PRESS RELEASE

GENFIT Updates 2024 Outlook Following Acceptance of Elafibranor Filings in Primary Biliary Cholangitis (PBC)

- **US Food and Drug Administration (FDA) has granted Priority Review for New Drug Application (NDA) for elafibranor in PBC, and European Medicine Agency (EMA) has also validated the Marketing Authorization Application (MAA) for elafibranor.**
- **Acceptance triggers a first milestone payment. Further milestones are expected upon US and European launches which could now happen in 2Q24 in the US (FDA PDUFA[1] action date: June 10, 2024) and 2H24 in Europe. These milestones total approximately 89M€.**
- **Launches in the US and Europe will also make GENFIT eligible for royalty payments.**
- **Revenues will fund the development of GENFIT's pipeline, now mainly focused on Acute On-Chronic Liver Failure (ACLF) with 5 differentiated assets.**

Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), December 8, 2023 – **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 announces its revised outlook for 2024 and reflects on recent progress.

Elafibranor in PBC

Ipsen has made significant progress since the announcement of positive interim data of ELATIVE® pivotal Phase 3 trial in June 2023:

- Strong leadership presence at AASLD The Liver Meeting® and additional results from ELATIVE® presented as late breaker, including data showing statistically significant improvement (nominal p-value < 0.05) on multidimensional measures of pruritus (PBC-40 and 5D-itch scores)
- Publication of ELATIVE® Phase 3 data in the *New England Journal of Medicine*
- Regulatory filing acceptance obtained in the US, Europe and United Kingdom[2] in less than 6 months after topline Phase 3 data, and Priority Review granted for NDA by the US FDA with PDUFA target action date on June 10, 2024

During its Capital Market Day on December 7, Ipsen reiterated its confidence in elafibranor as its profile could be very beneficial for patients suffering from PBC. In the ELATIVE® Phase 3 trial, significant treatment benefit in the primary composite endpoint was achieved with elafibranor, with a high responder rate, and a low placebo effect[3]. The key secondary endpoint on ALP normalization was achieved – despite a high baseline ALP level – with high statistical significance, the pruritus

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

improvements on PBC-40 and 5D-itch scores were also statistically significant[4] and elafibranor was generally well-tolerated with a well-documented safety profile consistent with previous trials.

Acceptance of filings in the US and Europe have triggered the first milestone payment for GENFIT. We also expect additional milestones after US and European launches and as a result should receive a total of approximately 89M€ by the end of next year. Ipsen also indicated that they were expecting global peak sales to exceed 500M€ for elafibranor in PBC. With eligibility for tiered double-digit royalties under the agreement with Ipsen, this could mean a very significant revenue stream for GENFIT based on these royalties and additional milestone payments.

Ipsen also indicated that it is developing elafibranor in Primary Sclerosing Cholangitis (PSC) which could lead to further revenues for GENFIT under the licensing agreement.

Pascal Prigent, CEO of GENFIT, commented: *"We continue to be pleased by Ipsen's commitment and results already obtained. We believe that their excellent and proven launch capabilities will allow them, once approved, to quickly bring elafibranor to the many patients that need it. I have no doubt that they will maximize the potential of elafibranor, and this will obviously be very beneficial for GENFIT as it will help us accelerate the development of our deep and promising pipeline."*

Pipeline outlook for 2024

GENFIT's R&D efforts have pivoted from chronic to acute liver diseases, with a strong focus on ACLF where the unmet medical need is very important, with currently no approved therapies. Our therapeutic candidates have been strategically selected based on the pathophysiology of ACLF to address the most relevant pathways via differentiated and complementary modes of action.

In 2024, progress is expected to be made on all programs of the ACLF franchise:

- VS-01 (liposomal-based technology designed to remove ammonia and other ACLF toxins from the blood): Phase 2 initiated with interim data readout targeted for mid-2024
- NTZ (anti-inflammatory and anti-bacterial agent aiming to reduce systemic inflammation, and impede release of PAMPs[5] and bacterial translocation): reformulation and Phase 2 under preparation in 2024 with a proof-of-concept study initiation targeted for 1H25
- SRT-015 (ASK1 inhibitor, liver-centric, aimed at inhibiting cell death, inflammation and fibrosis): first-in-Human study initiation targeted 2H24
- CLM-022 (NLRP3 inflammasome inhibitor aimed at inhibiting systemic inflammation and cell death): preclinical Proof of Concept expected to initiate in 2024

- VS-02-HE (small molecule aiming at reducing hyperammonemia, stabilizing blood ammonia and preventing hepatic encephalopathy): IND enabling studies starting in 2024 with completion expected in 2025

GENFIT also develops assets in other rare and life-threatening liver diseases with high unmet medical needs:

- GNS561 for cholangiocarcinoma (CCA): Phase 1b interim biomarker data targeted as early as 1H24
- VS-01 for Urea Cycle Disorders (UCDs) and Organic Acidemias (OA): IND enabling non clinical studies completion expected in 2024

ABOUT 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.

ABOUT ELATIVE®

ELATIVE is a multi-center, randomized, double-blind, placebo-controlled Phase 3 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%) ($P<0.001$).

ABOUT ACLF

PRESS RELEASE

ACLF presents as a syndrome defined by a combination of hepatic and extrahepatic organ dysfunctions and failures and a uniformly poor prognosis. In patients with liver cirrhosis and acute hepatic decompensation, ACLF can be triggered by a precipitating event (e.g., an infection) that leads to a progressive functional deterioration of multiple organs with high short-term mortality (23% to 74% mortality at 28 days)[6].

ACLF represents a significant cost of care for healthcare systems, as it is characterized by an abrupt life-threatening worsening of a preexisting advanced chronic liver disease resulting in acute liver decompensation, liver failure and extrahepatic organ failure. With a $52k average cost per hospitalization per patient in the US and a 16-day average length of hospital stay, estimated annual cost burden in the US was $6.4bn in 2021, a nearly 4-fold increase since 2011[7].

ABOUT 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 Metabolic dysfunction-associated steatohepatitis (MASH) previously known as nonalcoholic steatohepatitis (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

FORWARD LOOKING STATEMENTS

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

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 to receive marketing authorization in the United States, Europe and United Kingdom for PBC, expected milestone and royalty payments for elafibranor in PBC, Ipsen's expectations regarding global peak sales for elafibranor in PBC, Ipsen's ability to effectively maximize commercialization of elafibranor and the ability of GENFIT to receive revenues related to development and future commercialization of elafibranor in PSC and 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.

CONTACT

GENFIT | Investors

GENFIT
TOWARDS BETTER MEDICINE

PRESS RELEASE

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

PRESS RELATIONS | Media

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

[1] Prescription Drug User Fee Act
[2] https://ir.genfit.com/news-releases/news-release-details/ipsen-confirms-us-fda-grants-priority-review-new-drug
[3] a 47% placebo-adjusted difference (P<0.001) between patients on elafibranor 80mg (51%) compared with patients on placebo (4%) achieving a biochemical response
[4] nominal p-value < 0.05
[5] pathogen-associated molecular pattern molecules
[6] Arroyo V et al., Nat. Rev. Dis. Primers 2 (2016)
[7] IQVIA presentation GENFIT's ACLF Day Nov 2023