



PRESS RELEASE

GENFIT TO BEGIN ELAFIBRANOR CLINICAL PROGRAM IN PBC

- › **Other clinical trials to be launched in 2016:**
 - **Elafibranor in pediatric NASH**
 - **New anti-fibrotic compound in Phase 2**

Lille (France), Cambridge (Massachusetts, United States), March 31, 2016 – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a biopharmaceutical company at the forefront of developing therapeutic and diagnostic solutions in metabolic and inflammatory diseases, that notably affect the liver or the gastrointestinal system, today announced at the GENFIT R&D Event in New York City, that the Company plans to begin a second Elafibranor clinical program in 2016, targeting unmet need in the liver disease Primary Biliary Cholangitis (PBC).

GENFIT intends to begin a Phase 2 clinical trial of Elafibranor in the treatment of PBC before the end of 2016, in patients that do not tolerate or do not respond sufficiently to the standard primary treatment, with ursodeoxycholic acid (UDCA), which may occur in approximately 70% of patients. The Company will work with regulatory agencies to confirm the most appropriate trial endpoints and study design in the coming months.

GENFIT also announced its intention to launch new trials in NASH for pediatric as well as cirrhosis subpopulations. In addition, the Company provided an overview of other research programs currently in progress and/or planned.

Professor Velimir A. C. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine, Richmond, VA, USA commented: *“PBC is a rare disease that can adversely affect patients’ quality of life and survival. Since the currently approved treatment has been associated with side-effects and is ineffective in a significant proportion of patients, there is a major need for newer therapies with an improved profile.”*

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT said: *“Based upon the known mechanistic effect of PPAR alpha on bile acid metabolism, as well as positive effects seen on surrogate markers in Elafibranor clinical studies, we have decided after discussions with KOLs and Primary Biliary Cholangitis experts that PBC is the next logical target in our development plan. When it comes to NASH, we are happy to expand our investigational studies with Elafibranor, and we are confident on the drug’s ability to address further unmet needs.”*

Dean Hum, Chief Scientific Officer (CSO) of GENFIT commented: *“It was useful to share an updated overview on our pipeline today, because the work currently done by our teams in the field of gastroenterology and liver diseases is important for the future of GENFIT. NASH and Elafibranor have indeed had so much exposure recently that there have been few opportunities to shed light*



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on other research work, and related achievements. It was therefore important for us to explain the diversity of our pipeline and provide insights on our global research strategy.”

The R&D Event held on Thursday March 31, 2016, is webcast live from New York City from 8:00am – 10:00am ET and can be accessed via link at www.genfit.com.

For those not able to listen to the live broadcast, a replay will be archived for 7 days and available on www.genfit.com.

About Elafibranor:

Elafibranor (GFT505) is GENFIT’s lead pipeline product. Elafibranor is an oral once-daily treatment, and a first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways to treat nonalcoholic steatohepatitis (NASH). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers.

About PBC:

“PBC” or Primary Biliary Cholangitis, is a chronic 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.

About NASH:

“NASH”, or nonalcoholic steatohepatitis, is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also progression to liver cancer.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the discovery and development of drug candidates in areas of high unmet medical needs corresponding to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT’s R&D efforts are focused on bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH – Nonalcoholic steatohepatitis) and more generally the gastrointestinal arena. GENFIT’s approach combines novel treatments and biomarkers. Its lead proprietary compound, Elafibranor (GFT505), completed a Phase 2b study in NASH and is currently in a Phase 3 study. With facilities in Lille, France, and Cambridge, MA (USA), the Company has



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approximately 100 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT - ISIN: FR0004163111). www.genfit.com

Forward Looking Statement / Disclaimer:

This press release contains certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous 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 related to biomarkers, results of clinical data from the RESOLVE-IT trial, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding Elafibranor and biomarkers, the success of any inlicensing strategies, the Company's continued ability to raise capital to fund its development, as well as those discussed or identified in the Company's public filings with the AMF, including those listed under Section 4.2 "Risk Factors" ("Facteurs de Risque") of the Company's Annual Financial Report for the year ended December 31, 2015, which is available on GENFIT's website (www.genfit.com). Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements.

This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in GENFIT in any country. This press release has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

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