

2015
Press release



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GENFIT: A CLINICAL STUDY DEMONSTRATES THE SAFETY OF GFT505 ON CARDIAC ACTIVITY

- **168 volunteers were included in the cardiac safety study**
- **Two doses were tested: a therapeutic dose of 120mg/d and a supra-therapeutic dose of 300mg/d**

Lille (France), Boston (Massachusetts, United States), January 6th, 2015

– 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 the company successfully completed a thorough QT/QTc cardiac safety study of GFT505. In accordance with regulatory guidance (ICH E14) on the evaluation of the cardiac safety of products under development, the potential effects of GFT505 on the electrical activity of the heart were assessed.

In the study, 168 healthy volunteers were divided into four groups: placebo, GFT505 at 120mg/day (therapeutic dose), GFT505 at 300mg/day (supra-therapeutic dose), and moxifloxacin at 400mg (positive control). The electrical activity of the heart (electrocardiogram) was continuously monitored over a 24-hour period before and at the end of the 14-day treatment period.

The data showed that repeated daily administration of GFT505 dosed up to 2.5 fold higher than the therapeutic dose had no effect on cardiac electrical activity. In particular, the ventricular contraction time (measured by the QT interval of the electrocardiogram) was not altered. Doses of 120mg/day and 300mg/day were well tolerated in the study.

Dr. Sophie Mégnien, Chief Medical Officer of GENFIT, commented: *«The development of numerous products has been halted because they provoked arrhythmia such as 'torsade de pointes', resulting from the prolongation of the QT interval. Such arrhythmia can lead to syncope and even sudden cardiac death. The current study perfectly meets regulatory requirements, and opens the way to the evaluation of GFT505 in Phase 3 on a large number of NASH patients, without risking an alteration in cardiac electrical activity. »*

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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