Lilly to present new clinical data for Verzenio (abemaciclib) and multiple novel pipeline programs at the 2025 European Society for Medical Oncology (ESMO) Annual Meeting

October 13, 2025

Primary overall survival analysis from the Phase 3 monarchE study of Verzenio (abemaciclib) in HR+HER2-, node-positive, high-risk early breast cancer to be presented as a late-breaking oral presentation

Additional presentations showcase Lilly's robust oncology pipeline with data from studies of investigational therapies targeting FRα positive ovarian cancer, KRAS G12C-mutant lung cancer, FGFR3-altered bladder cancer, and PIK3CA-mutant advanced breast cancer

INDIANAPOLIS, Oct. 13, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that new data from across its oncology portfolio and pipeline will be presented at the European Society for Medical Oncology (ESMO) Annual Meeting, taking place October 17-21 in Berlin, Germany. These presentations highlight the breadth of Lilly's portfolio across treatment modalities and tumor types.

Presentation Highlights

Verzenio (abemaciclib; CDK4/6 inhibitor):
In a late-breaking oral presentation, Lilly will share results from the landmark seven-year analysis of monarchE, including primary overall survival analysis and updated invasive disease-free survival and distant relapse-free survival, in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), node-positive, high-risk early breast cancer. Additionally, in a mini-oral presentation, Lilly will share an in-depth analysis from monarchE examining the prognostic and predictive value of the Ki-67 index, pre- and post-neoadjuvant chemotherapy.

Olomorasib (investigational KRAS G12C inhibitor):
In a mini oral presentation, Lilly will share results from the Phase 1/2 study on the intracranial efficacy of olomorasib, a next-generation *KRAS* G12C inhibitor, in patients with *KRAS* G12C-mutant non-small cell lung cancer (NSCLC) who have active, untreated brain metastases.

LY4064809 (investigational pan-mutant-selective PI3Ka inhibitor):
In a late-breaking oral presentation, Lilly will share updated results from the Phase 1/2 PIKALO-1 trial, a study of LY4064809 (STX-478), a pan-mutant-selective PI3Ka inhibitor, in *PIK3CA*-mutant advanced breast cancer and other solid tumors.

Vepugratinib (investigational FGFR3 inhibitor):
In a mini oral presentation, Lilly will share updated results from the FORAGER-1 study, a first-in-human Phase 1 study of vepugratinib (LY3866288), a potent, highly isoform-selective FGFR3 inhibitor, in FGFR3-altered urothelial cancer.

LY4170156 (investigational ADC targeting FRα):
In a poster presentation, Lilly will share updated safety and efficacy results from the Phase 1a/1b study of LY4170156 in patients with platinum-resistant ovarian cancer.

"At ESMO 2025, we're proud to showcase new clinical data from several studies that underscore Lilly's commitment to advancing cancer care, including the primary overall survival analysis for Verzenio in the Phase 3 monarchE trial, as well as updated safety and efficacy data from our FRα ADC, PI3Kα and FGFR3 programs, all of which are poised to advance to late stage studies over the next several months," said Jacob Van Naarden, executive vice president and president of Lilly Oncology. "These data reflect the meaningful progress we have made in strengthening our oncology portfolio and our dedication to improving outcomes for people living with cancer."

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

Abstract Title	Author	Presentation Type/#	Session Title	Session Date/Time (CEST)
Verzenio (abemaciclib; CDK4/6 inhibitor)				
monarchE: Primary overall survival results of adjuvant abemaciclib plus endocrine therapy for high-risk, HR+, HER2-, early breast cancer	Stephen Johnston	Oral Abstract #LBA13	Proffered Paper session: Breast cancer, early stage	Friday, October 17 2:00-3:30 p.m. CEST
monarchE: Evaluation of prognostic and predictive value of Ki-67 index pre and post neoadjuvant chemotherapy (NAC) and changes following NAC	Miguel Martin	Mini Oral Abstract #295MO	Mini oral session: Breast cancer, early stage	Sunday, October 19 10:15-11:45 a.m. CEST
Olomorasib (investigational KRAS G12C inhibitor)				

Intracranial efficacy of olomorasib, a second-generation KRAS G12C inhibitor, in patients with *KRAS* G12C-mutant NSCLC who have active, untreated brain metastases	Philippe Cassier	Mini Oral Abstract #1846MO	Mini oral session 1: NSCLC metastatic	Sunday, October 19 8:30-10:00 a.m. CEST
LY4064809 (investigational pan-mutant-selective PI3Ka inhibitor)				
A phase 1/2 trial of LY4064809 (STX-478), a pan-mutant-selective PI3Ka inhibitor in *PIK3CA*-mutant advanced breast cancer (ABC) and other solid tumors: Updated results from the PIKALO-1 study	Dejan Juric	Mini Oral Abstract #LBA26	Mini oral session: Breast cancer, metastatic	Monday, October 20 10:15-11:45 a.m. CEST
Vepugratinib (investigational FGFR3 inhibitor)				
Phase 1 study of LY3866288, a potent, highly isoform-selective FGFR3 inhibitor in FGFR3-altered advanced solid tumors (FORAGER-1): Dose optimization	Alexandra Drakaki	Mini Oral Abstract #3070MO	Mini oral session 1: GU tumors, renal & urothelial	Friday, October 17 4:00-5:30 p.m. CEST
LY4170156 (investigational ADC targeting FRα)				
Results from the first-in-human phase 1 study of LY4170156, an antibody drug conjugate (ADC) targeting folate receptor alpha in recurrent platinum resistant high-grade serous ovarian cancer (HGSOC)	Isabelle Ray-Coquard	Poster Abstract #1067P	Gynaecological cancers	Saturday, October 18 12:00-12:45 p.m. CEST
Translational PK/PD modelling of LY4170156, an antibody-drug conjugate linked to exatecan via a novel cleavable polysarcosine linker	Bhavana Pothuri	Poster Abstract #236eP	Biomarkers & translational research (agnostic)	Monday, October 20 12:00-12:45 p.m. CEST
Inluriyo (imlunestrant; ER antagonist)				
Inluriyo plus abemaciclib versus fulvestrant plus abemaciclib in estrogen receptor positive (ER+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer (ABC): An indirect treatment comparison (ITC) of three phase 3 trials	François Clément Bidard	Poster Abstract #496P	Breast cancer metastatic	Monday, October 20 12:00-12:45 p.m. CEST

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

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 Olomorasib

Olomorasib (LY3537982) is an investigational, oral, potent, and highly selective next-generation inhibitor of the KRAS G12C protein. *KRAS* is the most common oncogene across all tumor types, and *KRAS* G12C mutations occur in 13% of patients with non-small cell lung cancer (NSCLC), and 1-3% of patients with other solid tumors.[1] Olomorasib was specifically designed to target *KRAS* G12C mutations and has pharmacokinetic properties which potentially allow for high predicted target occupancy and high potency when used as monotherapy or in combination.[2]

Olomorasib is currently being studied in combination with pembrolizumab with or without chemotherapy for first-line treatment of *KRAS* G12C-mutant advanced NSCLC, and other advanced solid tumors, including: NCT06119581 and NCT06890598.

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.[5]

About Vepugratinib (LY3866288/LOXO-435)
Vepugratinib is an investigational, oral, isoform-selective fibroblast growth factor receptor 3 (FGFR3) inhibitor that has shown antitumor activity across FGFR3-mutant in vivo preclinical models, with preserved potency against FGFR3 gatekeeper resistance mutants.[6] Inhibition of oncogenic FGFR3 shows clinical benefit in advanced urothelial cancer; however, currently approved FGFR-targeted therapies that are not selective for FGFR3 demonstrate dose-limiting off target toxicities, and susceptibility to resistance mutations.

Vepugratinib is designed to selectively target FGFR3 alterations with the goal of avoiding dose-limiting hyperphosphatemia and other clinical adverse events that drive chronic intolerance to pan-FGFR inhibitors.[6] Vepugratinib is currently being studied in an open-label, multicenter, Phase 1a/b study in patients with FGFR3-altered advanced urothelial carcinoma and other solid tumors, NCT05614739.

About LY4170156
LY4170156 is an investigational, next-generation ADC targeting folate receptor alpha (FRα). Folate receptor alpha (FRα) is a cell-surface glycoprotein encoded by the gene FOLR1 that binds to the essential nutrients folic acid and reduced folates, bringing them into cells to facilitate cell division and growth.[7] FRα is overexpressed in many solid tumors such as ovarian, non-small cell lung, and colorectal cancers.[7]

LY4170156 was designed to target FRα across expression levels with improved therapeutic index. LY4170156 is composed of a Fcγ silent, humanized monoclonal antibody, a proprietary polysarcosine hydrophobicity masking agent (PSARlink®) with a cleavable linker, and a topoisomerase 1 inhibitor exatecan payload. LY4170156 is currently being studied in patients with ovarian cancer as well as other FRα-expressing solid tumors, NCT06400472.

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 estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (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 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 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, olomorasib as a potential treatment for certain *KRAS* G12C-mutant advanced solid tumors, preclinical data for an antibody-drug conjugate targeting folate receptor alpha 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.

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2. Peng S-B, Si C, Zhang Y, et al. Abstract 1259: Preclinical characterization of Ly3537982, a novel, highly selective and potent KRAS-G12C inhibitor. Cancer Research. 2021;81(13_Supplement):1259-1259. doi:10.1158/1538-7445.am2021-1259
3. Dirican E, et al. Tumor Biol. 2016;37(6):7033-7045.
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