US FDA approves Jazz Pharma's drug for rare brain tumor

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Bengaluru: The U.S. Food and Drug Administration said on Wednesday that it has approved Jazz Pharmaceuticals' drug to treat diffuse midline glioma, a rare and aggressive tumor, in adults and children aged one year and older.

The approval expands Jazz's cancer drug portfolio beyond its existing treatments for certain blood and lung cancers.

This is the first FDA-approved systemic therapy for diffuse midline glioma with a specific mutation that has progressed despite prior treatments, the agency said.

The drug, Modeyso, is expected to become available in the U.S. in the coming weeks and is administered as a once-weekly oral capsule.

Diffuse midline glioma (DMG) is a rare and aggressive brain tumor that primarily affects children and young adults. It develops in the brain's and spinal cord's midline structures, such as the brainstem, thalamus, and spinal cord.

An estimated 3,940 people are living with this tumor in the United States, according to NIH data.

The FDA decision was based on data from 50 patients in five clinical studies, showing that the drug helped shrink tumors in about 22% of cases. Among those who responded, the benefit lasted a median of just over 10 months.

"We think it fits very well in terms of addressing a very high unmet need," said Rob Iannone, Chief Medical Officer at Jazz Pharmaceuticals, ahead of the decision.

Jazz Pharmaceuticals acquired the drug in March through its $935 million purchase of Chimerix.

The company says it plans to work with doctors and advocates to make the treatment available as quickly as possible. (Reporting by Padmanabhan Ananthan in Bengaluru; Editing by Tasim Zahid)

News Source:

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