Press Release

Late-breaking data from EASL reinforces IQIRVO's impact on ALP reduction with fatigue and pruritus improvement in patients with PBC

- Three late-breaking abstracts accepted, including:
    - Real-world benefit of IQIRVO (elafibranor) in PBC patients with Alkaline Phosphatase (ALP) 1-1.67 x Upper Limit of Normal (ULN) and on fatigue and pruritus symptoms
    - ELATIVE Phase III trial data on the impact of IQIRVO on PBC fatigue

PARIS, FRANCE, 15 MAY 2026 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today the latest data on IQIRVO (elafibranor) demonstrating clinically meaningful improvements in ALP, a surrogate marker of primary biliary cholangitis (PBC) disease progression, and symptom management, achieved in a real-world setting, will be presented at the European Association for the Study of Liver Disease (EASL) 2026 congress in Barcelona. IQIRVO is the only PBC therapy with data on meaningful improvements on Alkaline Phosphatase (ALP) reduction and both fatigue and pruritus symptoms.

In a late-breaking presentation, the depth of effect of IQIRVO on ALP normalization in PBC patients with ALP 1-1.67 x upper limit of normal (ULN) in the real-world setting will be presented. Normalization of ALP levels (<1 x ULN) is associated with improved prognosis and increased survival rates. Ipsen is currently conducting a Phase III study, ELSPIRE, which is evaluating IQIRVO in this patient population, in a clinical setting.

Additionally, Ipsen will present interim real-world data from the ELFINITY Phase IV study confirming real-world effectiveness of IQIRVO in both biochemical outcomes and symptom control, including fatigue and pruritus, with a favorable safety profile.

Further late-breaking data includes a new post-hoc analysis from the Phase III pivotal ELATIVE trial, which will provide further evidence of the impact of IQIRVO on fatigue, using the established Patient-Reported Outcome Measurement Information System Fatigue Short Form 7a (PROMIS PFSF 7a) tool. Fatigue is the most common and debilitating symptom reported by PBC patients. IQIRVO is the only medicine to have demonstrated a positive effect on fatigue in patients with moderate to severe fatigue at baseline and occurring independently of its effect on pruritus.[1]

With two molecules approved for three different rare cholestatic liver diseases and a pipeline with two additional late-stage indications, Ipsen is leading research and development for treatments where unmet need is high and treatments are often few or do not exist.

Ipsen Abstracts

LBP-033	LATE-BREAKER - Elafibranor treatment results in rapid reductions in biochemical markers and symptom burden: data from the ongoing prospective, non-interventional ELFINITY phase IV global study in patients with primary biliary cholangitis	Jörn M. Schattenberg, et al	Session Poster – Late Breaker Posters Location: Poster Area - Hall 7 Date: Wednesday 27 May - Saturday 30 May Time: 08:30–16:00
LBP-018	LATE-BREAKER - Improvements in fatigue in patients with primary biliary cholangitis treated with elafibranor: Patient-Reported Outcome Measurement Information System Fatigue Short Form 7a (PFSF 7a) data from the phase III ELATIVE® trial	David Jones, et al	Session Poster – Late Breaker Posters Location: Poster Area - Hall 7 Date: Wednesday 27 May - Saturday 30 May Time: 08:30–16:00
LBP-023	LATE – BREAKER - Real-world outcomes in patients with primary biliary cholangitis who initiated elafibranor treatment with baseline alkaline phosphatase less than 1.67× the upper limit of normal	Cynthia Levy, et al	Session Poster – Late Breaking Location: Poster Area - Hall 7 Date: Wednesday 27 May - Saturday 30 May Time: 08:30–16:00
SAT-396	Bone mineral density is stable in patients with primary biliary cholangitis receiving up to 3.5 years of elafibranor treatment	Jörn M. Schattenberg, et al	Session: Poster - Immune-mediated and cholestatic disease: Clinical aspects Location: Poster Area - Hall 7 Date: Saturday 30 May Time: 08:30–16:00
SAT-364	Long-term improvements in lipid profiles with elafibranor treatment, and favourable safety with concomitant statin use, in patients with primary biliary cholangitis during the open-label extension of the phase III ELATIVE® trial	Marlyn J. Mayo, et al	Session: Poster - Immune-mediated and cholestatic disease: Clinical aspects Location: Poster Area - Hall 7 Date: Saturday 30 May Time: 08:30–16:00
SAT-300	Long-term treatment with elafibranor improves markers of immune response and inflammation in primary biliary cholangitis	David Jones, et al	Session: Poster - Immune-mediated and cholestatic disease: Clinical aspects Location: Poster Area - Hall 7 Date: Saturday 30 May Time: 08:30–16:00

About IQIRVO® (elafibranor)

IQIRVO 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 and expanded the geographical scope to China, Hong Kong, Taiwan and Macau in March 2026.

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

1. Jones. D. et al. Clinically significant improvements in fatigue with elafibranor in patients with primary biliary cholangitis and limited association with pruritus: Analyses from the phase III ELATIVE.® European Association for the Study of the Liver (EASL) congress, 2025. Abstract LB25220