US FDA approve GSK's blood cancer treatment

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Bengaluru: The U.S. Food and Drug Administration has approved British drugmaker GSK's blood cancer drug, Blenrep, in one combination regimen, the company said on Thursday, clearing the way for its return to the market nearly three years after it was withdrawn.

The FDA approved Blenrep in combination with bortezomib and dexamethasone for patients with multiple myeloma whose disease has returned or stopped responding to treatment after at least one prior therapy.

A second regimen pairing Blenrep with pomalidomide and dexamethasone, tested in a separate trial, was not included in the approval.

U.S.-listed shares of the company were down 4% in after-hours trading.

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Blenrep was pulled from the market in 2022 after it failed to outperform an existing therapy in a confirmatory trial. The FDA's latest decision goes against the recommendation of an advisory panel in July, which had voted against both combinations.

GSK said the drug will be available under a simplified safety monitoring programme to help doctors manage risks, especially those affecting vision.

The FDA approval is expected to boost investor confidence in GSK's forecast of more than 3 billion pounds ($4.03 billion) in peak sales for Blenrep. The drug is already approved in several countries including the UK, Japan, Canada and Switzerland.

With the multiple myeloma market projected to reach $45 billion by 2032, GSK expects Blenrep to be a material growth driver in the next three to four years, said Tony Wood, GSK's chief scientific officer.

The company is in the early stages of a rollout and launch, and does not expect "significant sales this quarter," Wood said.

The combinations were already cleared in the European Union in July, making the U.S. approval a later step in the drug's global rollout.

Multiple myeloma is the third most common blood cancer globally, with about 180,000 new cases diagnosed each year, according to GSK. ($1 = 0.7451 pounds) (Reporting by Padmanabhan Ananthan and Mariam Sunny in Bengaluru; Additional reporting by Bhanvi Satija in London and Kamal Choudhury in Bengaluru; Editing by Maju Samuel)

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