Press release

Intended for international media and investor audiences only

Ipsen confirms U.S. FDA grants priority review for New Drug Application for elafibranor for the treatment of rare cholestatic liver disease, PBC

- New Drug Application granted priority review with PDUFA date set for June 10, 2024
- European Medicines Agency (EMA) has also validated the Marketing Authorization Application (MAA) for elafibranor
- Investigational elafibranor is the first novel second-line treatment for primary biliary cholangitis (PBC) to be filed in E.U. and U.S. in nearly a decade

PARIS, FRANCE, 07 December 2023 - Ipsen (Euronext: IPN; ADR: IPSEY) and GENFIT (Nasdaq and Euronext: GNFT) today announced that the U.S. Food and Drug Administration (FDA) has accepted the New Drug Application (NDA) for investigational elafibranor. An oral, once-daily dual peroxisome activated receptor alpha/delta (PPAR α,δ) agonist, investigational elafibranor could potentially be the first novel second-line treatment for the rare, cholestatic liver disease, PBC, in nearly a decade. The target FDA PDUFA date under priority review is June 10, 2024.

The European Medicines Agency (EMA) has also validated Ipsen's Marketing Authorization Application (MAA) for elafibranor and the review of the submission to the EMA's Committee for Medicinal Products for Human Use (CHMP) began on 26 October 2023. Furthermore, a third simultaneous regulatory filing of elafibranor has been validated for review by the UK Medicines and Healthcare products Regulatory Agency (MHRA).

"We are delighted to have achieved simultaneous filings for elafibranor, which is in line with our ambition to be able to bring a new and much needed medicine to as many people living with PBC as rapidly as possible," said Christelle Huguet, EVP and Head of Research & Development, Ipsen. "This is a condition where many patients are living with worsening disease and debilitating symptoms despite being on treatment. Elafibranor, if approved, has the potential to change the management of this challenging condition for people living with PBC, offering a new second line treatment choice, where the number of effective options are currently limited."

PBC is a rare, progressive, autoimmune cholestatic liver disease[1] in which bile ducts in the liver are gradually destroyed.[2] The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue, known as cirrhosis.[1,2,3] Common symptoms of PBC include fatigue and pruritus (itch), which can be severely debilitating.[4] Untreated, PBC can lead to liver failure, or in some cases death.[1] It primarily affects women, with nine women diagnosed for every man.[3] A significant proportion of people living with PBC do not benefit from existing therapies.[5,6,7]

"These simultaneous regulatory submission acceptances are another important step in the elafibranor journey. We are pleased to be partnering with Ipsen, who we know has a good understanding of the rare-disease regulatory process," said Pascal Prigent, Chief Executive Officer of GENFIT. "We know they share the same goal as GENFIT, to bring a new, much needed treatment option to people living with PBC as fast as possible; we look forward to elafibranor's progress through the regulatory review processes."

ENDS

Elafibranor

Elafibranor is an oral, once-daily, dual peroxisome activated receptor (PPAR) alpha/delta (α,δ) agonist, currently under investigation as a treatment for patients with PBC, a rare cholestatic liver disease. Elafibranor, through activation of PPAR α,δ targets multiple cell types and biological processes involved in the pathophysiology of PBC, including cholestasis (impairment of bile flow in the liver), bile toxicity, inflammation and fibrosis and bile acid output. In 2019, elafibranor was granted a Breakthrough Therapy Designation by the U.S Food and Drug Administration in adults with PBC who have an inadequate response to ursodeoxycholic acid (UDCA) the existing first-line therapy for PBC. Elafibranor has not received approval by regulatory authorities anywhere in the world.

ELATIVE

ELATIVE is a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial, with an open-label long-term extension (NCT04526665). ELATIVE evaluated 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 UDCA. The trial enrolled 161 patients who were randomized 2:1 to receive either 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. Data confirmed the potential for elafibranor to be an effective new treatment option for PBC, with 13 times more patients achieving a biochemical response, suggesting an improvement in disease progression, when treated with elafibranor compared with patients on placebo: 47% placebo-adjusted difference, elafibranor 80mg (51%) compared with placebo (4%) ($P<0.001$).[8]

Reductions in levels of alkaline phosphatase (ALP) were rapid, seen as early as Week 4 in the elafibranor group, and were sustained through Week 52, with a decrease in ALP of 41% on elafibranor compared with placebo.[8] ALP and bilirubin are important predictors of PBC disease progression. ELATIVE also investigated the effect of treatment with elafibranor on pruritus (severe itch), a significant symptom burden amongst people living with PBC. Findings from the secondary endpoint using the PBC Worst Itch NRS score, showed a reduction in pruritis for elafibranor, which was not statistically significant. Data reported from two separate patient-reported outcome measures demonstrated reductions in moderate to severe pruritus, which favored elafibranor versus placebo.[8] Elafibranor was well-tolerated in the trial and has a well-documented safety profile. Adverse events occurring in >10% of patients and more frequently on elafibranor versus placebo included abdominal pain, diarrhea, nausea, and vomiting.[8]

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 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.

GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Today, GENFIT has a growing and diversified pipeline with programs at various development stages. The Company's area of focus is Acute on Chronic Liver Failure (ACLF). Its ACLF franchise consists of five assets in development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE. These are all based on differentiated mechanisms of action leveraging complementary pathways. Other assets target other life-threatening disease indications such as cholangiocarcinoma (CCA) and Urea Cycle Disorders (UCD)/Organic Acidemias (OA). GENFIT's track record

in bringing early-stage assets with high potential to late development and pre-commercialization stages is highlighted in the successful 52-week Phase 3 ELATIVE® trial evaluating elafibranor in PBC. Beyond therapeutics, GENFIT's pipeline also includes a diagnostic franchise focused on MASH (previously known as NASH) and ammonia. GENFIT has facilities in Lille and Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. For more information, visit www.genfit.com

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Ipsen 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; 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.

GENFIT Forward-Looking Statements

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about the potential of elafibranor as a safe and effective second-line treatment for PBC, the opportunity to manage the disease progression and the potential of elafibranor to improve pruritus, reduce cholestatic injury and improve liver function. The use of certain words, including "believe", "potential," "expect", "target", "may" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown risks and uncertainties, which could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, among other things, the uncertainties inherent in research and development, including in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, potential commercial success of elafibranor if approved, exchange rate fluctuations, our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023, which is available on the Company's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC") including the Company's 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023 and subsequent filings and reports filed with the AMF or SEC, including the Half-Year Business and Financial Report at June 30, 2023 or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.

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