

**2014**  
Press release



[www.genfit.com](http://www.genfit.com)

## **GENFIT: THE END OF THE GOLDEN-505 TRIAL REVEALS AN INCREASED STATISTICAL POWER FOR THE STUDY**

- All patients have completed the one year treatment period.
- The statistical power of the study and the chances of achieving its objectives are increased.

**Lille (France), Boston (Massachusetts, United States), December 1<sup>st</sup>, 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 system, today announces that, in keeping with the scheduled agenda, all the patients of the GOLDEN-505 study (GFT505-212-7) have completed the one-year treatment period.

A total of 351 patients were screened according to the inclusion and exclusion criteria of the protocol, with the aim of recruiting 270 patients for the study.

Two hundred and seventy-five (275) patients that met all required criteria gave their consent, and were randomized to one of the three treatment groups of the study.

Two hundred and forty-one (241) patients completed the entire 12-month treatment period, and there were no safety issues during the study. It should be recalled that patient safety is ensured by an independent expert committee (the DSMB). The DSMB entirely reviewed the study safety data on two occasions during the treatment phase, and each time they gave a favorable opinion for the continuation of the study.

The drop-out rate during the treatment phase (34/275, i.e. 12%) is low for this type of study, and is two-fold lower than initially expected in the protocol (25%), thus illustrating the good tolerance of GFT505 and the patients' willingness to accept the study constraints. In particular, the two liver biopsies, at beginning and end of treatment, did not lead to any consent withdrawal. This low drop-out rate increases the overall statistical power of

all the primary and secondary efficacy parameters, and increases the chances of achieving the statistical objectives of the study.

All the patients are followed for 3 months after end of treatment, and the last patient will have his end-of-study visit in early March 2015.

On this occasion, **Dr. Sophie Mégnier, Chief Medical Officer of GENFIT**, declared: *«The study investigators that we recently met in Boston during the AASLD meeting and to whom we presented this progress report confirm the good treatment tolerance, and indicate that they have not encountered any problems of patient compliance during the study. Their implication and that of their patients has undoubtedly contributed to the successful completion of the study.»*

#### **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](http://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](http://www.amf-france.org)) or on GENFIT's website ([www.genfit.com](http://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.

#### **Contacts**

**GENFIT** | Jean-François Mouney - CEO & Chairman of the Management Board | Ph. +333 2016 4000

**MILESTONES** – Relation Presse | Bruno Arabian | Ph. +331 8362 3484 / +336 8788 4726 – [barabian@milestones.fr](mailto:barabian@milestones.fr)