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GENFIT: HALF-YEAR RESULTS FOR 2012

- **Major clinical and regulatory progress achieved by GFT505 in the field of NASH**
- **Control of the net loss, at a level that is stable over 12 months**
- **Promising perspectives for several proprietary programs**
- **ESM to prepare the eventual entry of new reference shareholders**

Lille (France), Boston (Massachusetts, United States), September 26th, 2012 – GENFIT (Alternext: ALGFT; ISIN: FR0004163111), a biopharmaceutical company at the forefront of drug discovery and development, focusing on the early diagnosis and preventive treatment of cardiometabolic and associated disorders, today announces its financial results for the first half of 2012.

Jean-François Mouney, Chairman and Chief Executive Officer of GENFIT, declared: *«The first half of 2012 was particularly marked by the major progress achieved by GFT505, the Company's leading drug candidate, in the field of NASH. The efforts devoted to the development of this product are in line with our strategy. Financially speaking, these efforts continue to impact our operating result to a similar extent as during the first half of 2011. In the wake of these important developments that valorize GENFIT as a leader in an indication with considerable unmet medical needs, the newsflow of the second half of the year should confirm this tendency, attract new partners, and mark a new phase in the development of the Group.»*

1. Major achievements for the first half of 2012

- **The drug candidate GFT505 achieved all of its clinical and regulatory objectives**

Developed by GENFIT particularly for the treatment of NASH, the drug candidate showed beneficial effects on multiple parameters in this indication, and achieved all of its efficacy and safety objectives during clinical studies GFT505-210-6 and GFT505-111-7, without any undesirable side-effects.

Long-term animal toxicology studies have confirmed the safety of GFT505 and enabled the completion of the regulatory dossier for clinical phases IIb and III. Moreover, new data revealed that GFT505 has beneficial effects on the regression of liver fibrosis and on multiple hepatic markers of inflammation and fibrosis.

In parallel, the intellectual property of GFT505 has been reinforced, with the granting of new patents in Australia, Canada, Japan, and India, after the United States, Europe, and China. This patent cover spans the use of GFT505 in several hepatic complications, including NASH.

Armed with the pre-clinical and clinical data obtained over this period, GFT505 received a positive opinion from the European Medicines Agency (EMA), confirming the proposed development plan for the drug candidate in Phase IIb and III.

- **Encouraging progress on the research programs TGFTX1 and TGFTX3 (circadian rhythm)**

Following the submission of patent applications at the end of 2011, the proprietary compounds developed within the TGFTX1 and TGFTX3 programs, dedicated to the treatment of diseases linked to the dysregulation of the biological clock, were evaluated in *in vivo* models during this period. The results obtained strengthen the pharmacological validation of these two targets. Concerning in particular the TGFTX3 program, during the second trimester of 2012, GENFIT initiated a period of evaluation of their results with pharmaceutical laboratories, with the aim of continuing or sharing the future development of the recently identified lead compounds.

- **Strategic research partnership with SANOFI**

Within the context of the collaborative R&D program initiated in March 2011 for a period of 3 years, GENFIT and SANOFI achieved during the period a first scientific milestone towards a treatment for metabolic diseases. Several chemical series targeting mitochondrial dysfunction have thus been selected after having met the pre-defined selection criteria.

The optimization of the selected molecules is currently ongoing, in accordance with the development plan drawn up by the two parties. The results obtained during this period led to the first milestone payment by SANOFI. A second payment is expected at the end of this year. The total of revenues included in this strategic alliance could reach € 39.6 million.

2. Financial results for the first half of 2012

- Over the first six months of the 2012 financial year, the **total operating revenues** amounted to € 2.65 million versus € 3.34 million for the first half of 2011.

- **Industrial revenues** amounted to € 0.95 million as of June 30, 2012, versus € 1.22 million for the first half of 2011. They were generated by the « research fees » from collaborative research programs with industrial partners, in particular SANOFI. Their evolution corresponds to a global policy change in pharmaceutical industry alliances, initiated last year, that privileges « risk-sharing » partnerships characterized by a reduction in upfront payments, but more substantial milestone payments.

- The revenue from **public funding of R&D expenses** amounted to € 1.69 million for the first six months of 2012 versus € 2.11 million for the first half of 2011. The evolution of this revenue depends on the period at which the validation of scientific milestones occurs.

- As of 30 June 2012, the **operating charges** amounted to € 7.3 million, a slight decrease compared to the same period in 2011 (€ 7.63 million), in keeping with the development plan. This may be explained by the subcontracting expenses linked in particular to the clinical development of GFT505.

- The **operating loss** amounts to € 4.65 million in the first half of 2012 versus € 4.33 million in the first half of 2011.

- The **financial result** amounts to € 0.1 million versus € (0.02) million as of 30 June 2011, due essentially to an improved performance of the Company's financial investments.

- Consequently, the **net result** amounts to € (4.54) million as of 30 June 2012 versus € (4.93) million as of 30 June 2011.

- The Company's **cash balance and treasury equivalents** amounted to € 11.05 million as of June 30, 2012 versus € 10.19 million as of June 30, 2011. This stability may be explained by the capital increases that took place during the first half of the year for a total of € 2.7 million. While the level of the available mid-year treasury allows GENFIT to have visibility for its operating needs up to the first trimester of 2013, the Company intends to secure the financing of its development through ongoing discussions with industrial and financial partners.

Summary of the key financial figures for the first half of 2012 (IFRS standards)

(million EUR)	**30/06/12**	**30/06/11**
Revenues from industrial alliances	0.95	1.22
Public funding of R&D expenses	1.69	2.11
Total revenues	**2.65**	**3.34**
Operating result	**(4.65)**	**(4.33)**
Financial result	**0.1**	**(0.02)**
Pre-tax income	**(4.54)**	**(4.35)**
Net result	**(4.54)**	**(4.93)**
Gross cash	**11.05**	**10.19**

3. Post-closure events and perspectives

- **Signing of a convertible bond loan agreement of € 2 million**

In accordance with the 26th and 27th resolutions of the Shareholders' Meeting held on June 26, 2012, the Company contracted a € 2 million bond loan agreement, convertible in ordinary shares of the Company, reserved to YA Global Master SPV Ltd – a holding managed by the investment company Yorkville Advisors LLC. This operation enabled GENFIT to reinforce its treasury situation.

- **FDA approval for the Phase IIb clinical development of GFT505 in the United States**

After the positive opinion of the European Medicines Agency (EMA) received in July, GFT505 obtained the authorization of the Food and Drug Administration (FDA) in early September for the immediate initiation of a Phase IIb clinical study in the United States in the indication of NASH. The FDA approval followed an extensive review of the pre-clinical and clinical data obtained with GFT505, and confirmed that GFT505 shows a favorable activity on the spectrum of biological markers associated with NASH. GENFIT is continuing its discussions with companies in the Healthcare field in the context of future exploitation rights of GFT505.

- **Extraordinary Shareholders Meeting (ESM) on October 31, 2012 to prepare the eventual entry of new reference shareholders**

The Company annonces that its shareholders are called to attend an Extraordinary Shareholders Meeting to be held on Wednesday October 31, 2012 at 10.30 am at the Company's registered office, with the view to ruling upon the following agenda (publication in the Bulletin des Annonces Légales Obligatoires (BALO) this day):

- Delegation of authority to the Executive Board (*Directoire*) for the purpose of carrying out one or more reserved share capital increases by way of issue of ordinary shares; cancellation of the preferential subscription right of the shareholders to in favor of the following category of persons:

    - Any investment funds or investment company, private or public, the investment program or investment policy of which are targeting more particularly health, life sciences, pharmaceutical, biotechnology or innovation sectors;
    - Any insurance company, mutual insurance company or union of mutual insurance companies investing in the above-mentioned sectors;

- Any foreign legal person or entity, including those established under the law of non EU members states, provided that they meet the characteristics of the entities set out above.

- Delegation of authority to the Executive Board (*Directoire*) for the purpose of carrying out one or more share capital increases with maintaining of the preferential subscription right of the shareholders and by way of issue of ordinary shares;

- Delegation of powers to the Executive Board (*Directoire*) for the purpose of carrying out one or more share capital increases reserved to the benefit of employees members of a company's saving plan (*plan d'épargne entreprise*) pursuant to article L.225-129-6 of the French commercial Code and articles L.3332-18 and seq. of the French labor code; cancellation of the preferential subscription right of the shareholders to in favor a category of persons for the purpose of this delegation of powers;

- Powers to carry out formalities.

Next press release (mid-October): Update on the TGFTX3 program (circadian rhythm).

About GENFIT:

GENFIT is a biopharmaceutical company focused on the Discovery and Development of drug candidates in therapeutic fields linked to cardiometabolic disorders (prediabetes/diabetes, atherosclerosis, dyslipidemia, inflammatory diseases…). GENFIT uses a multi-pronged approach based on early diagnosis, preventive solutions, and therapeutic treatments and advances therapeutic research programs, either independently or in partnership with leading pharmaceutical companies, including Sanofi, to address these major public health concerns and their unmet medical needs.
GENFIT's research programs have resulted in the creation of a rich and diversified pipeline of drug candidates at different stages of development, including GENFIT's lead proprietary compound, GFT505, that is currently in Phase II.
With facilities in Lille, France, and Cambridge, MA (USA), the Company has approximately 80 employees. GENFIT is a public company listed on the Alternext trading market by Euronext™ Paris (Alternext: ALGFT; ISIN: FR0004163111). www.genfit.com

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