILD or pneumonitis occurred in 2.9% of patients who received Inluriyo in combination with Verzenio. Monitor for clinical symptoms or radiological changes indicative of ILD/pneumonitis. Permanently discontinue Verzenio in all patients with Grade 3 or 4 ILD or pneumonitis. Follow specific dose modification and management instructions located in the Prescribing Information for each drug.

Hepatotoxicity: Increases in serum transaminase levels have been observed. Perform liver function tests (LFTs) before initiating treatment with Verzenio. Monitor LFTs every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated with Verzenio. Monitor ALT and AST during treatment with Inluriyo as clinically indicated. In EMBER-3, ALT increase occurred in 33% for all grades (Grade 3 or 4: 5%) and AST increase occurred in 36% for all grades (Grade 3 or 4: 2.5%) of patients who received Inluriyo in combination with Verzenio. Follow specific dose modification and management instructions located in the Prescribing Information for each drug.

Venous Thromboembolism: Deaths due to venous thromboembolism have been reported in patients treated with Verzenio. In EMBER-3, venous thromboembolic events occurred in 4.8% of patients who received Inluriyo in combination with Verzenio. Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate. Follow specific dose modification and management instructions located in the Prescribing Information for each drug.

Embryo-Fetal Toxicity: Inluriyo and Verzenio can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to initiating treatment. Advise females of reproductive potential to use effective contraception during treatment with Inluriyo in combination with Verzenio and for 3 weeks after the last dose of Verzenio or 1 week after the last dose of Inluriyo, whichever is longer. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Inluriyo.

For Inluriyo monotherapy, 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.

Increased Serum Creatinine Without Affecting Renal Function: Verzenio can increase serum creatinine. These increases were not associated with changes in glomerular function. In EMBER-3, creatinine increase occurred in 36% for all grades (Grade 3 or 4: 1.1%) of patients who received Inluriyo in combination with Verzenio. During Verzenio treatment, use alternative measures that are not based on serum creatinine to assess renal function such as BUN, cystatin C, or calculated GFR.

Serious and Fatal Adverse Reactions for Inluriyo in combination with Verzenio: Serious adverse reactions occurred in 21% of patients who received Inluriyo in combination with Verzenio. Serious adverse reactions in >1% of patients who received Inluriyo in combination with Verzenio included pneumonia (2.4%), abdominal pain, and renal failure (each 1.4%). **Fatal adverse reactions** occurred in 3.8% of patients who received Inluriyo in combination with Verzenio, including pneumonia (1.4%), myocardial infarction, interstitial lung disease, and sepsis (0.5% each).

Most Common Adverse Reactions for Inluriyo in combination with Verzenio: The most common (≥10%) adverse reactions with Inluriyo in combination with Verzenio, including laboratory abnormalities, were decreased neutrophils, diarrhea, decreased hemoglobin, decreased lymphocytes, nausea, decreased platelets, fatigue, increased triglycerides, infections, increased AST, increased creatinine, increased ALT, vomiting, musculoskeletal pain, abdominal pain, decreased appetite, increased cholesterol, rash, cough, headache, and decreased weight.

Serious and Fatal Adverse Reactions for Inluriyo Monotherapy: 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 for Inluriyo Monotherapy: The most common (≥10%) adverse reactions with Inluriyo monotherapy, including laboratory abnormalities were decreased hemoglobin, musculoskeletal pain, decreased calcium, decreased neutrophils, increased AST, fatigue, diarrhea, increased ALT, increased triglycerides, nausea, decreased platelets, constipation, increased cholesterol, and abdominal pain.

Drug Interactions – Inluriyo:

- Avoid concomitant use with **strong CYP3A inhibitors**. If concomitant use cannot be avoided, decrease the Inluriyo dosage. Avoid concomitant use with **strong CYP3A inducers**. If concomitant use cannot be avoided, increase the Inluriyo dosage. See Prescribing Information for recommended dosage modifications.

- 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.

Drug Interactions – Verzenio:

- **CYP3A Inhibitors:** Avoid concomitant use of ketoconazole. Reduce the Verzenio dose with concomitant use of other strong and moderate CYP3A inhibitors. Monitor for adverse reactions and follow the specific dose modification instructions located in the Prescribing Information. Patients should avoid grapefruit products.
- **CYP3A Inducers:** Avoid concomitant use of strong and moderate CYP3A inducers and consider alternative agents.

Lactation: Because of the potential for serious adverse reactions in the breastfed child, advise lactating women to not breastfeed during treatment with Inluriyo in combination with Verzenio and for 3 weeks after the last dose of Verzenio or 1 week after the last dose of Inluriyo, whichever is longer.

For Inluriyo monotherapy, advise lactating women to not breastfeed during treatment with Inluriyo and for 1 week after the last dose.

Hepatic Impairment: With **Inluriyo**, reduce the dose in patients with moderate or severe **hepatic impairment**. The recommended dosage for patients with moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment is 200 mg once daily. No dosage modification is recommended for patients with mild hepatic impairment (Child-Pugh A).

With **Verzenio**, reduce the dosing frequency to once daily in patients with severe **hepatic impairment** (Child-Pugh C). No dosage adjustments are necessary in patients with mild or moderate hepatic impairment (Child-Pugh A or B).

Inluriyo may impair fertility in females and males of reproductive potential.

Verzenio may impair fertility in males of reproductive potential.

Inluriyo (imlunestrant) is available as 200 mg tablets.

Verzenio (abemaciclib) is available as 50 mg, 100 mg, 150 mg, and 200 mg tablets.

Please click to access full Prescribing Information for Inluriyo and Verzenio.

IN VZ HCP ISI Combo+Mono APPR

INDICATIONS FOR VERZENIO

Verzenio (abemaciclib) is a kinase inhibitor indicated[1,2]:

- in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adults 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 adults with HR-positive, HER2-negative advanced or metastatic breast cancer.
- in combination with fulvestrant for the treatment of adults with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- in combination with Inluriyo for the treatment of adults with estrogen receptor (ER)-positive, HER2-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.
- as monotherapy for the treatment of adults 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 five clinical trials in 3899 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, withhold Verzenio until resolution 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 five clinical trials in 3899 patients, neutropenia occurred in 37% to 51% 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 days to 34 days, and the median duration of Grade ≥3 neutropenia ranged from 10 days 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 early breast cancer (monarchE, N=2791), 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 advanced or metastatic breast cancer (N=1108) (MONARCH 1, MONARCH 2, MONARCH 3, EMBER-3), 3.2% of Verzenio-treated patients had ILD or pneumonitis of any grade: 0.5% had Grade 3 or 4, and 0.5% 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.

Withhold or reduce dose for 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 four clinical trials in 3767 patients (monarchE, MONARCH 2, MONARCH 3, EMBER-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 Grade 4 hepatic transaminase elevation.

Venous thromboembolic events (VTE) were reported in 2% to 5% of patients treated with Verzenio across four clinical trials in 3767 patients (monarchE, MONARCH 2, MONARCH 3, EMBER-3). VTE events included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, inferior vena cava thrombosis, jugular vein thrombosis, peripheral vein thrombosis and superficial vein thrombosis. In clinical trials, deaths due to VTE occurred 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 early breast cancer patients with any grade VTE event and for advanced or metastatic breast cancer patients with a Grade 3 or 4 VTE event.

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.

Verzenio can **increase serum creatinine** without affecting renal function. These increases were not associated with changes in glomerular function. In EMBER-3, creatinine increase occurred in 36% for all grades (Grade 3 or 4: 1.1%) of patients who received Inluriyo in combination with Verzenio. During Verzenio treatment, use alternative measures that are not based on serum creatinine to assess renal function such as BUN, cystatin C, or calculated GFR.

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%; 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%).

Serious and Fatal Adverse Reactions for Inluriyo in combination with Verzenio: Serious adverse reactions occurred in 21% of patients who received Inluriyo in combination with Verzenio. Serious adverse reactions in >1% of patients who received Inluriyo in combination with Verzenio included pneumonia (2.4%), abdominal pain, and renal failure (each 1.4%). **Fatal adverse reactions** occurred in 3.8% of patients who received Inluriyo in combination with Verzenio, including pneumonia (1.4%), myocardial infarction, interstitial lung disease, and sepsis (0.5% each).

Most Common Adverse Reactions for Inluriyo in combination with Verzenio: The most common (≥10%) adverse reactions with Inluriyo in combination with Verzenio, including laboratory abnormalities, were decreased neutrophils, diarrhea, decreased hemoglobin, decreased lymphocytes, nausea, decreased platelets, fatigue, increased triglycerides, infections, increased AST, increased creatinine, increased ALT, vomiting, musculoskeletal pain, abdominal pain, decreased appetite, increased cholesterol, rash, cough, headache, and decreased weight.

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 3-5 half-lives of the inhibitor) to the dose that was used before starting the inhibitor. Patients should avoid grapefruit products. With concomitant use of moderate CYP3A inhibitors, monitor for adverse reactions and consider reducing the Verzenio dose in 50 mg decrements.

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. No dosage adjustments are necessary in patients with mild or moderate hepatic impairment (Child-Pugh A or B).

Please see full Prescribing Information and Patient Information for Verzenio.

VZ IN HCP ISI ALL APPR

About Tersolisib

Tersolisib (LY4064809/STX-478) is an investigational, oral, next-generation 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– breast cancers and occur at lower frequencies in many other cancers.[3,4] Tersolisib is currently being studied in patients with HR+ breast cancer and other solid tumors with *PIK3CA* mutations in the Phase 1/2 PIKALO-1 study (NCT05768139) and in the Phase 3 PIKALO-2 trial (NCT07174336) in patients with HR+/HER2– advanced breast cancer with a *PIK3CA* mutation.

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 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

Trademarks and Trade Names

All trademarks or trade names referred to in this press release are the property of the company, or, to the extent trademarks or trade names belonging to other companies are references in this press release, the property of their respective owners. Solely for convenience, the trademarks and trade names in this press release are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that the company or, to the extent applicable, their respective owners will not assert, to the fullest extent under applicable law, the company's or their rights thereto. We do not intend the use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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 Inluriyo (imlunestrant) alone and in combination with Verzenio (abemaciclib) as a treatment for certain ER+, HER2– *ESR1*-mutated advanced breast cancers, Inluriyo as a potential adjuvant treatment for people with ER+, HER2– early breast cancer, tersolisib as a potential treatment for people with *PIK3CA*-mutant HR+, HER2– advanced breast cancer, and Verzenio as a treatment for certain HR+, HER2– breast cancers in the adjuvant and advanced or metastatic setting, and the timeline for future readouts, presentations, and other milestones relating to these medicines 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 any of these therapies will prove to be a safe and effective treatment for the indications described, that tersolisib or Inluriyo as an adjuvant treatment for early breast cancer will 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.

Endnotes and References

1. Verzenio. Prescribing information. Lilly USA, LLC.
2. Inluriyo. Prescribing information. Lilly USA, LLC.
3. Dirican E, et al. Tumor Biol. 2016;37(6):7033-7045.
4. Martínez-Sáez O, et al. Breast Cancer Res. 2020;22(1):45.

Refer to: Michelle Webb; michelle.webb@lilly.com (Media)
Michael Czapar; czapar_michael_c@lilly.com (Investors)

View original content to download multimedia:https://www.prnewswire.com/news-releases/lilly-highlights-strength-of-breast-cancer-portfolio-with-new-data-across-validated-drivers-of-hormone-receptor-positive-disease-at-the-2026-san-antonio-breast-cancer-symposium-302948353.html

SOURCE Eli Lilly and Company