# US FDA approves Celcuity's breast cancer drug

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Bengaluru: The U.S. FDA has approved Celcuity's drug for an advanced form of breast cancer, the regulator said on Tuesday, making it the company's first product to gain market entry.

Shares of the company were down more than 5% in extended trading, after closing up 6.9% on Tuesday.

The Food and Drug Administration's approval was based on late-stage data showing the drug, gedatolisib, branded as Revtorpyk, when combined with Pfizer's Ibrance and fulvestrant, reduced the risk of disease progression or death by 76% compared with fulvestrant alone.

Patients receiving the combination remained progression-free for a median of 9.3 months, compared with 2.0 months for patients receiving fulvestrant alone.

With Revtorpyk, Celcuity will enter a broader advanced breast cancer market that includes treatments such as AstraZeneca's Truqap, Novartis' Piqray and Eli Lilly's Verzenio. The company sees a long-term opportunity to treat more than 130,000 breast cancer patients, including potential first-line use, representing a market of more than $10 billion, Chief Executive Officer Brian Sullivan said in a investor call.

Revtorpyk is intended to treat patients with advanced breast cancer whose tumors have low levels of a protein called HER2 and no mutation in a gene called PIK3CA, and whose disease has worsened after hormone therapy and a CDK inhibitor, a type of therapy.

Hormone receptor-positive, HER2-negative disease is the most common form of breast cancer. While patients are typically treated with hormone therapies and CDK inhibitors, many eventually develop resistance and need additional treatment options.

Revtorpyk targets the PI3K pathway, a key driver of cancer growth and treatment resistance. Unlike approved medicines that generally target a single component, it acts on multiple parts of the pathway.

The company is seeking to position gedatolisib as an option for patients whose tumors do not carry a PIK3CA mutation, which is a group with fewer targeted treatment options. Celcuity expects to begin marketing the drug in the third quarter.

**News Source:**

https://pharma.economictimes.indiatimes.com/news/drug-approvals-and-launches/us-fda-approves-celcuitys-breast-cancer-drug/132403836