EU regulator backs approval for AstraZeneca's experimental breast cancer pill

The positive opinion comes weeks after a panel of advisers to the U.S. Food and Drug Administration voted against the treatment, raising concerns about the design of a key late-stage trial rather than the treatment's safety or effectiveness.

London: A European Medicines Agency committee on Friday backed approval for AstraZeneca's experimental breast cancer pill, camizestrant, differing from a U.S. regulatory panel's opinion about the drug.

The positive opinion comes weeks after a panel of advisers to the U.S. Food and Drug Administration voted against the treatment, raising concerns about the design of a key late-stage trial rather than the treatment's safety or effectiveness.

Friday's decision paves the way for approval from the European Commission to use the drug in combination with another type of therapy known as CDK4/6 inhibitor.

Camizestrant is among the 20 new medicines that the Anglo-Swedish drugmaker expects to launch by 2030 to hit its $80 billion revenue target. It expects the drug will contribute more than $5 billion in peak annual sales.

Susan Galbraith, a senior executive at AstraZeneca, said that the recommendation was "an important first step" and the company will work with different countries for access after approval.

EMA's recommendation is based on a late-stage study in which the drug, in combination with other cancer medicines, reduced the risk of cancer progression or death by 56%.

The combination helped keep the disease under control for about 16 months on average, compared with just over nine months with standard treatment.

Expert advisors to the FDA had largely expressed concerns about the trial design. The FDA typically follows the advice of its experts but is not bound to do so.

"We're really pleased to see that the CHMP (Committee for Medicinal Products for Human Use) has recognized the value of this monitoring approach," said Galbraith.

She said discussions were ongoing with regulatory authorities in the U.S. and the company will present additional data from the trial at a medical conference at the end of this month. (Reporting by Ankita Bora in Bengaluru and Bhanvi Satija in London; Editing by Tasim Zahid and Devika Syamnath)

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