

2015 Press release



GENFIT: HALF-YEAR RESULTS FOR 2015

- Income amounts to €2.41 million
- Decrease of the current operating loss to €7.34 million (H1 2014: €9.19 million)
- Treasury amounts to €61.30 million as of June 30, 2015

Lille (France), Boston (Massachusetts, United States), September 25th 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 announces its financial results for the first half of 2015.

1. Key events of the first half of 2015

January 2015:

• Publication of the results of a clinical trial of cardiac safety of GFT505 in which two doses were tested: a therapeutic dose of 120mg/d and a supra-therapeutic dose of 300mg/d. These results showed that a repeated daily administration for 14 days of GFT505 at up to 2.5 times the therapeutic dose had no effect on cardiac electrical activity, thus meeting regulatory requirements.

March and April 2015:

- Publication of the topline results of the Phase 2b clinical trial of GFT505 in NASH (GOLDEN-505 study). This 52-week Phase 2b trial evaluated the efficacy and safety of GFT505 in 274 subjects (double blind, placebo-controlled; three arms: placebo, 80mg, 120mg) with centrally-read, liver biopsy-proven NASH. The results showed that:
 - GFT505 at the dose of 120mg met the primary endpoint of the study, reversal of NASH without worsening of fibrosis, after correction for baseline severity and site heterogeneity,
 - treatment with GFT505 showed significant cardiometabolic benefits,
 - GFT505 is safe and was well tolerated throughout the one-year treatment study.

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Items in this press release may contain forward-looking statements involving risks and uncertainties. The Company's actual results could differ substantially from those anticipated in these statements owing to various risk factors which are described in the Company's prospectus. 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.



May 2015:

• The end of the extension of the shared research phase between the scientific teams of Sanofi and GENFIT set up by the two companies within the framework of their collaboration and license contract. The results obtained after this additional phase are currently being evaluated by both parties.

June 2015:

• Approval by the World Health Organization (WHO) of the International Non-proprietary Name (INN, or generic name) Elafibranor for GENFIT's leading drug candidate previously referred to as GFT505. This new non-proprietary name reflects the first-in-class nature of the drug candidate, since it does not contain a pre-existing INN stem.

2. <u>Key post-closure events</u>

September 2015:

• Publication of positive results from the proprietary NASH biomarker program, including the development of a diagnostic tool designed by the Company – as an alternative to invasive liver biopsy – to identify NASH patients that should be treated, according to the consensual definition agreed between experts and regulatory agencies.

3. <u>Principal financial results for the first half of 2015</u>

- The total revenue of the Group amounts to 2 409.4 thousands of Euros as of June 30, 2015 compared to 3 578.2 thousands of Euros as of June 30, 2014. Amongst this revenue, almost all the **industrial** revenue, amounting to 394.9 thousands of Euros as of June 30, 2015 (1201.8 thousands of Euros as of June 30, 2014), was generated by a scientific milestone payment resulting from the research collaboration program initiated in 2011 with Sanofi. This decrease is may be explained by the income generated in 2014 thanks to a milestone payment of 1000 thousand € paid by Sanofi. The public financing of research expenditure corresponds to the operating grants and the year's Research Tax Credit. The latter decreases slightly to 1.963.8 thousands of Euros as of June 30, 2015 compared to 2.333.5 thousands of Euros as of June 30, 2014.
- As of June 30, 2015, the current operating expenses decreased to -9752.4 thousands of Euros compared to -12767.2 thousands of Euros as of June 30, 2014. Amongst these expenses, operating subcontracting expenses have decreased compared to the same period last year since they represent a total of -3045.2 thousands of Euros as of June 30, 2015 compared to -4530.3 thousands of Euros for the same period in 2014. This reduction between two periods is mainly due to the decrease of the financial weight of the Phase 2 program of GFT505 / Elafibranor in NASH, and to the decrease of the pharmaceutical development costs linked to this program which were particularly high during the first half of the 2014 financial year. The Group's personnel costs have also decreased to -3558.5 thousands of Euros as of June 30, 2015 compared to -5195.8 thousands of Euros at the same period one year ago. This decrease is largely due to the exceptional bonuses that were recorded as of June 30, 2014, to compensate the implication of the staff in the scientific and financial successes obtained specifically during that period.



- The increase of the consumed purchases, for a total of 1019.5 thousand € as of June 30, 2015 against 750.8 thousand € on June 30, 2014, reflects the resources allocated by the Company to its other R&D programs; in particular to its development program of new drug candidates baptized TGFTX1 and to its development program of biomarker candidates in NASH called BMGFT03.
- **The current operating income** thus amounts to 7343.1 thousands of Euros against 9188.9 thousands of Euros in the first half of 2014.
- Taking into account a **financial result** of 259.9 thousands of Euros as of June 30, 2015 (compared with 42 thousands of Euros as of June 30, 2014), of an **expense related to share-based payments** resulting from an evaluation of the BSA and the BSAAR set up by the Company (amounting to 1787.1 thousands of Euros as of June 30, 2015), and an **income tax expense** of almost zero (-0.4 thousands of Euros), the **net financial result** amounted to -8870.7 thousands of Euros as of June 30, 2015 compared to -9147.7 thousands of Euros for the same period one year earlier. The net loss per share is limited to -€0.37 as of June 30, 2015 against -€0.76 as of December 31, 2014.
- As of June 30, 2015, the **closing treasury** of the Group amounted to 61 305.6 thousands of Euros, compared to 72 004.8 thousands of Euros as of December 31, 2014 and 65 654.7 thousands of Euros as of June 30, 2014.

Summary of the key financial figures for the first half of 2015 (IFRS standards)

(million EUR)	06/30/15	06/30/14
Industrial revenue	0.39	1.2
Public funding of R&D expenses	1.96	2.33
Total revenues	2.41	3.58
Current operating result	(7.34)	(9.19)
Share-based payments	(1.8)	-
Financial result	0.26	0.04
Pre-tax income	(8.87)	(9.15)
Net result	(8.87)	(9.15)
Treasury at closure	61.30	65.65

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/Elafibranor, that has completed a positive Phase 2b study in NASH and is currently

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launching a Phase 3 study. With facilities in Lille, France, and Boston, MA (USA), the Company has approximately 90 employees. GENFIT is a public company listed in compartment B of Euronext's regulated market in Paris (Euronext: GNFT; ISIN: FR0004163111). <u>www.genfit.com</u>

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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