

Inluriyo™ and Verzenio® Presentations at ASCO 2026

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The management of hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) breast cancer continues to evolve, with endocrine therapy forming the cornerstone of treatment.¹ Clinicians face ongoing challenges in optimising treatment sequences and identifying patients who will benefit most from novel agents, particularly in the context of acquired resistance. Upcoming presentations at the American Society of Clinical Oncology (ASCO) 2026 annual meeting will provide further data on imlunestrant (Inluriyo®) and abemaciclib (Verzenio®), offering insights into their potential roles in the therapeutic landscape.

KEY TAKEAWAYS

- ° The Pivot: New data on imlunestrant and abemaciclib will be presented, potentially refining their clinical application in HR+/HER2- breast cancer.
- ° The Data: Specific hazard ratios, progression-free survival, or overall survival data will be critical for evaluating clinical utility.
- ° The Action: Clinicians should review the presented data to understand the precise patient populations and treatment settings where these agents demonstrate benefit.

Endocrine therapy remains the primary systemic treatment for HR+/HER2- breast cancer, encompassing selective estrogen receptor modulators (SERMs), aromatase inhibitors (AIs), and selective estrogen receptor degraders (SERDs). Despite initial efficacy, resistance to endocrine therapy frequently develops, necessitating the development of new agents and combination strategies.¹ Cyclin-dependent kinase 4/6 (CDK4/6) inhibitors, such as abemaciclib, have significantly improved outcomes in advanced HR+/HER2- breast cancer when combined with endocrine therapy.^{2,8} Oral SERDs, including imlunestrant, represent a newer class of agents designed to overcome limitations of intramuscular fulvestrant and improve patient convenience.³

The global incidence of breast cancer continues to rise, with HR+/HER2- subtype accounting for approximately 70% of all cases. This prevalence underscores the critical need for effective and well-tolerated treatment options, particularly as patients navigate advanced stages of the disease. The development of targeted therapies like CDK4/6 inhibitors and oral SERDs aims to address the complex mechanisms of endocrine resistance and improve patient quality of life and survival outcomes. These advancements are crucial for a patient population that often requires long-term systemic treatment.

What the ASCO 2026 Presentations Will Cover

The ASCO 2026 annual meeting will feature separate presentations on imlunestrant and abemaciclib. The presentation on imlunestrant (Inluriyo™) is expected to detail efficacy and safety data from ongoing clinical trials. Imlunestrant is an investigational oral SERD. Early phase studies have explored its activity in HR+/HER2- advanced breast cancer, including in patients previously treated with endocrine therapy.⁴ Specific data points to anticipate include objective response rates (ORR), clinical benefit rates (CBR), progression-free survival (PFS), and the safety profile, particularly gastrointestinal adverse events and QT prolongation, which can be concerns with oral SERDs.⁵ The context of the data, whether in the first-line, second-line, or later-line settings, and in specific patient subgroups, will be critical for interpretation.⁴ Imlunestrant functions by binding to the estrogen receptor (ER) and inducing its degradation, thereby reducing ER levels and inhibiting ER-mediated gene transcription, a key driver of HR+ breast cancer growth. This mechanism offers a direct approach to counter estrogen signaling, even in cases of acquired resistance to other endocrine therapies.

A separate presentation will focus on abemaciclib (Verzenio®). Abemaciclib is an oral CDK4/6 inhibitor approved for use in HR+/HER2- advanced or metastatic breast cancer in combination with endocrine therapy, and as adjuvant therapy in certain high-risk patients.^{2,6,8} The upcoming presentation may provide updated long-term follow-up data from pivotal trials, further subgroup analyses, or data from studies exploring novel combinations or expanded indications. For example, data on the duration of benefit, the incidence of late-onset toxicities, or outcomes in specific patient populations, such as those with visceral metastases or brain metastases, would be of interest.⁷ Abemaciclib is known for its distinct toxicity profile compared to other CDK4/6 inhibitors, with a higher incidence of diarrhoea and a lower incidence of neutropenia.^{2,6,8} Any new data on managing these toxicities or their long-term impact would be relevant for clinical practice.⁸ Abemaciclib selectively inhibits CDK4 and CDK6, enzymes that regulate cell cycle progression.² By blocking these kinases, abemaciclib prevents cancer cells from proliferating, thereby slowing tumor growth.² Its continuous dosing schedule, unlike other CDK4/6 inhibitors, may contribute to its efficacy and distinct safety profile.⁶ The presentations will likely include detailed statistical analyses, such as hazard ratios (HR) for PFS or overall survival (OS), confidence intervals (CI), and p-values, to quantify the observed treatment effects.^{2,6} Patient numbers (N) and baseline characteristics will be essential for assessing the generalisability of the findings.⁶ The specific trial designs, including primary and secondary endpoints, will dictate the scope of the data presented.⁶ For imlunestrant, data on its efficacy in patients with ESR1 mutations, a common mechanism of resistance to aromatase inhibitors, would be particularly relevant.⁹ For abemaciclib, any data clarifying its role in patients who have progressed on prior CDK4/6 inhibitors, or in combination with other targeted agents, would be important.¹⁰ The methodology sections of the presentations will likely detail patient eligibility criteria, prior treatment lines, and specific definitions for endpoints such as ORR (e.g., RECIST 1.1 criteria) and PFS. Information on dose modifications, concomitant medications, and patient-reported outcomes will also enhance the understanding of the clinical utility of these agents.

Limitations of the presented data will likely include the typical constraints of conference presentations, which may not always provide the full detail available in peer-reviewed publications. The follow-up duration for imlunestrant trials may still be relatively short, limiting conclusions on long-term efficacy and safety. For abemaciclib, while extensive data exists, the focus of the new presentation will determine its specific limitations. For instance, data from highly selected patient populations might not be fully generalizable to the broader real-world patient population. Additionally, the absence of direct head-to-head comparisons with other agents in the same class could limit definitive conclusions on

comparative efficacy or safety. Future research will need to integrate these findings into the broader context of existing therapies and ongoing trials to refine treatment algorithms for HR+/HER2- breast cancer.

CLINICAL IMPLICATIONS

The forthcoming ASCO 2026 presentations on imlunestrant and abemaciclib underscore the pharmaceutical industry's persistent focus on refining endocrine therapy for HR+/HER2- breast cancer. For clinicians, the imlunestrant data will be scrutinised for its precise efficacy in various lines of therapy and its safety profile, particularly in comparison to existing oral SERDs and intramuscular fulvestrant. The convenience of an oral formulation is undeniable for patients, but this must be weighed against any differences in efficacy or tolerability. If imlunestrant demonstrates a favourable risk-benefit profile, it could offer a valuable alternative, potentially shifting prescribing patterns away from less convenient agents, especially in community oncology settings where patient preference for oral medications is high.

Regarding abemaciclib, any new data, particularly long-term follow-up or subgroup analyses, will serve to solidify its already established role. Given its approval in both advanced and adjuvant settings, further insights into its sustained benefit or the management of its specific adverse events, such as diarrhoea, will be directly applicable to daily practice. Clinicians are already adept at managing CDK4/6 inhibitor toxicities, but nuanced data could lead to more individualised treatment strategies, potentially improving patient adherence and quality of life. The industry, particularly Eli Lilly, will be keen to reinforce abemaciclib's market position against competitors like palbociclib and ribociclib, highlighting any unique advantages or expanded indications. Ultimately, these presentations contribute to an increasingly complex therapeutic landscape. While new agents and data are welcome, they also demand a higher degree of precision from clinicians in patient selection and treatment sequencing. The challenge for guideline bodies, such as ESMO and NCCN, will be to rapidly integrate these findings into updated recommendations, ensuring that the evidence-based benefits reach patients efficiently. For patients, these developments offer continued hope for improved outcomes and potentially more tolerable treatment options, though the financial implications of novel therapies remain a significant consideration for healthcare systems globally.

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