



## PRESS RELEASE

### **GENFIT: Q1 2017 FINANCIAL INFORMATION**

*(Unaudited financial information under IFRS)*

- > **Cash and cash equivalents amounting to €137 million at March 31, 2017**
- > **Revenues for the first three months of 2017 amounting to €26 thousand**
- > **Main developments in the R&D pipeline during the first quarter 2017**

**Lille (France), Cambridge (Massachusetts, United States), April 24, 2017** – 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 its cash at March 31, 2017, revenues for the first three months of 2017 and a progress report on its R&D pipeline during the first quarter 2017.

- **Main financial information**

- **Cash position**

At March 31, 2017, the Company's cash and cash equivalents amounted to €137.03 million compared with €102.8 million the previous year. At December 31, 2016, cash and cash equivalents totaled €152.28 million.

- **Revenues**

Revenues for the first three months of 2017 amounted to €26 thousand compared with €88 thousand for the same period 2016.

- **Main developments in the Company's R&D pipeline in the first quarter 2017**

- **Elafibranor NASH development program**

#### **RESOLVE-IT Phase 3 study in NASH**

The RESOLVE-IT Phase 3 study is progressing actively. Authorization has been received by the healthcare regulatory authorities in each of the 25 countries where the study is being conducted



## PRESS RELEASE

and 81% of the centers are now open, allowing for an intensive screening of patients who are candidates for enrollment in the clinical trial.

While enrollment of patients with F1 fibrosis stage is in advance of expectations, patients with F2 and F3 fibrosis stages follow a more moderate enrollment curve compared to the initial projections. Enrollment of the first ~1000 patients to participate in the first phase of the trial is therefore expected to be completed in Q1 2018.

This change of 4 to 6 months from the current timeline is partly due to the increasing number of clinical trials now being launched in NASH, but is mainly attributable to the Company's desire to ensure enrollment quality so as to produce the most statistically robust clinical trial by ensuring that patient stratification ratios remain as close as possible to the medical reality.

Thus, based on its past experience, the Company is paying close attention to the following factors:

- Ethnically-balanced enrollment, even if the diversity sought creates administrative delays, in particular in certain countries in South America;
- Balance between the two arms of the study in each study center, leading to the selection of those centers which are able to mobilize a sufficiently large number of potentially eligible patients;
- Balance within the randomized patient population (gender, disease severity) and among geographical regions of enrollment.

The Company considers that this change has no significant impact on the main goal for elafibranor to be prescribed as a first-line treatment in NASH and to constitute a cornerstone in combination therapy.

More centers will be opened to limit deviations from the initial timeline.

### **Progress in the disease awareness program**

In March 2017, the Company launched a disease awareness initiative, *The NASH Education Program™*, asserting its leadership in this area, and sparked an unprecedented wave of interest in the French media. This initiative is an important element in the awareness of all the stakeholders in NASH. It is also crucial in the context of enrollment for a little known and asymptomatic pathology like NASH. This initiative, welcomed by a growing number of industry specialists and analysts, is planned to be launched in other countries.

### **Combination therapy opportunities**

The Company is proactive in its combination therapy approaches in NASH, with elafibranor as the cornerstone drug.

To address the multifactoral nature of the disease and the multiple co-morbidities that NASH patients face, the Company is evaluating the therapeutic potential of combinations with elafibranor and:

- compounds from other GENFIT programs,



## PRESS RELEASE

- already marketed drugs with complementary mechanisms of action,
- the most advanced compounds in the current NASH clinical landscape.

The goal is to treat the largest number of NASH patients, and if possible, at lower reduced dosages.

In this context, during the International Liver Congress (held on April 19-23, 2017 in Amsterdam, and organized by EASL), the Company presented preclinical data on the therapeutic complementarity of elafibranor with an FXR agonist (exemplified with obeticholic acid). These results illustrate the potential for new combination treatments with elafibranor for the best possible care of NASH patients. The synergistic effect obtained in the disease models used showed an attenuation of fibrosis at submaximal doses, which confirmed the relevance of these combination approaches.

- **Elafibranor development program in Primary Biliary Cholangitis (PBC)**

The Phase 2a clinical trial which is designed to evaluate the efficacy and safety of elafibranor in patients with primary biliary cholangitis (PBC) and inadequate response to ursodeoxycholic acid, is entering its active enrollment phase. The trial is designed as follows:

- 3 arms: elafibranor 80mg, 120mg, placebo
- 45 patients (15 patients per arm)
- 12 weeks treatment
- International, multicenter study in the U.S. and in three European countries

The primary objective is to determine the effect of daily oral administration of elafibranor on serum alkaline phosphatase (ALP) in these patients, based on relative change from baseline to end of treatment compared to placebo.

Secondary endpoints will include:

- ALP < 1.67 × upper limit of normal (ULN) and total bilirubin within normal limit and > 15% decrease in ALP
- Paris, Toronto, UK PBC scores
- Pruritus and QoL (Quality of Life)
- Safety of elafibranor in a PBC population

The European and American centers participating in the Phase 2 study have all been identified, and the first ones are already active.

Screening of the first patients is underway.

- **Diagnostic biomarker program in NASH (BMGFT03)**

At the International Liver Congress organized by EASL, the Company presented, through two abstracts, the latest developments in its biomarker program and development opportunities for a non-invasive in-vitro diagnostic (IVD) test in NASH.



## PRESS RELEASE

The Company presented new data on:

- Discovery of nine miRNAs with potential use in the identification of NASH patients for treatment;
- Identification of a simplified diagnostic score to identify NASH patients and monitor their disease evolution.

These new, innovative miRNAs were identified by analyzing samples of over 500 NAFLD patients from different cohorts, including those from the RESOLVE-IT Phase 3 study.

The scoring method is the result of identifying a new algorithm based on a smaller number of variables, generating a powerful score with good performance based on AUROC (Area Under the Receiver Operating Curve), sensitivity, specificity, NPV (Negative Predictive Value) and PPV (Positive Predictive Value).

The two presentations/posters confirmed the potential of the approach developed by the Company and its ability to provide an IVD solution based on a blood test which is non-invasive, easy to use, and at lower cost and thus able to be widely available compared with other existing approaches or those in development. Although these other approaches, such as imaging and elastography, are complementary, they nevertheless require greater investment in equipment and training and would not, in any case, be able to replace a widely available point-of-care IVD tool.

Following the main discovery stage ending in summer 2017, the Company will begin the development stage with a goal to obtain regulatory approval of the IVD diagnostic tool. With this in mind, the Company plans to partner with a major diagnostic company to ensure the industrial development, distribution and marketing of the IVD test worldwide.

- **Repurposing of nitazoxanide in fibrosis (TGFTX4 program)**

In the context of the TGFTX4 program, the Company has identified several potential drug candidates that show a strong anti-fibrotic activity in both cell-based assays and in vivo disease models.

These results were obtained either by the therapeutic repurposing of compounds approved in another indication – allowing the Company to shorten development time – or by a more classical hit-to-lead optimization of the Company's proprietary compounds using a phenotypic screening approach in TGF beta-activated human hepatic stellate cells.

Nitazoxanide, an antiparasitic drug with proven safety, was repurposed as a potent antifibrotic agent with efficacy demonstrated in two disease models of liver fibrosis, as presented at the International Liver Congress organized by EASL.

The Company plans to file an IND before the end of the year 2017 for a first Proof-of-concept phase 2 study of nitazoxanide in NASH patients with advanced fibrosis.

- **TGFTX1 program (RORgt)**



## PRESS RELEASE

As part of ambitious efforts to diversify and expand its development pipeline in the treatment of autoimmune, inflammatory and fibrotic diseases, the Company has conducted significant work in the design and optimization of novel ROR $\gamma$ t inverse agonists.

The Company has recently launched pre-IND studies for a topically delivered treatment in mild to moderate psoriasis vulgaris. The Company is currently looking to forge a partnership with a company that has an established dermatology franchise for both topically and orally administered drugs, to move this program forward.

- **Upcoming Event : Shareholders' Meeting in Lille, Friday, June 16, 2017 at 10:30am**

In addition to the usual items on the agenda of this ordinary and extraordinary shareholders meeting (review of the management report and financial statements for 2016, regular and special reports of the Executive Board and statutory auditors, delegations for capital increases,...), the Executive Board will propose to change the Company's current governance structure (Supervisory Board and Executive Board) to a one-tier structure with a Board of Directors and implement the provisions of the "Copé-Zimmermann" law (relating to the balanced representation of men and women on corporate boards).

**Jean-François Mouney, Chairman & CEO of GENFIT, commented:**

*"Regarding our elafibranor program, the highlight of the first quarter is undoubtedly the growing interest in NASH in the global pharmaceutical industry. The launch of many early stage clinical trials addressing NASH or liver fibrosis (Phases 1 and Phases 2 proof of concept in particular) is a perfect illustration of this. While we are obviously pleased with this situation, above all in the interest of the patients, but also because our program is much more advanced than the vast majority of these new developments, this situation nevertheless creates congestion in enrolling patients that we need to take into account.*

*Despite this situation and the delay of several months it has created in the first phase of enrollment in the RESOLVE-IT study, we consider that the main objective for elafibranor and any other drug for NASH patients is that it is prescribed as a first-line treatment. We therefore decided to continue ensuring the quality of patient recruitment in the study. By doing so, the robustness of the intermediate results obtained along with the excellent safety profile of the product will assist us in obtaining a marketing authorization in a timely manner.*

*Our well-controlled cash burn for the first quarter essentially reflects the current rate of enrollment, and this delay as well as the measures we are taking to limit it should not change our cash forecast (Q4 2018/Q1 2019).*

*This first quarter was also very rich in terms of the progress of our other programs, and was marked by the launch of our international Phase 2a study of elafibranor in PBC, the major advances in our IVD biomarker program in NASH, and those of our program for the repurposing of nitazoxanide in fibrotic diseases*

*All these advances mean that the Company is growing and becoming more international as our programs advance. In response to this growth and to provide us the means to accompany this evolution on the corporate level, we plan to propose at our next shareholders' meeting to transform the current two-tier governance of GENFIT SA (Supervisory Board and Executive Board)*



## PRESS RELEASE

*to a one-tier structure with a Board of Directors. The latter seems to us to be closer to international standards and therefore more likely to allow us to welcome the expert board members whom we wish to recruit to accompany the development of the Company in the years to come. If the shareholders approve this proposal, I would of course be very happy to preside over the future Board of Directors while continuing on in my role as CEO of the Company."*

### **About elafibranor:**

Elafibranor is GENFIT's lead pipeline product. Elafibranor is an oral once-daily treatment, and a first-in-class drug acting via dual peroxisome proliferator-activated alpha/delta pathways developed to treat, in particular, nonalcoholic steatohepatitis (NASH). Elafibranor is believed to address multiple facets of NASH, including inflammation, insulin sensitivity, lipid/metabolic profile, and liver markers.

### **About NASH:**

"NASH", or nonalcoholic steatohepatitis, is a liver disease characterized by an accumulation of fat (lipid droplets), along with inflammation and degeneration of hepatocytes. The disease is associated with long term risk of progression to cirrhosis, a state where liver function is diminished, leading to liver insufficiency, and also progression to liver cancer.

### **About PBC:**

"PBC", or Primary Biliary Cholangitis, is a chronic disease in which bile ducts in the liver are gradually destroyed. The damage to bile ducts can inhibit the liver's ability to rid the body of toxins, and can lead to scarring of liver tissue known as cirrhosis.

### **About GENFIT:**

GENFIT is a biopharmaceutical company focused on the discovery and development of drug candidates in areas of high unmet medical needs corresponding to a lack of suitable treatment and an increasing number of patients worldwide. GENFIT's R&D efforts are focused on bringing new medicines to market for patients with metabolic, inflammatory, autoimmune and fibrotic diseases, that affect the liver (such as NASH – Nonalcoholic steatohepatitis) and more generally the gastrointestinal arena. GENFIT's approach combines novel treatments and biomarkers. Its lead proprietary compound, elafibranor, is currently in a Phase 3 study. With facilities in Lille and Paris, France, and Cambridge, MA (USA), the Company has approximately 130 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)

### **Forward Looking Statement / 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 expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, including related to biomarkers, progression of, and results of clinical data from, the RESOLVE-IT trial, review and approvals by regulatory authorities, such as the FDA or the EMA, regarding in particular, elafibranor in NASH and PBC, as well as other indications, and biomarkers, the success



## PRESS RELEASE

of any inlicensing strategies, the Company's continued ability to raise capital to fund its development, as well as those discussed or identified in the Company's public filings with the AMF, including those listed under Section 7 "Main Risks and Uncertainties" of the Company's Half Year 2016 Business and Financial Report, which is available on GENFIT's website ([www.genfit.com](http://www.genfit.com)) and on the website of the AMF ([www.amf-france.org](http://www.amf-france.org)). Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements.

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. 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.

### CONTACT

**GENFIT** | Jean-François Mouney – Chairman & CEO | Ph. +333 2016 4000

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

**GENFIT** | 885 Avenue Eugène Avinée, 59120 Loos - FRANCE | +333 2016 4000 | [www.genfit.com](http://www.genfit.com)