US FDA grants accelerated approval to Genfit and Ipsen's liver disease drug

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By Puyaan Singh and Mariam Sunny

London: The U.S. Food and Drug Administration granted accelerated approval to French drugmakers Ipsen and Genfit's drug for a chronic inflammatory liver disease, Iqirvo, the companies said on Monday.

Primary biliary cholangitis (PBC) causes inflammation of the small bile ducts in the liver and eventually destroys them. It primarily affects women aged 30 to 60, impacting 75,000 in the United States.

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Ipsen added that standard approval for Iqirvo may be contingent on confirmatory trials, as improvement in survival or prevention of liver decompensation events that can include abdominal swelling or gastrointestinal bleeding was not demonstrated.

Intercept Pharmaceuticals' Ocaliva is approved for PBC patients in combination with ursodeoxycholic acid (UDCA), or as a monotherapy in patients unable to tolerate UDCA. Iqirvo is also to be used under similar conditions, based on this approval.

Iqirvo's approval was based on data from a 161-patient late-stage trial, in which it reduced levels of an enzyme called alkaline phosphatase that can lead to liver damage.

It works by activating certain receptors, which reduce inflammation, increases transport of bile acids outside the liver and promotes their detoxification, said Christelle Huguet, Executive Vice President at Ipsen.

Current treatments do not address inflammation or scarring of the liver and do not promote detoxification of bile acids, Huguet added.

In the study, Iqirvo also showed an improvement in itchy skin - a symptom of PBC - over placebo. Other treatments such as Ocaliva can worsen itching.

Ipsen acquired global rights to license the drug from Genfit in 2021. Genfit received 120 million euros ($129.19 million) upfront and is eligible to receive double-digit royalties of up to 20%.

Gilead is also developing a drug for PBC, on which the FDA is expected to decide in August. ($1 = 0.9289 euros) (Reporting by Puyaan Singh and Mariam Sunny in Bengaluru; Editing by Krishna Chandra Eluri and Alan Barona)

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