

Genentech Gains FDA Priority Review for Oral SERD in Early Breast Cancer

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The NDA acceptance for giredestrant could support a new endocrine therapy option for ER-positive, HER2-negative early-stage breast cancer.



Genentech has received U.S. FDA acceptance and Priority Review for its New Drug Application for giredestrant as an adjuvant treatment for adults with estrogen receptor-positive, HER2-negative stage I to III breast cancer.

The FDA has set a Prescription Drug User Fee Act target action date of November 30, 2026. If approved, giredestrant could become an oral selective estrogen receptor degrader option in the early-stage curative setting.

This is relevant because ER-positive breast cancer accounts for around 70 per cent of breast cancer cases, and most patients are diagnosed at an early stage. However, recurrence remains a concern, with up to one-third of patients eventually experiencing recurrence on or after adjuvant endocrine therapy.

The filing is supported by the Phase 3 lidERA Breast Cancer study, which enrolled more than 4,100 patients. Giredestrant reduced the risk of invasive disease recurrence or death by 30 per cent compared with standard-of-care endocrine therapy. At three years, 92.4 per cent of patients in the giredestrant arm were alive and free of invasive disease, compared with 89.6 per cent in the standard therapy arm.

Giredestrant is designed to block estrogen from binding to the estrogen receptor and trigger receptor degradation. This differentiates it from conventional endocrine therapy and may help address resistance and tolerability issues that affect long-term adherence.

The development reflects the continued shift toward more targeted endocrine strategies in breast cancer. For the biopharma sector, the commercial question will be whether oral SERDs can move beyond metastatic disease and reshape earlier-line treatment where the goal is preventing recurrence.