



PRESS RELEASE

GENFIT: Risk of confusion between PPAR alpha/delta Phase 3 drug candidate elafibranor and PPAR a/d/gamma Phase 2 compound lanifibranor

- **Initial alert on potential medication error raised by *Prescrire*, an independent continuing education organization for healthcare professionals**
- **Risk of confusion due to the broad similarity between INNs elafibranor and lanifibranor, the latter re-using 10 of the 11 letters of the former, including the whole suffix**
- **Confusion is potentially detrimental for patients in the future, both molecules intending to treat NASH but having different mechanisms of action and pharmacological profiles**
- **Elafibranor (INN granted in 2015), first-in-class PPAR alpha/delta dual agonist, has shown no PPAR gamma activity nor side effects in clinical trials**

Lille (France), Cambridge (Massachusetts, United States), September 20, 2017 – 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 alerts the public to the potential risk of confusion between GENFIT's drug candidate **elafibranor** currently evaluated in Phase 3 in NASH (INN granted by WHO in 2015, List 74) and Inventiva's newly named Phase 2 compound **lanifibranor** (INN granted by WHO in September 2017, List 78).

The INN (International Nonproprietary Name) system provides health professionals with a unique and universal designated name for each pharmaceutical substance. This is an important reference for the clear identification of substances, as well as for safe prescription and dispensing of medicines to patients. In the INN system, the names of pharmacologically-related substances have a common "stem", enabling health professionals to recognize substances having similar pharmacological activity.

Elafibranor is a specific dual agonist of the PPAR alpha and PPAR delta isoforms, but is pharmacologically inactive on PPAR gamma, whereas lanifibranor is a PPAR alpha/delta/gamma. The suffix "-fibranor", present in the names elafibranor and lanifibranor, is not a WHO-recognized INN stem. Healthcare professionals and patients could mistakenly assume that the two molecules have similar pharmacological activity. This may result in confusion and medication errors, particularly since both molecules are being developed for the same indication, nonalcoholic steatohepatitis (NASH).

It is important for future prescribers and patients to be able to distinguish molecules and mechanisms of action without any risk of confusion.

Elafibranor is now a well-established INN, thanks to an extensive amount of data gained through Phase 1, 2a and 2b clinical trials. IVA-337 (newly granted INN lanifibranor) has not yet completed its Phase 2b



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trial and to date, no PPAR gamma compound has been able to demonstrate efficacy on resolution of NASH without worsening of fibrosis – based on the disappearance of ballooning and mild or no inflammation – without the known associated PPAR gamma side effects. PPAR gamma activity is therefore an important element of differentiation between PPAR compounds under development for NASH, and as such the similarity between the INN lanifibranor and the INN elafibranor is regrettable.

ABOUT ELAFIBRANOR

Elafibranor is GENFIT's lead pipeline product. Elafibranor is an oral once-daily administered molecule, and a first-in-class compound 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.

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 gastro-intestinal arena. GENFIT's approach combines novel treatments and biomarkers. Its lead proprietary compound, elafibranor, is currently in a Phase 3 study. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 130 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 of clinical data from, the RESOLVE-IT trial and the trial evaluating elafibranor in PBC, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, elafibranor in NASH and PBC, as well as other drug candidates in other indications and biomarker candidates, 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 "Main Risks and Uncertainties" of the Company's 2016 Registration Document registered with the French Autorité des marchés financiers on April 28, 2017 under n° R.17-034, which is available on GENFIT's website (www.genfit.com) and on the website of the



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