
PRESS RELEASE

GENFIT: Positive Phase 2 Results from Study of Elafibranor in Primary Biliary Cholangitis

- **Elafibranor successfully meets primary endpoint with high statistical significance of $p < 0.001$**
- **Substantial reductions in alkaline phosphatase in patients receiving elafibranor; 52% (80 mg) and 44% (120 mg) when compared to placebo**
- **Significant response rate on composite endpoint used for regulatory approval, with 67% (80 mg) and 79% (120 mg) responders vs 6.7% for placebo ($p \leq 0.001$)**
- **Potential for improved efficacy and tolerability compared to existing second-line PBC therapy, supports advancement to the next stage of development**

Lille (France), Cambridge (Massachusetts, United States), December 6, 2018 – GENFIT (Euronext: GNFT - ISIN: FR0004163111), a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases, today announced positive results from its Phase 2 study of elafibranor in patients with primary biliary cholangitis (PBC), a chronic liver disease.

This trial was a multicenter (US and Europe), double-blind, randomized, placebo-controlled, 12-week treatment, Phase 2 study to evaluate the efficacy and safety of elafibranor (80 mg and 120 mg once-daily) in adult patients with PBC who had an inadequate response to ursodeoxycholic acid (UDCA).

The primary endpoint of “Change at week 12 in serum alkaline phosphatase (ALP) from baseline” was met. Both elafibranor doses demonstrated significant decrease in mean ALP: -48% for 80 mg -41% for 120 mg with +3% increase for placebo leading to highly significant treatment effect versus placebo: -52% for 80 mg ($p < 0.001$) and -44% for 120 mg ($p < 0.001$).

A key secondary endpoint was the responder rate for patients achieving the composite endpoint of serum ALP $< 1.67 \times \text{ULN}$, an ALP decrease $> 15\%$, and total bilirubin (TB) $< \text{ULN}$. On this endpoint, elafibranor achieved the substantially higher response rates of 67% for 80 mg and 79% for 120 mg as compared to 6.7% for placebo ($p = 0.001$ and $p < 0.001$, respectively). ALP is an established

PRESS RELEASE

surrogate marker of disease progression in PBC, and this composite endpoint has been previously used for regulatory approval.

Alongside substantial reductions in ALP, in both elafibranor-treated groups, patients showed improvement in other PBC markers such as gamma-glutamyl transferase and metabolic markers such as total cholesterol, low-density lipoprotein-C, and triglycerides. Improvement in pruritus was observed and will be confirmed in a study of longer duration. Treatment with elafibranor was generally well-tolerated, with similar adverse events across the treatment and placebo groups.

Dr. Velimir A. Luketic, MD, Division of Gastroenterology, Hepatology and Nutrition Virginia Commonwealth University School of Medicine, Richmond, VA (USA), commented: *“A substantial number of patients do not benefit from the currently available therapies – UDCA or OCA – either because of lack of response or intolerable side effects. The data emerging from this clinical trial are very impressive, particularly the substantial reduction in ALP in just 12 weeks.”*

Dr. Jörn Schattenberg, MD, Division of Gastroenterology and Hepatology, University Medical Center, Mainz (Germany), further added: *“The study data are impressive and support the rationale for elafibranor’s PPAR alpha/delta approach in PBC. Not only does elafibranor greatly reduce ALP, which is arguably the most important prognostic marker for PBC patients, but it also improves many other biochemical parameters and may reduce pruritus. With these benefits, elafibranor has the potential to offer patients significant advantages over existing treatments.”*

Jean-François Mouney, Chairman & CEO of GENFIT, added: *“We are thrilled with the results of our Phase 2 trial. We believe the strength of evidence on the surrogate endpoint for registration as well as the potential benefits on itching qualify the program to rapidly advance into Phase 3 in PBC. This trial strongly supports elafibranor, our dual PPAR alpha & delta agonist in PBC, to treat a vast majority of target patients while potentially improving their quality of life. We thank all of the patients, patient families, and investigators of the Phase 2 trial for their dedication”.*

ABOUT ELAFIBRANOR

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

PRESS RELEASE

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 GENFIT

GENFIT is a biopharmaceutical company focused on discovering and developing drug candidates and diagnostic solutions targeting liver diseases, in particular those of metabolic origin, and hepatobiliary diseases. GENFIT concentrates its R&D efforts in areas of high unmet medical needs corresponding to a lack of approved treatments. GENFIT’s lead proprietary compound, elafibranor, is a drug candidate currently being evaluated in one of the most advanced Phase 3 studies worldwide (“RESOLVE-IT”) in nonalcoholic steatohepatitis (NASH), considered by regulatory authorities as a medical emergency because it is silent, with potentially severe consequences, and with a prevalence on the rise. It is also being evaluated in a Phase 2 study in Primary Biliary Cholangitis (PBC), a chronic liver disease. As part of its comprehensive approach to clinical management of NASH patients, GENFIT is conducting an ambitious discovery and development program aimed at providing patients and physicians with a blood-based test for the diagnosis of NASH, i.e. non-invasive and easy-to-access. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 150 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, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities, such as the FDA or the EMA, of its drug and diagnostic candidates, the success of any licensing 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 in Section 4 “Main Risks and Uncertainties” of the Company’s 2017 Registration Document registered with the French Autorité des marchés financiers on April 27, 2018 under n° R.18-032, which is available on GENFIT’s website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and as

PRESS RELEASE

updated by the 2018 Half Year Business and Financial Report and available on the Investors page of GENFIT's website. 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.

CONTACT

GENFIT | Investors

Naomi EICHENBAUM - Investor Relations | Tel: +1 (617) 714 5252 | investors@genfit.com

PRESS RELATIONS | Media

Hélène LAVIN - Press relations | Tel: +333 2016 4000 | helene.lavin@genfit.com