Overall survival from the phase III postMONARCH trial of abemaciclib plus fulvestrant versus placebo plus fulvestrant for HR+, HER2- advanced breast cancer following progression on a prior CDK4/6 inhibitor plus endocrine therapy

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

Abemaciclib has not been approved by the FDA for use following disease progression on a prior CDK4/6 inhibitor. The safety and effectiveness of this unapproved use has not been established.

Abemaciclib is approved by the FDA for use in combination with an aromatase inhibitor or fulvestrant for the treatment of adult patients with hormonal receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, advanced or metastatic breast cancer.

Limitations of the OS analysis of postMONARCH:

The postMONARCH trial was designed and powered primarily to detect a difference in PFS, not OS, so the trial had limited statistical power to detect a significant overall survival difference between arms. Most participants in both arms went on to receive subsequent systemic therapy after discontinuation (77% in the abemaciclib plus fulvestrant arm and 83% in the placebo plus fulvestrant arm), with similar rates of chemotherapy, endocrine therapy, and targeted therapy. This balanced access to effective later-line treatments, regardless of initial randomization, likely constrained the degree to which a single line of therapy could influence OS in this pretreated population. Secondary and exploratory endpoints, including PFS2, chemotherapy-free survival, and time to chemotherapy, were assessed using nominal P values that were not adjusted for multiplicity, so these results should be interpreted as descriptive rather than confirmatory.

This study was conducted by Eli Lilly and Company.

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Click here to access the full Prescribing Information for abemaciclib.

Highlights of Prescribing Information | The recommended Dose and Schedule:

- When used in combination with fulvestrant, tamoxifen, or an aromatase inhibitor, the recommended dose of VERZENIO is 150 mg taken orally twice daily. Refer to the Full Prescribing Information for the recommended dose of fulvestrant, tamoxifen, or aromatase inhibitor being used. (2.1)
- Pre/perimenopausal women or men treated with the combination of VERZENIO plus an aromatase inhibitor should be treated with a gonadotropin-releasing hormone agonist (GnRH) according to current clinical practice standards. (2.1)
- Pre/perimenopausal women treated with the combination of VERZENIO plus fulvestrant should be treated with a GnRH according to current clinical practice standards. (2.1)
- For early breast cancer, continue VERZENIO until completion of 2 years of treatment or until disease recurrence, or unacceptable toxicity. (2.1)

Highlights of Prescribing Information | Dose Modification

- The recommended VERZENIO dose modifications for adverse reactions are provided in Tables 1-7 within 2.2. Discontinue VERZENIO for patients unable to tolerate 50 mg twice daily. (2.2)

Highlights of Prescribing Information | Warnings and Precautions:

- Diarrhea: VERZENIO 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 VERZENIO 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 VERZENIO 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 VERZENIO. 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 ***Annals of Oncology***

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