PRESS RELEASE

GENFIT: Historic Milestone Achieved with U.S. FDA Accelerated Approval of Ipsen's Iqirvo® for Primary Biliary Cholangitis

- **Ipsen's Iqirvo® (elafibranor) 80 mg tablets receives U.S. FDA accelerated approval as a first-in-class treatment for Primary Biliary Cholangitis (PBC)**
- **First-ever drug developed in-house by GENFIT to achieve U.S. FDA's approval**
- **GENFIT is eligible to receive a €48.7 million milestone payment from Ipsen upon the first commercial sale of Iqirvo in the U.S., as well as tiered double-digit royalties of up to 20%**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), June 10, 2024 - **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced the achievement of a historic corporate milestone: the U.S. Food and Drug Administration (FDA) accelerated approval of Iqirvo[1] (elafibranor)[2] 80 mg tablets – as unveiled today by Ipsen (Euronext: IPN; ADR: IPSEY) – as a first-in-class treatment for PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA.

Elafibranor will be marketed and commercialized by Ipsen under the trademark Iqirvo and may be prescribed immediately in the U.S. for eligible patients.

This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Iqirvo is not recommended for people who have or who develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy).

Pascal Prigent, CEO of GENFIT, commented: *"This approval is a source of pride for all GENFIT employees. We took elafibranor (Iqirvo) all the way from drug discovery to the end of Phase 3 and now, thanks to our partnership with Ipsen, it will be made available to healthcare providers in the US and ultimately provide patients with a valuable therapeutic alternative. The upcoming launch is both a major*

[1] Iqirvo® and ELATIVE® are registered trademarks.
[2] In December 2021, Ipsen acquired global rights to develop and commercialize the molecule (except for China, Hong Kong, Taiwan, and Macau, where Terns Pharmaceuticals holds the exclusive license to develop and market elafibranor)

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

achievement and the beginning of a new chapter, as we expect that the revenues derived from the commercialization of elafibranor will now finance the development of a new and exciting portfolio of programs focused on ACLF."

In 2024, as previously communicated, GENFIT expects to receive total milestone payments from Ipsen of approximately €89 million, including €48.7 million upon the first commercial sale of Iqirvo in the U.S., and a €13.3 million milestone payment which was invoiced in December 2023, and received in February 2024.

These revenues present GENFIT with new financial opportunities and will help to finance our strategic pivot towards Acute on-Chronic Liver Failure (ACLF) and other liver diseases.

ENDS

IMPORTANT SAFETY INFORMATION

Myalgia, Myopathy, and Rhabdomyolysis: Rhabdomyolysis resulting in acute kidney injury occurred in one IQIRVO-treated patient who had cirrhosis at baseline and was also taking a stable dose of an HMG-CoA reductase inhibitor (statin). Myalgia or myopathy, with or without CPK elevations, occurred in patients treated with IQIRVO alone or treated concomitantly with a stable dose of an HMG-CoA reductase inhibitor. Assess for myalgia and myopathy prior to IQIRVO initiation. Consider periodic assessment (clinical exam, CPK measurement) during treatment with IQIRVO, especially in those who have signs and symptoms of new onset or worsening of muscle pain or myopathy. Interrupt IQIRVO treatment if there is new onset or worsening of muscle pain, or myopathy, or rhabdomyolysis.

Fractures: Fractures occurred in 7% of IQIRVO-treated patients compared to 0% in placebo-treated patients. Consider the risk of fracture in the care of patients treated with IQIRVO and monitor bone health according to current standards of care.

Adverse Effects on Fetal and Newborn Development: IQIRVO may cause fetal harm when administered during pregnancy. For females of reproductive potential, verify that the patient is not pregnant prior to initiation of therapy. Advise females of reproductive potential to use effective non-hormonal contraceptives or add a barrier method when using systemic hormonal contraceptives during treatment with IQIRVO and for 3 weeks following the last dose of IQIRVO.

Drug-Induced Liver Injury: Suspected drug-induced liver injury occurred in one patient who took IQIRVO 80 mg once daily and two patients who took IQIRVO at 1.5-times the recommended dosage, of which one presented with autoimmune-like hepatitis. The median time to onset of elevation in liver tests was 85 days. Obtain baseline clinical, laboratory and imaging assessments at treatment initiation with IQIRVO and monitor thereafter according to routine patient management. Interrupt IQIRVO treatment if liver tests (ALT, AST, total bilirubin [TB], and/or

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

alkaline phosphatase [ALP]) worsen, or the patient develops signs and symptoms consistent with clinical hepatitis (e.g., jaundice, right upper quadrant pain, eosinophilia). Consider permanent discontinuation if liver tests worsen after restarting IQIRVO.

Hypersensitivity Reactions: Hypersensitivity reactions have occurred in a clinical trial with IQIRVO at 1.5-times the recommended dosage. Three patients (0.2%) had rash or unspecified allergic reaction that occurred 2 to 30 days after IQIRVO initiation. Hypersensitivity reactions resolved after discontinuation of IQIRVO and treatment with steroids and/or antihistamines. If a severe hypersensitivity reaction occurs, permanently discontinue IQIRVO. If a mild or moderate hypersensitivity reaction occurs, interrupt IQIRVO and treat promptly. Monitor the patient until signs and symptoms resolve. If a hypersensitivity reaction recurs after IQIRVO rechallenge, then permanently discontinue IQIRVO.

Biliary Obstruction: Avoid use of IQIRVO in patients with complete biliary obstruction. If biliary obstruction is suspected, interrupt IQIRVO and treat as clinically indicated.

Drug-Drug Interactions
IQIRVO may reduce the systemic exposure of progestin and ethinyl estradiol (CYP3A4 substrates), which may lead to contraceptive failure and/or an increase in breakthrough bleeding. Switch to effective non-hormonal contraceptives or add a barrier method when using hormonal contraceptives during treatment with IQIRVO and for at least 3 weeks after last dose.

CPK elevation and/or myalgia occurred in patients on IQIRVO monotherapy. Co-administration of IQIRVO and HMG-CoA reductase inhibitors can increase the risk of myopathy. Monitor for signs and symptoms of muscle injury. Consider periodic assessment (clinical exam, CPK) during treatment. Interrupt IQIRVO treatment if there is new onset or worsening of muscle pain or myopathy.

Co-administration of IQIRVO with rifampin, an inducer of metabolizing enzymes, may reduce the systemic exposure of elafibranor resulting in delayed or suboptimal biochemical response. Monitor the biochemical response (e.g., ALP and bilirubin) when patients initiate rifampin during treatment with IQIRVO.

Bile acid sequestrants may interfere with IQIRVO absorption and systemic exposure, which may reduce efficacy. Administer IQIRVO at least 4 hours before or after a bile acid sequestrant, or at as great an interval as possible.

Use in Special Populations
Pregnancy: Based on data from animal reproduction studies, IQIRVO may cause fetal harm when administered during pregnancy. There are insufficient data from human pregnancies exposed to IQIRVO to allow an assessment of a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Report pregnancies to Ipsen Pharmaceuticals, Inc. Adverse Event reporting line at 1-855-463-5127 or https://www.ipsen.com/contact-us/.

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

Lactation: There are no data available on the presence of IQIRVO or its metabolites in human milk, or on effects of the drug on the breastfed infant or the effects on milk production. IQIRVO is not recommended during breastfeeding and for at least 3 weeks following last dose of IQIRVO because the risk to breastfed child cannot be excluded.

Females and Males of Reproductive Potential: IQIRVO may cause fetal harm when administered to pregnant women. Verify the pregnancy status of females of reproductive potential prior to initiating IQIRVO. Advise females of reproductive potential to use effective contraception during treatment with IQIRVO and for 3 weeks after the final dose.

The most common adverse events occurring in ≥10% of patients were weight gain (23%), abdominal pain (11%), nausea (11%), vomiting (11%), and diarrhea (11%).

You are encouraged to report side effects to FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Ipsen Pharmaceuticals at 1-855-463-5127.

Please see full Prescribing Information for IQIRVO.

ABOUT IQIRVO

Iqirvo (pronounced EYE-KER-VO) is an oral, once-daily, peroxisome proliferator-activated receptor (PPAR) agonist indicated 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. While the mechanism is not well understood, pharmacological activity that is potentially relevant to Iqirvo therapeutic effects includes inhibition of bile acid synthesis through activation of PPAR-alpha and PPAR-delta. 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 has not received approval by regulatory authorities outside of the U.S. Iqirvo is currently under regulatory review with the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). Iqirvo was discovered and developed by GENFIT and Ipsen licensed the exclusive worldwide rights (except China, Hong Kong, Taiwan and Macau) to elafibranor from GENFIT in 2021.

Iqirvo has been granted approval under the FDA accelerated approval program, which allows for approval of medicines that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. Under the program, Ipsen is required to conduct a trial to confirm anticipated clinical benefit. The confirmatory trial for Iqirvo, ELFIDENCE, is ongoing.

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

Iqirvo is a 80 mg tablet administered orally once daily. To ensure access to Iqirvo for eligible individuals in the U.S., the IPSEN CARES® patient support program is available as a resource to people living with PBC and their caregivers to provide educational support and address coverage, access and reimbursement questions (1-866-435-5677).

ABOUT THE PHASE III ELATIVE® TRIAL

ELATIVE[1] is a multi-center, randomized double-blind, placebo-controlled Phase III clinical trial (n=161) that evaluated the efficacy and safety of Iqirvo 80mg once daily plus UDCA (n=108) versus placebo plus UDCA (n=53). Iqirvo or placebo was administered in combination with UDCA in 95% of patients and as monotherapy in 5% of patients who were unable to tolerate UDCA. The 52-week study was completed by 92% of participants with 97% of those who completed the study continuing in an extension study. The results were published in the *New England Journal of Medicine*[3].

- The ELATIVE trial demonstrated that Iqirvo had a statistically significant treatment benefit with 51% of patients on Iqirvo achieving a biochemical response compared with 4% on the placebo arm, a treatment benefit of 47% (95% CI 32, 57; p<0.0001). Biochemical response was defined as ALP less than 1.67 Upper Limit of Normal (ULN), an ALP decrease of greater than or equal to 15% from baseline and total bilirubin (TB) ≤ ULN at week 52.
- ALP normalization at week 52 was a key secondary endpoint with 15% of Iqirvo-treated patients demonstrating normalization versus 0% placebo (p=0.002).
- The significant biochemical response to Iqirvo was further supported by data demonstrating reductions from baseline in ALP levels were sustained through week 52 and response was rapid, seen as early as Week 4 in the Iqirvo group.
- The most common adverse reactions with Iqirvo reported in ≥ 10% of study participants were weight gain, abdominal pain, diarrhea, nausea and vomiting.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades. Today, GENFIT has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Other assets target other serious diseases, such as cholangiocarcinoma

[3] Kowdley. K.V, et al. Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis. NEJM. 2023. DOI: 10.1056/NEJMoa2306185

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

(CCA), urea cycle disorder (UCD) and organic acidemia (OA). GENFIT's expertise in the development of high-potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated with the success of the 52-week Phase 3 ELATIVE® study evaluating elafibranor in Primary Biliary Cholangitis (PBC). Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels. GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Nasdaq Global Select Market and on the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

ABOUT IPSEN

Ipsen is a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience. Ipsen's 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. Its teams in more than 40 countries and its partnerships around the world enable Ipsen to bring medicines to patients in more than 80 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.

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 future development and commercialization of IQIVRO® by Ipsen, sales thereof and financial projections regarding milestones and royalty payments that GENFIT anticipates receiving. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" 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 others, 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, and our

PRESS RELEASE

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 "Risk Factors and Internal Control" of the Company's 2023 Universal Registration Document filed on April 5, 2024 (no. D.24-0246) with the *Autorité des marchés financiers* ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024 and subsequent filings and reports filed with the AMF or SEC or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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.

CONTACT

GENFIT | Investors

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

PRESS RELATIONS | Media

Stephanie Boyer – Press relations | Tel: +333 2016 4000 | stephanie.boyer@genfit.com