Press Release

IQIRVO® demonstrates statistically significant improvement in ALP normalization in patients with PBC in Phase IIIb ELSPIRE study

- The primary endpoint of ALP normalization was achieved in 85% of patients treated with IQIRVO® (elafibranor) vs 23% on placebo
- Normalization of ALP (≤1 ULN) is recognized as a key treatment goal for improved long-term prognosis and slowing disease progression in PBC[1,2,3]
- ELSPIRE evaluated IQIRVO in PBC patients with ALP 1-1.67 x ULN on or after UDCA treatment, having the potential to double the addressable population for IQIRVO where there are significant unmet needs

PARIS, FRANCE, 13 JULY 2026 – Ipsen (Euronext: IPN; ADR: IPSEY) announced today that the Phase IIIb ELSPIRE trial evaluating IQIRVO® (elafibranor) in patients with PBC with an Alkaline Phosphatase (ALP) 1-1.67 times the upper limit of normal (x ULN) met the primary endpoint with statistical significance, showing an ALP normalization rate of 85% with IQIRVO vs 23% for placebo (p=<0.0001) at Week 52. The safety profile of IQIRVO was consistent with the known profile and no new safety signals were identified. Ipsen plans to present these data at an upcoming medical meeting and submit to regulatory authorities.

"We now recognize that patients who maintain normal serum alkaline phosphatase (ALP) have the best outcomes in PBC; therefore, our treatment goals are evolving to aim for ALP normalization as the optimal treatment target for this progressive and chronic liver disease," said Kris Kowdley, MD, Director, Liver Institute Northwest, Medical Director and Senior Scientific Advisor, Velocity Clinical Research, and Professor, Elson S. Floyd College of Medicine, Washington State University. "These data from the ELSPIRE trial show that ALP normalization is an achievable goal for patients with PBC and will hopefully improve the prognosis for people living with PBC."

"Normalizing ALP is not just a biochemical outcome, but a tangible objective to delay the need for a liver transplant and improve prognosis for PBC patients," said Christelle Huguet, PhD, EVP, Head of R&D, Ipsen. "These results contribute to the growing body of evidence on the potential of IQIRVO to help people achieve ALP normalisation."

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 the ELSPIRE Phase IIIb trial

ELSPIRE is a Phase IIIb randomized, double-blind, placebo-controlled study (NCT06383403) evaluating the efficacy and safety of elafibranor in adults with PBC who have had an inadequate response or intolerance to ursodeoxycholic acid, the existing first-line therapy for PBC. The trial enrolled 92 patients across 10 countries who had an ALP of 1-1.67 x ULN and were randomized 2:1 to receive IQIRVO 80 mg once daily or placebo. The primary endpoint of the trial was the proportion of patients with normalization of ALP at week 52. Data are based on patients in the IQIRVO treatment arm (n=62) compared to patients in the placebo treatment arm (n=30) within the treatment period, who achieved ALP normalization.

About PBC

PBC is a rare, autoimmune liver disease where a build-up of bile and toxins and chronic inflammation cause fibrosis of the liver and destruction of the bile ducts.[4] With approximately 1.8 people per 100,000 diagnosed worldwide each year, 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. [5,6]

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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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.

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[1] Murillo Perez CF, et al. Am J Gastroenterol. 2020;115(7):1066–1074
[2] European Association for the Study of the Liver Clinical Practice Guidelines: Primary Biliary Cholangitis. Available: https://easl.eu/publication/the-diagnosis-and-management-of-patients-with-primary-biliary-cholangitis/
[3] American Association for the Study of Liver Diseases Practice Guidelines: Primary Biliary Cholangitis. Available: https://www.aasld.org/practice-guidelines/primary-biliary-cholangitis
[4] Lleo *et al.* Primary biliary cholangitis. *The Lancet.* 2020;396:1915–1926.
[5] Tan *et al.* Global Epidemiology of Primary Biliary Cholangitis: An Updated Systematic Review and Meta-Analysis. *Clin Gastroenterol Hepatol.* 2026 Mar;24(3):621-632. doi: 10.1016/j.cgh.2025.03.025.
[6] Trivella *et al.* Primary biliary cholangitis: Epidemiology, prognosis, and treatment. *Hepatol Commun.* 2023 Jun 2;7(6):e0179. doi: 10.1097/HC9.0000000000000179