PRESS RELEASE

Ipsen and GENFIT enter into exclusive licensing agreement for elafibranor, a Phase III asset evaluated in Primary Biliary Cholangitis, as part of a long-term global partnership

- Agreement gives Ipsen global* rights to develop and commercialize GENFIT's late-stage, first-in-class PPAR alpha and delta agonist elafibranor in Primary Biliary Cholangitis (PBC)
- Investigational treatment elafibranor being evaluated in the global Phase III trial, ELATIVE™, with topline data expected early 2023
- GENFIT receives €120m upfront and is eligible to receive up to €360m in milestone payments as well as tiered double-digit royalties of up to 20%
- Ipsen becomes 8% shareholder of GENFIT via an equity investment of €28m

Paris (France), 17 December 2021 – Ipsen (Euronext: IPN; ADR: IPSEY) and GENFIT (Nasdaq and Euronext: GNFT) have entered into a long-term strategic partnership for global collaboration between the two companies. The agreement gives Ipsen exclusive worldwide* license to develop, manufacture and commercialize GENFIT's investigational treatment elafibranor, for people living with Primary Biliary Cholangitis (PBC). The partnership also gives Ipsen access to future clinical programs led by GENFIT and combines GENFIT's scientific expertise and proprietary technologies in liver disease with Ipsen's development and commercialization capabilities. To underscore the long-term commitment represented by this partnership, Ipsen will also purchase newly issued GENFIT equity representing 8% post-issuance through a €28m investment in GENFIT, becoming one of the largest shareholders.

The ongoing, pivotal Phase III global trial, ELATIVE™,[1] is evaluating the safety and efficacy of elafibranor in 150 people living with PBC who have an inadequate response or intolerance to ursodeoxycholic acid (UDCA). Global recruitment is well underway. There is significant unmet medical need for people with PBC and, following positive Phase II data,[2] elafibranor was granted Breakthrough Therapy Designation by the U.S Food and Drug Administration (FDA) and Orphan Drug Designation by the U.S. FDA and European Medicines Agency (EMA).[3,4] Results from the Phase II randomized double-blind, placebo controlled trial found that after 12 weeks of dosing with elafibranor, patients with PBC unresponsive to UDCA experienced significantly reduced levels of disease-activity markers including alkaline phosphatase (ALP) and composite endpoints with bilirubin as well as other markers of disease activity when compared to placebo.[2]

David Loew, Chief Executive Officer, Ipsen, said "Today's announcement marks an exciting new stage in Ipsen's ambitions to expand our portfolio to support more people living with rare diseases around the world. We are excited by elafibranor's data package, demonstrating the potential benefit of this first-in-class, innovative treatment option to help the PBC community. We look forward to the results of the ongoing Phase III program and regulatory submissions around the world to bring this potential new treatment option to patients. Ipsen is pleased to partner with GENFIT, a company that shares our common values and goals of bringing to market first-in-class treatments to improve the lives of people living with rare conditions like PBC."

Pascal Prigent, Chief Executive Officer of GENFIT added: "We are excited to partner with Ipsen and launch this long-term strategic collaboration, with the goal to accelerate our growth and generate value for our shareholders. Ipsen's world-class development capabilities, well-established global commercial footprint and excellent track record in delivering therapies to patient populations with unmet medical need makes it the ideal partner for GENFIT. Today's landmark agreement demonstrates our ability to advance highly promising assets

* With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor.

into late-stage development in-house and derive significant value. While we hope, above all, that this partnership with Ipsen will be a significant step towards having a positive impact on the lives of millions of patients suffering from life-threatening liver diseases, we also believe our shareholders will recognize the benefit offered by this collaboration model. The transaction proceeds indeed reinforce GENFIT's long-term financial visibility, including further funding for GENFIT to expand its pipeline, and they also provide opportunities for targeted business development, as exemplified by today's other announcement regarding our in-licensing of a new molecule."

PBC is a rare, progressive, chronic autoimmune disease of the liver.[5] Bile is a liquid produced inside the liver that is used to help digest fats and remove waste products from the body.[6] PBC leads to a slow, progressive destruction of the small bile ducts of the liver, causing bile and other toxins to build up in the liver (known as cholestasis).[5] Further damage can lead to scarring, fibrosis and eventually cirrhosis of the liver.[5] Common symptoms of PBC include fatigue and pruritus' (itching) which can be debilitating and, in more advanced cases, jaundice.[5] Untreated, PBC can lead to liver failure, or in some cases death. PBC is more common in women with nine women diagnosed for every man; it is also a leading cause of liver transplantation.[5]

GENFIT remains responsible for the Phase III ELATIVE™ trial until the completion of the double-blind period. Ipsen will assume responsibility for all additional clinical development, including completion of the long-term extension period of the ELATIVE™ trial, and global* commercialization. This newly established strategic partnership will also provide Ipsen with access to GENFIT's research capabilities and other clinical programs through rights to first negotiation.

Under the agreement, Ipsen will pay GENFIT up to €480m, comprising upfront cash payment of €120m, as well as regulatory, commercial, and sales-based milestone payments up to €360m, plus tiered double-digit royalties of up to 20%. Ipsen also becomes a shareholder of GENFIT through the purchase of 3,985,239 newly issued shares representing 8% of GENFIT S.A after issuance, via a €28m investment. The new shares will be issued pursuant to the twentieth resolution of GENFIT's 30 June 2021 shareholders' meeting and will be subject, upon issuance, to a lock-up period ending, in the event of positive ELATIVE ™ results, on the earlier of the date on which the EMA makes a formal recommendation to the European Commission for the marketing authorisation of elafibranor in PBC or the date on which the U.S. FDA grants approval of elafibranor in PBC. Issuance of the new shares is expected to take place on or about December 22, 2021. In addition, the Board of Directors of GENFIT will propose at the next shareholders' meeting that Ipsen becomes a board member.

The transaction is expected to be dilutive to Ipsen's profitability over the near term, primarily reflecting R&D and launch-preparation expenses. This is in line with Ipsen's medium-term outlook regarding its strategic focus on building a high-value and sustainable pipeline through external innovation.

Conference call

A conference call and webcast for investors and analysts will begin at 14:30 CET today. Participants should dial in to the call early and can register here; a recording will be available on ipsen.com, while the webcast can be accessed here. The event ID is 7296852.

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Primary Biliary Cholangitis

Primary biliary cholangitis (PBC) is a chronic, autoimmune disease in which bile ducts in the liver are gradually destroyed. 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. PBC is a disease with high unmet medical needs, with many patients unable to benefit from existing therapies. The prevalence of people living with PBC in the US is estimated to be between 23.9-39.2 per 100,000.[7,8]

Elafibranor

Elafibranor, GENFIT's lead therapeutic candidate, is currently under evaluation in ELATIVE™, a Phase III clinical trial to evaluate its efficacy and safety in patients with PBC. Elafibranor is an oral, once-daily, first-in-class drug candidate acting via dual agonism of peroxisome proliferator-activated alpha/delta receptors. Data from a Phase II clinical trial demonstrated elafibranor has the potential to become an efficacious treatment in PBC, a rare liver disease. It was granted a Breakthrough Therapy designation by the FDA in this indication. Elafibranor is an investigational compound that has not been reviewed nor received approval by a regulatory authority.

ELATIVE™ Program
ELATIVE™ is a Phase III clinical trial evaluating the safety and efficacy of elafibranor 80mg versus placebo in 150 patients with Primary Biliary Cholangitis (PBC) with an inadequate response to ursodeoxycholic acid (UDCA), which is the existing first line therapy for PBC. ELATIVE™ is a multicenter, randomized, double blind study to evaluate the efficacy and safety of elafibranor versus placebo. Treatment duration until interim analysis for accelerated approval is 52 weeks. Top line data is expected in between the end of the first quarter and the middle of the second quarter 2023.

Ipsen
Ipsen is a global, mid-sized biopharmaceutical company focused on transformative medicines in Oncology, Rare Disease and Neuroscience; it also has a well-established Consumer Healthcare business. With Total Sales of over €2.5bn in FY 2020, Ipsen sells more than 20 medicines in over 115 countries, with a direct commercial presence in more than 30 countries. The Company's research and development efforts are focused on its innovative and differentiated technological platforms located in the heart of leading biotechnological and life-science hubs: Paris-Saclay, France; Oxford, U.K.; Cambridge, U.S.; Shanghai, China. Ipsen has c.5,700 colleagues worldwide and 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 severe chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. Today, GENFIT has a robust and diversified pipeline, using different compounds and technologies evaluated at different development stages and in different liver diseases. Leveraging its internal assets and in-house expertise, GENFIT's R&D is focused on cholestatic diseases and Acute on Chronic Liver Failure (ACLF): two therapeutic areas with significant unmet medical needs. Currently, the ELATIVE™ Phase III clinical trial evaluating elafibranor (elafibranor is an investigational compound that has not been reviewed nor been approved by a regulatory authority) in patients with Primary Biliary Cholangitis (PBC). A Phase I clinical program with nitazoxanide in ACLF has been initiated. GENFIT has facilities in Lille and Paris, France, 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). www.genfit.com

Ipsen contacts

Investors

Craig Marks
Vice President, Investor Relations
+44 7584 349 193

Adrien Dupin de Saint-Cyr
Investor Relations Manager
+33 6 64 26 17 49

Media

Jess Smith
Senior Director, Head of Global Communications R&D and Business Development
+44 7557 267 634

Fanny Allaire
Global Communications Director
+ 33 6 08 91 92 55

GENFIT contacts

GENFIT | Investors
Tel: +33 3 2016 4000 | investors@genfit.com

PRESS RELATIONS | Media
Stephanie Boyer – Press relations | Tel: +33 3 2016 4000 | stephanie.boyer@genfit.com

Ipsen's 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 product 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 products 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 product in which it has invested significant sums. Therefore, Ipsen cannot be certain that favorable results obtained during pre-clinical 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 product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product 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 health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product 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 products; 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 products 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 2020 Registration Document, available on ipsen.com.

GENFIT's forward-looking statements

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential of elafibranor in PBC and the success of the ELATIVE™ trial, including financial success, timelines for release of top-line results of the ELATIVE™ trial, and our ability to expand our pipeline through business development activities. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, impact of the ongoing COVID-19 pandemic, exchange rate fluctuations and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French Autorité des Marchés Financiers ("AMF"), including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2020 Universal Registration Document filed with the AMF on 23 April 2021 under n° D.21-0350, 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 2020 Annual Report on Form 20-F filed with the SEC on April 23, 2021 and subsequent filings and reports filed with the AMF or SEC, 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.

References

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