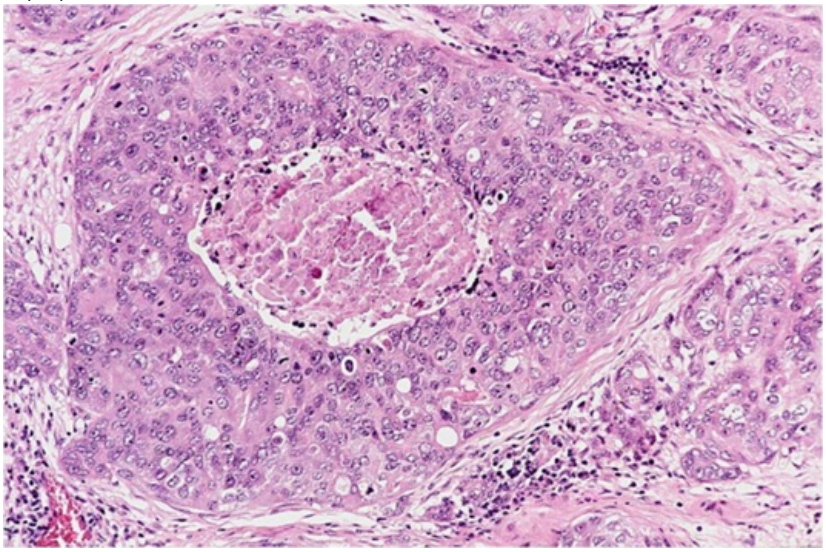
FDA Grants Accelerated Approval to a New Breast Cancer Treatment That Targets Drug Resistance

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by staff intern Morgan Manuel

Researchers found that switching to Camizestrant after detecting a specific tumor mutation helped patients with advanced breast cancer live longer without their disease progressing. The findings highlight how genetic testing may help doctors identify treatment resistance earlier and adjust therapy before cancer becomes detectable as worsening disease on imaging. However, additional studies are needed to confirm the treatment's long-term clinical benefits. Breast cancer treatment has increasingly shifted toward personalized medicine, in which therapies are selected according to the molecular characteristics of an individual's tumor. While hormone therapy can be effective for many patients, cancer cells can develop genetic changes that allow them to resist treatment. On September 4, 2026, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Etcamah (Camizestrant), in combination with a CDK4/6 inhibitor, for certain adults with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer. The treatment is intended for patients whose tumors develop an estrogen receptor 1 (ESR1) mutation while they are receiving an aromatase inhibitor and a CDK4/6 inhibitor. The mutation must be identified using an FDA-authorized test.

FDA announcement
The approval represents an important step toward using blood-based genetic testing to guide cancer treatment. Rather than waiting for imaging to show that a tumor has progressed, clinicians may be able to identify a molecular sign of resistance and consider changing therapy earlier. Detecting treatment resistance through genetic testing hormone receptor-positive breast cancer relies, in part, on estrogen signaling to support cancer cell growth. Aromatase inhibitors reduce estrogen production, helping slow the growth of hormone-sensitive tumors. These medications are commonly used alongside CDK4/6 inhibitors, which interfere with proteins that help cancer cells divide. Over time, however, some tumors develop ESR1 mutations. These genetic changes can alter the estrogen receptor and allow cancer cells to continue growing despite treatment with aromatase inhibitors. To identify these changes, clinicians can use circulating tumor DNA (ctDNA), which consists of small fragments of DNA released by tumors into the bloodstream. A blood test can detect certain mutations and provide information about how a tumor is responding to treatment. The FDA described this approval as the first for a cancer therapy guided by detection of a resistance mutation in circulating tumor DNA before imaging tests show disease progression. The approach may help clinicians make treatment decisions based on changes occurring at the molecular level.

Key Findings
The FDA evaluated Camizestrant in the SERENA-6 clinical trial, which compared switching to Camizestrant while continuing a CDK4/6 inhibitor with continuing an aromatase inhibitor alongside a CDK4/6 inhibitor in patients with detectable ESR1 mutations. The estimated median progression-free survival was 16 months among patients receiving Camizestrant with a CDK4/6 inhibitor, compared with 9.2 months among those continuing their aromatase inhibitor with a CDK4/6 inhibitor. Progression-free survival measures the length of time patients live without their disease worsening. These results suggest that changing treatment after detecting an ESR1 mutation may delay disease progression compared with continuing the original hormone therapy. The FDA also authorized the Guardant360 CDx assay as a companion diagnostic to identify patients with ESR1-mutated breast cancer who may be eligible for this treatment. However, the approval was granted under the FDA's accelerated approval pathway. Additional confirmatory studies are required to determine whether changing treatment at the time the mutation is detected, rather than waiting for confirmed disease progression, provides a meaningful overall clinical benefit.

Why This Matters
This approval highlights the growing role of precision medicine in cancer care. Instead of relying exclusively on tumor size, symptoms, or imaging results, healthcare professionals can use molecular information to help guide treatment decisions. For patients with advanced breast cancer, identifying resistance earlier may provide an opportunity to delay disease progression and extend the effectiveness of treatment. It also demonstrates how liquid biopsies, which analyze tumor-derived material in blood, may become increasingly important in monitoring cancer and detecting changes that influence therapy.
Safety remains an important consideration. The FDA prescribing information includes a boxed warning regarding the risk of irregular heart rhythm when Camizestrant is taken with certain other medications. Additional warnings include an abnormally slow heart rate and potential harm to an unborn baby. Treatment decisions therefore require individualized assessment and medical supervision.

The Takeaway
The FDA’s accelerated approval of Camizestrant in combination with a CDK4/6 inhibitor offers a new treatment option for certain patients with advanced hormone receptor-positive, HER2-negative breast cancer whose tumors develop ESR1 mutations during therapy. The clinical trial results showed longer median progression-free survival when treatment was switched following mutation detection. Although further research is needed to confirm the long-term clinical benefit, this development demonstrates how blood-based genetic testing can help identify treatment resistance and inform personalized cancer care. It also reinforces the importance of combining promising early evidence with continued clinical evaluation to determine how new therapies affect patients over time.

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