Patient-reported outcomes and qualitative interviews in patients with estrogen receptor-positive (ER+)/human epidermal growth factor receptor 2-negative (HER2−) advanced breast cancer: results from the Phase III EMBER-3 trial

This information is intended for U.S HCPs for medical, scientific and educational purposes. Not intended for product promotion.

Imlunestrant has not been approved for use in combination with abemaciclib by the FDA, and the safety and efficacy of the combination has not been established.

Imlunestrant is approved by the FDA for use in the treatment of adults with ER+, HER2- ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

Abemaciclib is approved by the FDA for use in combination with an aromatase inhibitor as initial endocrine therapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer; in combination with fulvestrant for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy; and as monotherapy for the treatment of adult patients with HR+, HER2- advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

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Limitations of this analysis of EMBER-3:

- PRO measures were included as an exploratory endpoint in the EMBER-3 trial to assess the impact of treatment from the patient perspective.
- Only a small fraction of patients enrolled in the EMBER-3 trial participated in the interview study as the interview study began several years into the ongoing clinical trial and was not pre-planned.
- Despite good PRO compliance, data availability over time was limited since PRO data were not collected after treatment discontinuation as per study design. This hinders understanding of patients' HRQL at and after discontinuation. In addition, this impacts the interpretation of analyses of available data, particularly time to deterioration of function and symptoms, given intercurrent events and the need for serial PRO assessments for long periods of time.
- Selection bias: interviewers were optional, patients who were well and satisfied may have been more likely to volunteer– biasing results positively.
- Survivor bias: Patients who discontinued due to progression were excluded, further skewing reported experiences toward positive.
- Expectation bias: imlunestrant recipients may have had a pre-existing positive expectation for an oral pill over an intramuscular injection.
- Combination arm absent: imlunestrant-abemaciclib treated patients were not included in the interview study; their experience cannot be characterized from this data

Click here to access the full Prescribing Information for imlunestrant.

Highlights of Prescribing Information | Warnings and Precautions:

- Embryo-Fetal Toxicity: INLURIYO™ (imlunestrant) can cause fetal harm. Advise of the potential risk to a fetus and to use effective contraception. (5.1, 8.1, 8.3)

Click here to access the full Prescribing Information for abemaciclib.

Highlights of Prescribing Information | Warnings and Precautions:

- Diarrhea: VERZENIO® (abemaciclib) can cause severe cases of diarrhea, associated with dehydration and infection. Instruct patients at the first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their healthcare provider. (2.2, 5.1)
- Neutropenia: Monitor complete blood counts prior to the start of abemaciclib therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. (2.2, 5.2)
- Interstitial Lung Disease (ILD)/Pneumonitis: Severe and fatal cases of ILD/pneumonitis have been reported. Monitor for clinical symptoms or radiological changes indicative of ILD/pneumonitis. Permanently discontinue abemaciclib in all patients with Grade 3 or 4 ILD or pneumonitis. (2.2, 5.3)
- Hepatotoxicity: Increases in serum transaminase levels have been observed. Perform liver function tests (LFTs) before initiating treatment with abemaciclib. Monitor LFTs every two weeks for the first two months, monthly for the next 2 months, and as clinically indicated. (2.2, 5.4)
- Venous Thromboembolism: Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate. (2.2, 5.5)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. (5.6, 8.1, 8.3)

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Click HERE to see the full results published in *ESMO Open*

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