On September 4, 2026, the FDA granted accelerated approval to camizestrant in combination with a CDK4/6 inhibitor (abemaciclib, palbociclib, or ribociclib) for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer upon detection of estrogen receptor-1 (*ESR1*) mutation during aromatase inhibitor and CDK 4/6 inhibitor therapy, based on an FDA-authorized test. Efficacy was evaluated in the SERENA-6 trial.

FDA.gov. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-camizestrant-cdk46-inhibitor-esr1-mutated-hr-positive-her2-negative

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On September 18, 2026, the FDA approved imlunestrant in combination with abemaciclib, for adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor 1 (*ESR1*)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy. Efficacy was evaluated in the EMBER-3 trial.

FDA. gov. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-imlunestrant-combination-abemaciclib-er-positive-her2-negative-esr1-mutated-advanced-or

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On November 16, 2026, the FDA approved giredestrant in combination with everolimus for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor 1 (*ESR1*)-mutated locally advanced or metastatic breast cancer, as detected by an FDA-authorized test, whose disease has recurred during or after completion of endocrine-based adjuvant therapy, or has progressed on at least one endocrine-based regimen in the metastatic setting.

FDA.gov. https://www.fda.gov/drugs/cancer-approvals/fda-approves-giredestrant-combination-everolimus-er-positive-her2-negative-esr1-mutated-locally

