

US FDA approves Lilly's breast cancer drug combo

The combination, Inluriyo-Verzenio, is meant for patients whose tumors are estrogen receptor-positive, HER2-negative and carry an ESR1 mutation, and whose cancer has worsened after at least one hormone treatment.



Bengaluru: The US FDA has approved Eli Lilly's drug combination to treat adults with a type of advanced breast cancer that has spread to other parts of the body, the drugmaker said on Friday.

The combination, Inluriyo-Verzenio, is meant for patients whose tumors are estrogen receptor-positive, HER2-negative and carry an ESR1 mutation, and whose cancer has worsened after at least one hormone treatment.

About half of the patients with ER-positive, HER2-negative metastatic breast cancer develop an ESR1 mutation during or after treatment with a widely used class of hormone-blocking therapies, Lilly said.

The US Food and Drug Administration had approved Inluriyo in September last year to treat metastatic breast cancer, also called Stage IV breast cancer with ESR1 mutations.

The approval was based on a late-stage study of 159 patients with this type of advanced breast cancer. Patients who took both drugs went a median of 11.1 months before their cancer worsened, compared with 5.5 months for those who took Inluriyo alone.

HR+/HER2- is the most common subtype of breast cancer - the second leading cause of cancer death in women.

Inluriyo is a daily pill that blocks and breaks down estrogen receptors that can help some breast cancers grow, while Verzenio is a twice-daily pill that slows cancer-cell division.

The combination also carries risks, Lilly said, including severe diarrhea, low white blood cell counts, lung inflammation, liver problems and blood clots.

Inluriyo's label includes a warning for embryo-fetal toxicity, which refers to potential risk of harm to a developing embryo and fetus if exposure occurs during pregnancy.

Lilly said Inluriyo plus Verzenio is available immediately in the United States.

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