U.S. FDA approves Inluriyo (imlunestrant) in combination with Verzenio (abemaciclib) for adults with ER+, HER2-, ESR1-mutated advanced or metastatic breast cancer

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Inluriyo plus Verzenio delivers proven clinical benefit after the evidence-based practice of maximizing initial treatment with an aromatase inhibitor, with or without a CDK4/6 inhibitor

In the Phase 3 EMBER-3 trial, Inluriyo in combination with Verzenio doubled median progression-free survival compared to Inluriyo alone, among patients with ESR1*-mutated MBC*

The all-oral combination of Inluriyo and Verzenio gives patients a treatment approach that targets the two central drivers of ER+ breast cancer, with an established tolerability profile and no new monitoring required

INDIANAPOLIS, Sept. 18, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has granted full approval to Inluriyo (imlunestrant), an oral estrogen receptor (ER) antagonist, in combination with Verzenio (abemaciclib), a CDK4/6 inhibitor, for the treatment of adults with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2–), *ESR1*-mutated locally advanced or metastatic breast cancer (MBC), as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy. The approval is based on the proven clinical benefit of switching to Inluriyo in combination with Verzenio at clinical progression as observed in the Phase 3 EMBER-3 trial.

"In less than a year since its approval, Inluriyo is the leading treatment option for people with ER+, HER2–, *ESR1*m metastatic breast cancer, now reaching over half of all patients starting an oral SERD," said Jacob Van Naarden, executive vice president and president of Lilly Oncology. "Today's full approval extends what Inluriyo in combination with Verzenio can do for patients, with a regimen that has confirmed benefit, is aligned to the clinically proven treatment paradigm of changing therapy at clinical progression, and doesn't introduce burdensome monitoring requirements for patients or physicians. In fact, all available evidence suggests that switching endocrine therapy and CDK4/6 inhibitor at clinical progression improves patient outcomes more than switching therapy earlier. Utilizing this evidence-based practice spares early exposure to additional side effects, reduces patient anxiety from unnecessary testing, and mitigates avoidable costs to the healthcare system."

This full FDA approval is based on the results of the Phase 3 EMBER-3 trial in patients with MBC whose tumors harbor an *ESR1* mutation (n=159). Patients received Inluriyo (n=92) or Inluriyo in combination with Verzenio (n=67) after an aromatase inhibitor (AI), with or without a CDK4/6 inhibitor, in either the adjuvant or metastatic setting. Among patients with *ESR1*-mutated MBC, Inluriyo in combination with Verzenio doubled median progression-free survival (PFS) versus Inluriyo alone, with a median PFS of 11.1 months versus 5.5 months (HR=0.53 [95% CI, 0.35–0.80]).

"We have an urgent need for effective and safe treatment options for patients with disease progression on adjuvant or first-line therapy. Combining therapies that work on two distinct drivers of tumor growth—the estrogen receptor and CDK4/6—is an important strategy to help address treatment resistance," said Komal Jhaveri, MD, FACP, FASCO, Associate Attending Breast Medicine and Early Drug Development Services, section head of the Endocrine Therapy Research Program at Memorial Sloan Kettering Cancer Center, and principal investigator for the EMBER-3 and EMBER-4 trials. "In EMBER-3, switching both the endocrine therapy and CDK 4/6 inhibitor, for the majority of patients, to imlunestrant plus abemaciclib at disease progression achieved a median progression-free survival of 11.1 months and a safety profile consistent with that of each medicine individually, establishing a meaningful new treatment option."

In about half of patients with ER+, HER2– MBC, tumors develop a genetic change called an *ESR1* mutation during or after treatment with a common class of hormone-blocking medicines known as AIs. These mutations can cause estrogen receptors to become overactive, fueling cancer growth. Inluriyo and Verzenio target two different drivers of tumor growth, offering a combined approach to help slow the disease. Inluriyo degrades mutated estrogen receptors, cutting off the signal that drives cancer cells to grow. Verzenio targets proteins that control how quickly cancer cells divide, helping to slow their growth.

The Inluriyo label contains a warning and precaution for embryo-fetal toxicity. See Important Safety Information below and full Prescribing Information for additional information.

The Verzenio label contains warnings and precautions for severe diarrhea, neutropenia, interstitial lung disease/pneumonitis, hepatotoxicity, venous thromboembolism, embryo-fetal toxicity, and increased serum creatinine without affecting renal function. See Important Safety Information below and full Prescribing Information for additional information.

In EMBER-3, the majority of adverse events (AEs) with Inluriyo in combination with Verzenio were Grade 1-2. The most common (≥10%) adverse reactions, 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. Permanent discontinuation of Inluriyo alone due to adverse reactions in the combination arm occurred in 1% of patients, and permanent discontinuation of Verzenio alone in the combination arm occurred in 3.4% of patients.

This marks the second FDA approval for Inluriyo in less than a year, following its September 2025 approval as monotherapy for the treatment of adults with ER+, HER2–, *ESR1*-mutated MBC whose disease progressed after at least one line of endocrine therapy (ET).

Inluriyo is also being studied in the Phase 3 EMBER-4 trial (NCT05514054) in the adjuvant setting for people with ER+, HER2– early-stage breast cancer (EBC) at increased risk of recurrence following standard of care endocrine therapy, including CDK4/6 inhibitors. EMBER-4 is the largest

adjuvant oral SERD clinical trial, with more than 8,000 patients enrolled worldwide across 650+ sites in 30+ countries. Initial results are anticipated in 2027.

Inluriyo in combination with Verzenio is now available in the United States.

See Important Safety Information below and full Prescribing Information for additional information.

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.

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.

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Frequently Asked Questions

1. What is Inluriyo (imlunestrant)?

Inluriyo (imlunestrant) is an FDA-approved oral estrogen receptor antagonist also described as an oral selective estrogen receptor degrader, or oral SERD. It is designed to bind to the estrogen receptor (ER) and inhibit ER-driven signaling. In September 2025, Inluriyo (imlunestrant) was FDA-approved for treatment of adults with ER+, HER2–, *ESR1*-mutated advanced or metastatic breast cancer (MBC) with disease progression following at least one line of endocrine therapy. In September 2026, Inluriyo in combination with Verzenio was approved for the treatment of adults with ER+, HER2–, *ESR1*-mutated advanced or MBC, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.

2. What is Verzenio (abemaciclib)?

Verzenio (abemaciclib) is approved to treat people with certain HR+, HER2– breast cancers in the adjuvant and advanced or metastatic setting. Verzenio is the first CDK4/6 inhibitor approved to treat node-positive, high risk early breast cancer (EBC) patients. In high risk EBC, Verzenio has shown a persistent and deepening benefit beyond the two-year treatment period in the monarchE trial, an adjuvant study designed specifically to investigate a CDK4/6 inhibitor in a node-positive, high risk EBC population. In metastatic breast cancer, Verzenio has demonstrated statistically significant overall survival in the Phase 3 MONARCH 2 study. Verzenio has shown a consistent and generally manageable safety profile across clinical trials.

3. What are the clinical benefits of the Inluriyo (imlunestrant) and Verzenio (abemaciclib) combination?

In an analysis of the primary outcome data, Inluriyo (imlunestrant) in combination with Verzenio (abemaciclib) doubled progression-free survival [11.1 months versus 5.5 months with Inluriyo (imlunestrant) alone (HR=0.53 [95% CI, 0.35–0.80]) in patients with ER+, HER2–, *ESR1*-mutated advanced or

metastatic breast cancer.

4. What type of FDA approval did Inluriyo in combination with Verzenio receive?

Inluriyo in combination with Verzenio received full approval from the FDA for the treatment of adults with ER+, HER2–, *ESR1*-mutated advanced or MBC based on the results of the Phase 3 EMBER-3 trial. Full approval is not contingent on confirmatory trial results, distinguishing it from accelerated approval, which the FDA grants based on a surrogate endpoint likely to predict clinical benefit and requires confirmatory trials to verify that benefit.

5. Do Inluriyo (imlunestrant) or Verzenio (abemaciclib) have any black box warnings?

Neither Inluriyo or Verzenio have boxed warnings.

6. What is metastatic or locally advanced breast cancer?

Metastatic or advanced breast cancer (MBC) is defined as breast cancer that has spread from the breast to other parts of the body. Locally advanced breast cancer has grown beyond the breast to nearby tissue or lymph nodes, but has not spread to other parts of the body.[1] Of all high risk early-stage breast cancer cases diagnosed in the U.S., approximately 30% will become metastatic[2] and an estimated 6-10% are metastatic at diagnosis.[3] Survival is lower among patients with a more advanced disease at diagnosis.[4] The estimated five-year survival rates for people living with breast cancer are 99% for localized disease, 86% for regional/locally advanced disease, and 30% for metastatic or advanced disease.[4] Other factors, such as tumor size, also impact five-year survival estimates.[4]

7. Why are estrogen receptors important in treating breast cancer?

Approximately 70% of breast cancers express the estrogen receptor (ER), which is a key driver of cancer growth and a common therapeutic target. Treatments that block, degrade, or interfere with ER signaling are designed to stop the growth signal the cancer cells need to grow and divide.

8. How does Inluriyo (imlunestrant) target the estrogen receptor?

Inluriyo (imlunestrant) is an estrogen receptor (ER) antagonist that works by binding to ER, switching off signals that tell cancer cells to grow, and triggering ER to be broken down, thus slowing cancer growth. Within the oncology community, this approach is often referred to as a selective estrogen receptor degrader (SERD).

9. Why are oral SERDs important for patients with treatment-resistant ER+ breast cancer?

Up to 50% of people with ER+, HER2– metastatic breast cancer previously treated with endocrine therapy may develop an *ESR1* mutation that is difficult to treat with other endocrine therapies. Inluriyo (imlunestrant) is an estrogen receptor antagonist that works by binding to ER, switching off signals that tell cancer cells to grow, and triggering ER to be broken down, thus slowing cancer growth.

10. In which Phase 3 clinical trials is Inluriyo (imlunestrant) being studied?

Inluriyo is currently being studied in two clinical trials:

- EMBER-3 (NCT04975308) is a Phase 3, randomized, open-label study of Inluriyo (imlunestrant), investigator's choice of endocrine therapy, and Inluriyo in combination with abemaciclib in patients with ER+, HER2– locally advanced or metastatic breast cancer (MBC), as detected by an FDA-authorized test, whose disease has recurred or progressed during or following an aromatase inhibitor (AI) therapy with or without a CDK 4/6 inhibitor. More information on the EMBER-3 study can be found on clinicaltrials.gov.
- EMBER-4 (NCT05514054) is a Phase 3, randomized, open-label study of adjuvant Inluriyo (imlunestrant) versus standard adjuvant endocrine therapy in patients with ER+, HER2– early breast cancer with an increased risk of recurrence following initial endocrine therapy, with or without a CDK4/6 inhibitor. More information on the EMBER-4 study can be found on clinicaltrials.gov.

11. What makes EMBER-4 different from other adjuvant breast cancer trials?

The Phase 3 EMBER-4 trial is the largest oral SERD study, enrolling more than 8,000 patients across 650+ sites in 30+ countries. The trial is studying Inluriyo (imlunestrant) in patients with ER+, HER2– early breast cancer at increased risk of recurrence, in the adjuvant (post-surgery) setting.

EMBER-4 was designed as a sequential trial: patients were enrolled following initial standard adjuvant endocrine therapy, including patients with or without prior CDK4/6 inhibitor treatment. This design mirrors how patients are actually treated today. It asks the question: can Inluriyo (imlunestrant) provide additional protection for patients who have already received initial standard of care hormone therapy with or without a CDK4/6 inhibitor, when risk of recurrence increases.

About Breast Cancer
Breast cancer is the second most commonly diagnosed cancer worldwide (following lung cancer), according to GLOBOCAN. The estimated 2.3 million new cases indicate that close to 1 in every 4 cancers diagnosed in 2022 is breast cancer. With approximately 666,000 deaths in 2022, breast cancer is the fourth-leading cause of cancer death worldwide.[5] In the U.S., it is estimated that there will be more than 310,000 new cases of breast cancer diagnosed in 2024. Breast cancer is the second leading cause of cancer death in women in the U.S.[6]

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

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MSK Disclosure: Dr. Jhaveri has financial interests related to Eli Lilly and Company.

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Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Inluriyo in combination with Verzenio as a treatment for people with certain types of breast cancer and other conditions 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 Inluriyo plus Verzenio will receive additional regulatory approvals, or that Inluriyo plus Verzenio will be commercially successful. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

Endnotes & References

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