
PRESS RELEASE

New Clinical Data on GENFIT's Investigational Compound Elafibranor to be Presented at AASLD The Liver Meeting®

Lille, France; Cambridge, MA; November 02, 2021 - **GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases, today announced that it will be presenting new clinical data on its investigational compound elafibranor at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2021 to be held from November 12 to November 15, 2021.

The data comes following the completion of a Phase 1 open-label, non-randomized, parallel-group trial. The objectives were to assess pharmacokinetics, safety and tolerability of elafibranor in hepatic impaired patients and to inform the potential need for dose adjustment in patients with hepatic impairment.

In the study, 20 subjects with hepatic impairment and 10 healthy volunteers with normal hepatic function were given a single oral dose of elafibranor 120mg.

Elafibranor was generally safe and well tolerated in this study, which is in keeping with previously conducted studies. The pharmacokinetic data suggest that total drug exposure of elafibranor and its active metabolite are not significantly altered in hepatic impaired patients. Increases in unbound drug in severe hepatic impairment are not anticipated to be clinically meaningful. As such, elafibranor dose adjustment is not likely to be required for patients with hepatic impairment.

POSTER PRESENTATION

Title: Pharmacokinetics and Safety of Elafibranor in Subjects with Impaired Hepatic Function

Presentation type: ePoster

Poster Number: 1287

Authors: Benoit Noel et al.

Session title: Human Cholestatic and Autoimmune Liver Diseases: PBC/PSC and Other Cholestatic Disease

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ABOUT AASLD

The Liver Meeting® organized by the AASLD is one of the most important hepatology congresses for the medical and scientific community. It brings together more than 10,000 scientists, gastroenterologists and hepatologists from around the world. Due to the COVID-19 pandemic, the 2021 edition of The Liver Meeting has become The Liver Meeting Digital Experience, an online forum for the exchange of groundbreaking ideas and findings in basic, translational, and clinical research in diseases of the liver and biliary tract, and in liver transplantation.

ABOUT 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 3 clinical trial evaluating elafibranor in patients with Primary Biliary Cholangitis (PBC) is being conducted following [a successful Phase 2 clinical trial](#). Patient enrolment is anticipated to be completed in the first quarter of 2022 and topline data is expected to be announced between the end of the first quarter and the end of the second quarter 2023. A Phase 2 clinical development program is also underway with elafibranor in Primary Sclerosing Cholangitis (PSC), and a Phase 1 clinical program with nitazoxanide in ACLF has been initiated.

As part of GENFIT's comprehensive approach to clinical management of patients with liver diseases, 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. Since May 2021, Labcorp® has commercialized NASHnext™, powered by NIS4®, for use in the clinic. GENFIT also continues to explore opportunities to obtain formal marketing authorization of an in vitro diagnostic (IVD) test.

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

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ABOUT ELAFIBRANOR

Elafibranor, GENFIT's lead therapeutic candidate, is currently under evaluation in ELATIVE™, a Phase 3 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 2 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.

GENFIT 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 pharmacokinetics, safety and tolerability of elafibranor in healthy subjects and subjects with hepatic impairment, the unlikelihood of elafibranor dosage adjustment in subjects with hepatic impairment and timelines for the data readout and patient enrolment of the ELATIVE™ trial. 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

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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.

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