Imlunestrant with or without Abemaciclib in Advanced Breast Cancer: Safety Analyses from the 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 this unapproved use 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.

Limitations of this analysis of EMBER-3:

- The open-label nature of the study which introduced some potential for bias in adverse event reporting, however the sizeable patient population and methods of collecting and classifying TEAEs minimized this.
- Subgroup analyses were limited by smaller patient numbers.

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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)

Click HERE to see the full results published in *npj Breast Cancer*

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