Press Release

New late-breaking data reinforces IQIRVO®'s impact on ALP, fatigue and pruritus in PBC

- IQIRVO® data expands scientific evidence in fatigue, showing clinically meaningful improvements in patients with moderate-to-severe fatigue at baseline
- In the first real-world analysis in patients with PBC and an ALP 1-1.67 x ULN, IQIRVO demonstrated a significant ALP reduction, with 59% of patients achieving ALP normalization at 6 months
- Interim analysis from the ELFINITY Phase IV study highlights real-world effectiveness and tolerability of IQIRVO in both biochemical and symptom control, including fatigue and pruritus

PARIS, FRANCE, 28 MAY 2026 – Ipsen (Euronext: IPN; ADR: IPSEY) today announced the presentation of new late-breaking results from the ELATIVE® Phase III trial and two real-world studies at the European Association for the Study of the Liver (EASL) congress. Together, these data further strengthen the growing body of evidence establishing IQIRVO® as the only second-line primary biliary cholangitis (PBC) treatment providing rapid and robust alkaline phosphatase (ALP) reduction with fatigue improvement (in patients with moderate-to-severe fatigue at baseline) and pruritus relief.

In a post hoc analysis of the pivotal ELATIVE study, shared in a late-breaking presentation, patients with moderate-to-severe fatigue at baseline experienced greater fatigue reductions with IQIRVO compared to placebo across 52 weeks. A clinically meaningful improvement in fatigue was achieved in 67% of patients on IQIRVO vs 31% on placebo (p=0.020) at Week 52, with improvements observed as early as Week 4. The benefits of IQIRVO vs placebo were observed across multiple dimensions of physical and mental fatigue, including extreme exhaustion (62% vs 31%), too tired to think clearly (57% vs 31%) and too tired to bath or shower (55% vs 25%), highlighting the breadth of improvement across several symptom domains.

"Fatigue is one of the most debilitating symptoms of PBC and has long represented a significant unmet need for patients and clinicians," said David Jones, Professor of Liver Immunology for the Faculty of Medical Science at Newcastle University. "These data are particularly encouraging, showing that IQIRVO led to clinically meaningful improvements in fatigue compared with placebo. Importantly, improvements were seen across multiple dimensions of fatigue, including outcomes that matter most to patients."

In a second late-breaking presentation, a U.S. real-world analysis using the Health Verity database, evaluated outcomes in patients with ALP elevated between 1-1.67 times the upper limit of normal (ULN). These data showed that improvements were observed through to month 6 in patients who were naïve to second-line treatment with 72% of patients having a ≥15% ALP reduction, a decline in mean ALP from 174 U/L to 131 U/L and 59% of patients achieving ALP normalization. Normalization of ALP is recognized as a key treatment goal for improved long-term prognosis and slowing disease progression in PBC. These data are the first real-world evidence establishing the benefit of IQIRVO on ALP normalization within this patient population.

In a third late-breaker, interim month 3 findings from the global Phase IV ELFINITY® study, conducted in routine clinical practice, showed IQIRVO delivered rapid and sustained reductions in ALP for three months, with biochemical response achieved in 55% of patients. More than half of patients with baseline moderate-to-severe fatigue experienced clinically meaningful improvements by month 3 as well as clinically important improvements in pruritus. IQIRVO demonstrated a favorable tolerability profile consistent with previous studies, with no serious or severe treatment-emergent adverse events reported.

"The growing evidence from both controlled trials and real-world practice highlights the meaningful difference IQIRVO can make for people living with PBC," said Sandra Silvestri, MD, PhD, Chief Medical Officer, Ipsen. "Across multiple studies, we see consistent improvements in both biochemical control, a key marker of disease progression, and in the debilitating symptoms of fatigue and pruritus, which are independent of each other. These data further reinforce IQIRVO's potential to address both disease biology and symptom burden in a meaningful and clinically relevant way."

About IQIRVO® (elafibranor)

IQIRVO is an oral, once-daily, peroxisome proliferator-activated receptor (PPAR) agonist. Activation of PPARα and PPARδ decreases bile toxicity and improves cholestasis by modulating bile acid synthesis, detoxification and transporters. IQIRVO is the first approved PPAR agonist with dual α and δ activation, shown to have complementary anti-inflammatory, anti-cholestatic, anti-fibrotic and metabolic effects. 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 in combination with ursodeoxycholic acid in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. The FDA and EMA approvals are contingent on the further verification of clinical benefit. In addition to the U.S., E.U. and UK, IQIRVO is approved in Canada, Australia, Brazil and 13 other countries and is in regulatory processes with other authorities. IQIRVO 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[1] and 115,000 people in Europe[2], 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.

Ipsen Contacts

Investors

Henry Wheeler	henry.wheeler@ipsen.com	+33 7 66 47 11 49
Khalid Deojee	khalid.deojee@ipsen.com	+33 6 66 01 95 26

Media

Sally Bain	sally.bain@ipsen.com	+1 857 320 0517
Anne Liontas	anne.liontas.ext@ipsen.com	+33 7 67 34 72 96

Disclaimers and/or forward-looking statements

The forward-looking statements, objectives and targets contained herein are based on Ipsen's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect Ipsen's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words 'believes', 'anticipates' and 'expects' and similar expressions are intended to identify forward-looking statements, including Ipsen's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external-growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by Ipsen. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising medicine in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. Ipsen must face or might face competition from generic medicine that might translate into a loss of market share. Furthermore, the research and development process involves several stages each of which involves the substantial risk that Ipsen may fail to achieve its objectives and be forced to abandon its efforts with regards to a medicine in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during preclinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the medicine concerned. There can be no guarantees a medicine will receive the necessary regulatory approvals or that the medicine will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation and risks arising from unexpected regulatory or political changes such as changes in tax regulation and regulations on trade and tariffs, such as protectionist measures, especially in the United States; global trends toward healthcare cost containment; technological advances, new medicine and patents attained by competitors; challenges inherent in new-medicine development, including obtaining regulatory approval; Ipsen's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Ipsen's patents and other protections for innovative medicines; and the exposure to litigation, including patent litigation, and/or regulatory actions. Ipsen also depends on third parties to develop and market some of its medicines which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to Ipsen's activities and financial results. Ipsen cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of Ipsen's partners could generate lower revenues than expected. Such situations could have a negative impact on Ipsen's business, financial position or performance. Ipsen expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. Ipsen's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to Ipsen's latest Universal Registration Document, available on ipsen.com

1. LU M, Zhou, et al. Fibrotic Liver Disease Consortium Investigators. Increasing Prevalence of Primary Biliary Cholangitis and Reduced Mortality With Treatment. Clin Gastroenterol Hepatol. 2018 Aug;16(8):1342-1350.e1. DOI: 10.1016/j.cgh.2017.12.033.
2. Gazda J, et. al. The Epidemiology of Primary Biliary Cholangitis in European Countries: A Systematic Review and Meta-Analysis. Can J Gastroenterol Hepatol. 2021 Jun 19;2021:9151525. doi: 10.1155/2021/9151525.