

On May 1, 2026, the FDA approved vepdegestrant for adults with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Efficacy was evaluated in the VERITAC-2 trial.

U.S. Food & Drug Administration. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-vepdegestrant-er-positive-her2-negative-esr1-mutated-advanced-or-metastatic-breast>

On September 4, 2026, the FDA granted accelerated approval to camizestrant in combination with a CDK4/6 inhibitor for the treatment of adult patients with HR-positive, HER2-negative locally advanced or metastatic breast cancer upon detection of *ESR1* mutation during aromatase inhibitor and CDK 4/6 inhibitor therapy. Efficacy was evaluated in the SERENA-6 trial.

U.S. Food & Drug Administration. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-camizestrant-cdk46-inhibitor-esr1-mutated-hr-positive-her2-negative>

On September 18, 2026, the FDA approved imlunestrant in combination with abemaciclib for adults with ER-positive, HER2-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Efficacy was evaluated in the EMBER-3 trial.

U.S. Food & Drug Administration. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-implunestrant-combination-abemaciclib-er-positive-her2-negative-esr1-mutated-advanced-or>

