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GENFIT: new market research data highlight potential of elafibranor in PBC

- **Insights from Pr. Sven Francque and Dr. Kris V. Kowdley on PBC, a chronic, cholestatic, autoimmune liver disease with high unmet medical needs despite available therapies**
- **Peak sales for elafibranor as potential second line treatment for PBC estimated at $515 million in 2035 on a total market of $1.5bn in 2035 according to research commissioned by GENFIT from IQVIA**

Lille, France; Cambridge, MA; February 22, 2021 - **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and liver diseases**,** today discusses the highlights from its KOL Analyst Event on Primary Biliary Cholangitis (PBC), the therapeutic landscape and commercial opportunity. The event focused on GENFIT's new priority program. It provided KOL insights on PBC, details on GENFIT's Phase 2 data recently published in the *Journal of Hepatology*, highlights on the ongoing ELATIVE™ Phase 3 clinical trial, and projections on elafibranor's commercial opportunity. The PBC KOL analyst event replay can be accessed here.

Pascal Prigent, CEO of GENFIT, commented: *"GENFIT has completed its restructuring efforts and we are now implementing our new corporate strategy announced last fall. R&D is focused on several key priority programs that we will present in more detail this summer. We have significantly reduced our cash burn from operations with a goal to reach roughly 50% of our 2020 cash burn in 2022, and with a 40% workforce reduction, we are a leaner organization with a specialty focus. We have renegotiated our debt which is less than half of what it was and is rescheduled to be due at the end of 2025. We are now fully committed to the successful execution of our PBC program and in particular our ELATIVE™ Phase 3 trial which began 5 months ago. In this context we felt it was useful to have an in-depth presentation of this exciting opportunity."*

What is PBC?

PBC is a severe chronic, cholestatic, autoimmune liver disease causing injury to the intrahepatic bile ducts, resulting in liver injury and cirrhosis. There is no known cure for PBC, and at present there are only two approved treatment options for first or second line treatment. The disease symptoms – pruritus and fatigue – are not addressed by existing therapies and ~40% of patients

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are non or partial responders to first line therapy[1], resulting in a highly underserved patient population.

Pr. Sven Francque, Chairman of the Department of Gastroenterology and Hepatology of the University Hospital Antwerp, commented: "*PBC is a serious liver disease, and unfortunately, we still see patients who inevitably progress to later stages, developing decompensated cirrhosis and requiring a liver transplant, confirming the significant need for novel PBC therapies. Clinical studies have demonstrated that PPAR alpha and PPAR delta agonists have positive effects on PBC patients. Elafibranor activates both PPAR alpha and delta simultaneously, therefore we can hypothesize a synergistic effect to potentially enhance the positive outcome in PBC patients.*"

Dr. Kris V. Kowdley, Director, Liver Institute Northwest, Clinical Professor Elson S. Floyd College of Medicine, Washington State University added: *"PBC can be a debilitating disease with a profound impact on a patient's quality of life. As one of my patients explained during the call, the most difficult symptom remains pruritus, a severe itching causing extreme discomfort which is experienced as a real burden. Finding a treatment that could halt the progression of the disease and concurrently improve symptoms would address many of the existing challenges faced by patients with PBC."*

PBC Commercial Opportunity

PBC represents a significant market opportunity for GENFIT as the disease has a clear regulatory pathway and is well understood by payors and KOLs. IQVIA, a recognized leader in research and consulting services for the pharmaceutical industry, was commissioned by GENFIT to conduct three comprehensive market research studies evaluating the potential market opportunity, should it be granted regulatory approval, of elafibranor as a second line treatment.

The total PBC market is estimated to reach $1.5 billion annually in 2035, and elafibranor, if approved, could achieve $515 million in peak year revenue, as second line treatment for patients with PBC that cannot benefit from the first line therapy.

Julien Perrier, VP Global Account at IQVIA, commented: "*It is estimated that 90,000 patients could be treated with elafibranor by 2030, if approved. Our payer and KOL research, based on a robust methodology involving 28 KOLs, 240 healthcare professionals and 15 US and EU payors, showed that elafibranor is considered to have the potential for a strongly differentiated profile in terms of safety, efficacy, and improvement on pruritus. Our research model, based on conservative assumptions, shows*

[1] Lindor, K. D., Bowlus, C. L., Boyer, J., Levy, C., & Mayo, M. (2018). Primary Biliary Cholangitis: 2018 Practice Guidance from the American Association for the Study of Liver Diseases. Hepatology, 394-419. https://doi.org/10.1002/hep.30145

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that elafibranor's profile could potentially justify a market penetration of ~32% in the United States and ~22% in the EU in 2035."

Upcoming Investor Events

- Following this PBC KOL event, GENFIT will be taking part in the SVB Leerink 10th Annual Global Healthcare Conference from Feb 22 to 26, with a fireside chat scheduled on February 24 from 10:40 am EST to 11:10 am EST.
- GENFIT will also be taking part in the H.C. Wainwright Global Life Sciences Conference on March 9 and 10, with a recorded fireside chat to be made available on March 9.

ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with cholestatic and metabolic 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. GENFIT is currently enrolling in ELATIVE™, a Phase 3 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC). Elafibranor is an investigational compound that has not been reviewed and has not received approval by any regulatory authority. As part of GENFIT's comprehensive approach to clinical management of patients with liver disease, the Company is also developing NIS4™, a new, non-invasive blood-based diagnostic technology which could enable easier identification of patients with at-risk NASH. NIS4™ technology has been licensed to LabCorp in the U.S. and Canada for the development and commercialization of a blood-based molecular diagnostic test powered by NIS4™ technology. 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

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, with respect to GENFIT, including statements regarding our expected future performance, business prospects, financial perspective, corporate strategy, events and plans, including timing ability to meet clinical, regulatory and commercial milestones and timelines in our PBC program, expectations for disease prevalence, growth and size of the PBC market, including GENFIT's potential market share and revenues. 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

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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, 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 AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2019 Universal Registration Document filed with the AMF on 27 May 2020 under n° D.20-0503 and in Section 2 "Risk Factors" of the Company's Amendment to the Universal Registration Document filed with the AMF on 22 December 2020 under n° D.20-0503-A01, which are 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 2019 Annual Report on Form 20-F filed with the SEC on May 27, 2020. 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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