

2014
Press release



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SAFETY OF USE OF GFT505: THE DSMB REITERATES ITS FAVORABLE RECOMMENDATION

- During its plenary session held on June 26th, 2014 in Paris, an independent Data and Safety Monitoring Board (DSMB) analysed the safety data collected to date during the ongoing phase 2b trial in NASH with GFT505. The DSMB recommends continuing the study according to the planned protocol.

Lille (France), Boston (Massachusetts, United States), June 27th, 2014 – 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 systems, today announces the recommendation of the independent Data and Safety Monitoring Board (DSMB) of international experts charged with ensuring the safety of use of GFT505 in the ongoing Phase 2b study.

The experts of the Data and Safety Monitoring Board in charge of assuring the security of patients in the GFT505-212-7 trial, consulted all safety data of the patients included since the launch of the trial, notably 120 patients who have already terminated the one year treatment period with the dose of 80mg/d and more than half of the patients treated for at least 6 months with the dose of 120mg/d.

Based on analysis performed after partial unblinding, the DMSB does not raise any safety concern which might jeopardize the security of the patients and provides its unrestricted approval to continue the Phase 2b clinical trial in NASH as planned in the initial protocol.

Jean-François MOUNEY, Chairman & Chief Executive Officer of GENFIT, declared: “We are extremely pleased with the DSMB conclusions which follow long treatment periods. They demonstrate the safety of use of GFT505 for treating NASH. The favorable advice from the DSMB further adds to the potential value of our drug candidate. Indeed, the NASH treatment will undoubtedly need to be continued during long time periods and no risk of drug intolerance will be taken neither by the Agencies, nor by the prescribers.”



GENFIT launched the Phase 2b study of GFT505 in NASH in September 2012, after obtaining FDA approval to perform the study in the United States. To date, the study has recruited 275 diabetic and non-diabetic patients with a histological diagnosis of NASH by liver biopsy at the time of recruitment. The study is currently ongoing in Europe and the United States in 56 clinical investigation centers and the first efficacy data should be available mid January 2015.

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in fields of high medical need due to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on contributing to bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH - Nonalcoholic steatohepatitis) or the bowel (such as the inflammatory bowel disease). GENFIT implements mutually beneficial approaches that combine novel treatments and biomarkers; its research programs have resulted in the creation of a rich and diversified pipeline of drug candidates, including GENFIT's lead proprietary compound, GFT505, that is completing a Phase 2b study in NASH.

With facilities in Lille, France, and Boston, MA (USA), the Company has approximately 80 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT; ISIN: FR0004163111). www.genfit.com

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 anticipated. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Listing Prospectus upon the admission of Company's shares for trading on the regulated market Euronext of Euronext Paris filed with the AMF, which is available on the AMF website (www.amf-france.org) or on GENFIT's website (www.genfit.com).

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.

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