**2014**
Press release

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# GENFIT: HALF-YEAR RESULTS FOR 2014

- **Income increased by 24%, to €3.58 million**
- **Increase of the current operating loss to €9.19 million (H1 2013: €5.53 million) due to strong investments linked to progress in the Phase 2b trial of GFT505 in NASH, and supporting studies**
- **Net loss per share stable at €0.43**
- **Treasury amounts to €65.65 million as of June 30, 2014 (compared to €20.9 million as of December 31, 2013)**

**Lille (France), Boston (Massachusetts, United States), September 26, 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 its financial results for the first half of 2014.

**Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, declared:** *«The first half of 2014 was, once again, particularly rich in terms of scientific results concerning GFT505. Studies conducted in parallel with our pivotal Phase 2b trial in NASH enabled the demonstration of the anti-fibrotic properties of our most advanced drug candidate, and widened its therapeutic potential to all stages of NASH, including cirrhosis, but also to chronic Inflammatory Bowel Diseases. On the financial front, these results have automatically led to a controlled increase in our operating expenses in view of the challenges that lie ahead. Finally, the clear strengthening of our treasury validates our international ambitions, with the significant arrival of Anglo-Saxon shareholders amongst our capital.»*





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.

## 1. Key events of the first half of 2014

January 2014:

- The effects of GFT505 on the proliferation of 21 human cancer cell lines were evaluated in vitro. GFT505 blocked the proliferation of a great majority of these cell types, suggesting that it might prevent not only the progression of NASH to liver cirrhosis, but also reduce the associated risk of liver cancer.

February 2014:

- Success of a €5 million capital increase operation, with maintenance of shareholders' preferential subscription rights.

- The Food and Drug Administration (FDA) granted Fast Track designation to the GFT505 development program in NASH.

March / April 2014:

- GENFIT and Sanofi achieved a new scientific key milestone in their industrial partnership, initiated upon the founding of GENFIT.

- In an experimental model of NASH reproducing the natural evolution of the disease observed in man and in a protocol of histological analysis of the liver pre- and post-treatment (foz/foz mice subjected to a high-fat diet), GFT505 eliminated NASH and improved fibrosis.

- New results related to the anti-fibrotic properties of GFT505 confirmed the widening of its therapeutic potential to non-hepatic fibrotic diseases, and suggested an original mechanism of action of the drug candidate as an inhibitor of a group of structurally related Receptor Tyrosine Kinases (RTKs), in addition to the "PPARα/δ effet" of the product.

- New studies in a model of chronic bowel inflammation that is widely used to identify new treatments for IBD (Inflammatory Bowel Diseases) suggested that an oral treatment with GFT505 protects the intestine from inflammatory attacks and reduces the associated fibrosis.

- Transfer of GENFIT's shares from the Alternext market onto the regulated market of Euronext Paris (Compartment B), and subsequently its admission to new Euronext indexes, in particular the SBF 120.

May 2014:

- Granting of a new patent for GFT505 in Europe (32 European countries) and in the US. These patents protect the use of GFT505 not only in NASH, but also in other hepatic diseases.

- Mr. Dean Hum, CSO and COO of the Company, appointed as a Member in order to strengthen GENFIT's Executive Board.





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June 2014:

- €49.7 million raised through a private placement to institutional investors primarily located in the USA.

- The Annual General Meeting of shareholders of GENFIT SA approved the cooptation of Mr. Frédéric Desdouits to the Supervisory Board in replacement of CM-CIC Capital Finance.

- The independent Data Safety Monitoring Board (DSMB) set up within the framework of the ongoing Phase 2b study of GFT505 in NASH, analyzed the safety data collected since the beginning of the study, and confirmed, after long periods of treatment of up to one year for patients treated with the dose of 80mg/day and up to six months for those treated with the dose of 120mg/day, its unrestricted approval to continue the study as planned in the initial protocol. The complete results of the Phase 2b trial should be available at the end of the first quarter of 2015.

## 2. Key post-closure events

July 2014:

- GENFIT SA received the refund of its claim of Research Tax Credit of approximately €3.5 million for the financial year 2013.

- Biotech Avenir conceded a block of 462,000 GENFIT shares to an Anglo-Saxon mutual fund, and confirmed that it wishes to maintain at least 10% of the capital of GENFIT SA.

September 2014:

- GENFIT signed an amendment to the collaboration agreement with Sanofi, engaged in March 2011. The scientific collaboration is extended, and GENFIT obtains an increase in the milestone payments linked to the achievement of the different clinical development phases of the drug candidates arising from this collaboration.

## 3. Principal financial results for the first half of 2014

- **The total revenue** of the Group increased considerably to 3 578.2 thousands of Euros as of June 30, 2014 compared to 2 873.3 thousands of Euros as of June 30, 2013. Amongst this revenue, almost all the **industrial revenue,** amounting to 1 201.8 thousands of Euros as of June 30, 2014, was generated by a scientific milestone payment resulting from the research collaboration program with Sanofi. The **public financing of research expenditure**, which comprises the operating grants (that have become marginal) and the year's Research Tax Credit, together amounted to 2 333.5 thousands of Euros as of June 30, 2014 compared to 1 787.6 thousands of Euros as of June 30, 2013.

- As of June 30, 2014, the **current operating expenses** increased to -12 767.2 thousands of Euros compared to -8 399.6 thousands of Euros as of June 30, 2013. Amongst these expenses, operating subcontracting expenses have significantly increased compared to the same period last





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year since they represent a total of -4 530.3 thousands of Euros as of June 30, 2014 compared to -2 035.7 thousands of Euros for the same period in 2013. This increase is due mainly to the progress of the ongoing phase 2b study of GFT505 in NASH. The Group's personnel costs increased to -5 195.8 thousands of Euros as of June 30, 2014 compared to -4 074.5 thousands of Euros in the same period one year ago. This payroll increase is due in particular to the strengthening of the clinical development team of the Group, and to the impact of provisions for the bonus that the Group plans to grant to its employees in the second half of 2014 to compensate them for their involvement in its development and, more significantly and especially, in the fundraising operations conducted in the first half of 2014. The average number of employees in the first half of 2014 is almost 80 compared to 75 in 2013. The current operating loss thus amounted to -9 188.9 thousands of Euros in the first half of 2014 compared to -5 526.2 thousands of Euros in the first half of 2013.

- Taking into account a **financial result** of 42 thousands of Euros as of June 30, 2014 (compared with 45.1 thousands of Euros as of June 30, 2013), and an **income tax expense** of almost zero (-0.4 thousands of Euros), the **net financial result** amounted to -9 147.7 thousands of Euros as of June 30, 2014 compared to -7 896.4 thousands of Euros for the same period one year earlier. The net loss per share is unchanged at -€0.43 per share as of June 30, 2014.

- As of June 30, 2014, the **closing treasury** of the Group amounted to 65,654.7 thousands of Euros, compared to 20,921.7 thousands of Euros as of December 31, 2013.

**Summary of the key financial figures for the first half of 2014 (IFRS standards)**

| *(million EUR)* | **30/06/14** | **30/06/13** |
|---|---|---|
| **Industrial revenue** | 1.2 | 0.96 |
| **Public funding of R&D expenses** | 2.33 | 1.79 |
| **Total revenues** | **3.58** | **2.87** |
| **Current operating result** | **(9.19)** | **(5.53)** |
| **Financial result** | **0.04** | **0.04** |
| **Pre-tax income** | **(9.15)** | **(5.58)** |
| **Net result** | **(9.15)** | **(7.89)** |
| **Treasury at closure** | **65.65** | **29.35** |



GENFIT | 885 Avenue Eugène Avinée, 59120 Loos, France | +333 2016 4000 | **www.genfit.com**

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**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.

**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



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