Press Release

Ipsen to present two late-breaking sessions at AASLD on new PBC data supporting IQIRVO®'s long-term efficacy, safety and mechanistic insights in fatigue

- Interim data from the IQIRVO® (elafibranor) ELATIVE long-term open label extension trial demonstrate sustained biochemical response, stabilization of fibrosis markers and consistent trends in improvement of fatigue and pruritus symptoms, with a well-characterized safety profile over more than three years of treatment
- Additional new data from the ELATIVE trial highlights the potential for IQIRVO, a PPAR α/δ agonist, to beneficially impact fatigue-associated pathways linked to mitochondrial function

Paris, France – 7 November, 2025 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced that new Primary Biliary Cholangitis (PBC) data with IQIRVO® from the ELATIVE trial[1, 2] will be presented in two late-breaking sessions, at The Liver Meeting® 2025, hosted by the American Association for the Study of Liver Diseases (AASLD).

In interim data from the ELATIVE long-term, open label extension trial, which includes over three years of follow-up in 115 patients with PBC, observed that IQIRVO delivers sustained improvements in biomarkers of cholestasis and stabilization in markers of fibrosis, with IQIRVO treatment, suggesting potential for slowing disease progression. In addition, consistent trends in improvements were shown in fatigue and pruritus symptoms. At week 182, 72% of patients receiving IQIRVO maintained a biochemical response, with a 47% reduction in alkaline phosphatase (ALP) from baseline. The proportion of patients achieving normal ALP levels remained consistent with previously presented Phase III results from the ELATIVE trial. Improvements in patients with moderate-to-severe fatigue were sustained, with similar results observed for pruritus and data also confirmed a long-term, well-characterized safety profile with no new safety signals.[1]

"PBC does not impact all patients in the same way. Therefore, it is important for us to have access to data associated with long-term treatment benefit on the disease biomarkers and liver tests, as well as a positive impact on symptoms. These preliminary results, which indicate a potential improvement not only in pruritus, but also in fatigue, are very encouraging," said Dr. Cynthia Levy, Professor of Medicine, Division of Digestive Health and Liver Diseases, University of Miami. "We need to regularly monitor our patients with PBC over their lifetime and this data from the ELATIVE trial confirms that elafibranor is an effective treatment, with a reassuring, well-characterized safety profile, over the long-term."

In a second late-breaking presentation of a further analysis of the ELATIVE trial, showing the relationship between changes in the expression of fatigue-associated proteins and reported outcomes of fatigue in patients on IQIRVO, was presented.[2] The clinical findings from this analysis are consistent with previously published mechanistic data[3], suggesting that PPAR α/δ agonist activation may modulate key pathways involved in energy metabolism and mitochondrial function. Fatigue remains one of the most common and burdensome symptoms for patients with PBC. Currently, there are no therapies approved to address it, however, clinically meaningful improvements in fatigue have been observed with IQIRVO, which is a PPAR α/δ agonist, versus placebo, in the ELATIVE trial with around one in two patients reporting a significant reduction in fatigue severity.[4] Together, these data support further research into how IQIRVO may help address fatigue in PBC.

"These findings underscore IQIRVO's potential as a long-term treatment option that not only manages the markers of disease progression and symptoms that impact the quality of life of people living with PBC, but also helps us better understand the mechanisms behind fatigue," said Sandra Silvestri, MD, PhD, Executive Vice President, Chief Medical Officer, Ipsen. "With a consistent safety profile over three years and these emerging mechanistic insights, IQIRVO is positioned to play a transformative role in the management of PBC."

About the ELATIVE Trial

ELATIVE is a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial, with an open-label long-term extension (NCT04526665). ELATIVE is evaluating the efficacy and safety of elafibranor 80mg once daily versus placebo for the treatment of patients with PBC with an inadequate response or intolerance to ursodeoxycholic acid (UDCA), the existing first-line therapy for PBC. The trial enrolled 161 patients who were randomized 2:1 to receive elafibranor 80mg once daily or placebo. Patients with an inadequate response to UDCA would continue to receive UDCA in combination with elafibranor or placebo, while patients unable to tolerate UDCA would receive only elafibranor or placebo. Patients continued their assigned treatment after Week 52 until all patients had completed their treatment, or for a maximum of 104 weeks. The open-label long-term extension of ELATIVE remains ongoing.

About IQIRVO® (elafibranor)

Iqirvo (pronounced EYE-KER-VO) is an oral, once-daily, peroxisome proliferator-activated receptor (PPAR) agonist, which exerts an effect on PPARα and PPARδ. Activation of PPARα and PPARδ decreases bile toxicity and improves cholestasis by modulating bile acid synthesis, detoxification and transporters. Activation of PPARα and PPARδ also has anti-inflammatory effects by acting on different pathways. In 2019, Iqirvo was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) in adults with PBC who have an inadequate response to ursodeoxycholic acid (UDCA), the existing first-line therapy for PBC. Iqirvo was granted U.S. FDA accelerated approval in June 2024, conditional approval by the EMA in September 2024 and UK Medicines and Healthcare products Regulatory Agency (MHRA) in October 2024, for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. The FDA, EMA and MHRA approvals are contingent on the further verification of clinical benefit. Iqirvo is currently in regulatory processes with other authorities. Iqirvo (elafibranor) was developed by GENFIT. Ipsen licensed the exclusive worldwide rights (except China, Hong Kong, Taiwan and Macau) to elafibranor from GENFIT in 2021.

About Primary Biliary Cholangitis

PBC is a rare, autoimmune liver disease where a build-up of bile and toxins and chronic inflammation cause irreversible fibrosis of the liver and destruction of the bile ducts. Impacting approximately 100,000 people in the US and 165,000 people in Europe, the majority being women, PBC is a lifelong condition that can worsen over time if not effectively treated and may lead to liver transplant and in some cases, premature death.

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience.

Our pipeline is fueled by internal and external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

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References

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