US FDA approves Pfizer, Arvinas' breast cancer drug

Branded as Veppanu, the pill is authorized for adults with estrogen receptor-positive, HER2-negative breast cancer, which has already spread or cannot be removed by surgery.

Bengaluru: The U.S. Food and Drug Administration on Friday approved Pfizer and Arvinas' breast cancer drug for patients with an advanced form of the disease whose tumors carry a specific genetic mutation.

Branded as Veppanu, the pill is authorized for adults with estrogen receptor-positive, HER2-negative breast cancer, which has already spread or cannot be removed by surgery.

Patients must carry an ESR1 mutation and show disease progression after at least one prior hormone therapy, the agency said.

Arvinas CEO Randy Teel told Reuters the approval would give stage-4 breast cancer patients a much-needed treatment option. "Patients really are in need of a new modality, a new technology and a new way of hitting disease," he said.

The FDA's decision was based on a late-stage trial of 624 participants that showed Veppanu helped patients survive for longer periods without their breast cancer worsening, compared with the older hormone therapy, fulvestrant.

Wedbush analyst Robert Driscoll said Veppanu's efficacy appears competitive with other approved breast cancer treatments, though differences across trials make clear differentiation difficult. He said the drug's tolerability profile looked "compelling."

The FDA said patients taking the pill had tumors shrink more often than those given injectable drugs.

The pill's label cautions that it can affect heart rhythm and may harm an unborn baby.

Teel said the company expects to announce a commercialization deal for Veppanu in the coming weeks, after which there would be more clarity on pricing.

The FDA also approved a companion blood test, Guardant360 CDx, to identify which patients carry the ESR1 mutation and are eligible for the drug.

The recommended dose is a 200 mg pill taken once a day with food, until the disease worsens or side effects become too severe, the health regulator said.

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