SCRIP
CITELINE COMMERCIAL

11 Jun 2024 | **News**

Ipsen Gets Ahead Of The Qirv in Cholangitis

by Elizabeth Cairns

Iqirvo gains accelerated approval, but Gilead's seladelpar is probably only two months behind.

It's not MASH, but it's something. *Ipsen SA* and *Genfit SA*'s elafibranor was approved on 10 June for second-line primary biliary cholangitis (PBC), becoming the first new medicine for the disease in nearly a decade and allowing the company to get the jump on rival *Gilead Sciences, Inc.*.

The US Food and Drug Administration (FDA) granted accelerated approval for the peroxisome proliferator-activated receptor (PPAR)-α/δ agonist, which will be sold under the name Iqirvo. It must be co-administered with ursodeoxycholic acid (UDCA), the current first-line therapy, in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. Genfit, which discovered elafibranor and licensed global rights for the asset, excluding China, Hong Kong, Macau and Taiwan, to Ipsen in 2021, stands to gain a milestone payment of €48.7m on the first commercial sale of Iqirvo in the US.

Key Takeaways

- Ipsen and Genfit's elafibranor has gained accelerated US approval in primary biliary cholangitis.
- But Gilead's seladelpar looks better on a cross-trial basis and has a PDUFA date of 14 August.
- Neither product made the cut in MASH, a far more profitable market.

The approval was based on data from the pivotal ELATIVE trial, in 161 PBC patients unresponsive to or intolerant of UDCA. The trial hit on the composite primary endpoint of cholestatic response at one year, but only mustered a numerical trend towards reducing itching, a key side effect. (Also see "*Genfit/Ipsen's PBC Data Leave Door Open For CymaBay*" - Scrip, 30 Jun, 2023.)

SCRIP
CITELINE COMMERCIAL

As a recipient of an accelerated nod, Iqirvo must undergo a confirmatory trial, the results of which could lead to either full approval or the drug's withdrawal from market. The placebo-controlled ELFIDENCE study has event-free survival as its primary endpoint and is due to run until 2030. A real-world trial, ELFINITY, is also ongoing.

Ipsen expects European and UK regulatory decisions in the second half of 2024.

Second Fiddle

According to *Evaluate Pharma*'s consensus of sellside forecasts, Iqirvo could sell $314m by 2030. But it will not lead the market; its major competitor, Gilead's PPAR-δ agonist seladelpar, is forecast to have 2030 sales of $404m.

Gilead got its hands on seladelpar earlier this year, having paid $4.3bn to acquire the asset's originator, CymaBay. Seladelpar is also awaiting expedited FDA approval and will receive a decision on or before 14 August. It did better than Iqirvo on similar endpoints when the two agents' pivotal trials are compared.

Ipsen Dealmaking Heats Up With Marengo Cold Tumor Collaboration

By Kevin Grogan

10 Jun 2024

The France-based mid-sized drugmaker has solidified its pipeline through several external pacts in the past few years and its dealmaking is showing no signs of slowing down.

Read the full article here

Click here to explore this interactive content online

But the competition to be the best in PBC is inherently a disappointment for both Ipsen/Genfit and Gilead. Iqirvo and seladelpar had both been big hopes for MASH, a far more lucrative indication, but the former failed in its pivotal trial and the latter was mothballed after a trial threw up evidence of interface hepatitis in liver biopsies (Also see "*RESOLVE-IT Failure Dashes Genfit's NASH Hopes*" - Scrip, 12 May, 2020.). Ipsen must make the most of its two-month head start in PBC.