

# DEAR SHAREHOLDERS,

The last several weeks have been particularly crucial for GENFIT.

On the one hand, in October we completed the largest convertible bond offering by a biopharmaceutical company in Europe and the first of significant size in France, with €180 million (~\$210 million) raised, thus strengthening GENFIT's cash position to a level in line with our ambitions.

On the other hand, NASH – a serious, widespread, but silent disease, still relatively unknown to the general public - played a central role at the AASLD Liver Meeting® in Washington, D.C. This is a strong trend, reflecting the importance of the unmet medical need today.

While a limited number of results have been announced by the main players in this field, it is above all the growing enthusiasm for the first phase 3 results that are attracting attention, as they are fast approaching in 2019.

# **SOMMAIRE**

Additional €180 million (~\$210 million) of cash	1
Feedback on the AASLD Liver Meeting® and the evolution of the NASH ecosystem	2-4
Meeting of investigators involved in the RESOLVE-IT Phase 3 trial	5
Open House for retail investors	6



## ADDITIONAL €180 MILLION (~\$210 MILLION) OF CASH

This fundraising is the largest convertible bond offering by a biopharmaceutical company in Europe, and an important milestone for GENFIT, which was able to benefit from the interest of numerous investors in the potential of the products we are developing, to both secure its long-term cash position and protect the interests of its shareholders, thanks to an intelligent and timely instrument with respect to market conditions.

The initial goal of raising €150 million was largely exceeded, reaching €180 million, the maximum amount authorized by your Board of Directors, with investor demand that represented several times the amount initially targeted.



Beyond the direct impact of this transaction on GENFIT's cash position, the other takeaways are very simple:

- > The size of the fundraising and the financial terms that characterized it indicate the high level of confidence of the many institutional investors involved;
- > The transaction allowed GENFIT to approach new types of investment funds, who are now largely committed to us and supportive;
- > The significant leverage offered by the 30% premium compared to the reference share price allowed GENFIT to maximize the amount raised in the transaction while limiting the dilution of existing shareholders;
- > The entire transaction was based on indepth discussions focused on GENFIT's scientific fundamentals and strategic vision.

It is important to understand how this major strengthening of its cash position will be a negotiating force for GENFIT in the months and years to come.

A financially solid company gives itself the means to defend its interests and those of its shareholders.

This is a strong signal, and a key asset for greater freedom of choice, whether it is through partnerships, direct marketing in certain jurisdictions, or opportunities to reinforce our pipeline.

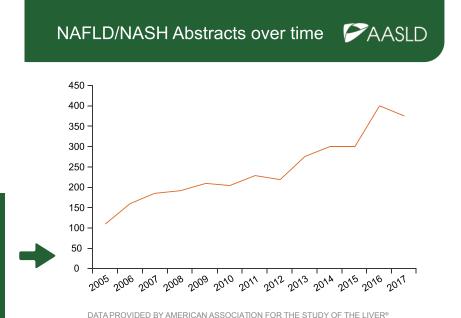




#### FEEDBACK ON THE AASLD LIVER MEETING®

NASH is continuing to gain prominence at major international liver disease conferences, although the amount of new information provided at the Liver Meeting® (Washington D.C., October 20-24, 2017) by the few companies with the most advanced programs on this disease remained relatively limited.

Evolution of the number of abstracts on NAFDL/NASH over time (NASH wrap-up)



The GENFIT team took advantage of the Liver Meeting® to exchange with the many speakers and participants on the overarching trends in preclinical/clinical/diagnostic research and to analyze changes in the scientific and competitive environment in order to maximize its position and maintain its leadership in the space.







### FEEDBACK ON THE EVOLUTION OF THE NASH ECHOSYSTEM

We believe it is helpful to share a number of these analyses with you.

With this in mind, I propose a quick overview to give some perspective on certain recently published information, which has been widely discussed by experts in the sector:

> As expected, Gilead announced the results of its phase 2 study for two doses of GS-0976 (ACC).

The trial protocol did not contain any of the relevant histological criteria for a phase 3 trial - neither the resolution of NASH as defined by the regulatory agencies, nor the improvement of fibrosis.

The test was limited to measuring some parameters such as steatosis or even liver stiffness (MRE-stiffness), whose measurements were performed without a biopsy, and do not meet the recognized efficacy criteria for phase 3 pivotal trials.

Not only are the majority of the results presented statistically inconclusive, but increased triglycerides may be of concern for a population already at cardiometabolic risk. As a reminder, the phase 2 trial with selonsertib (GS-4997 / ASK1) was conducted in very few patients and without placebo. These tests nonetheless demonstrate Gilead's desire to be present in this disease area.

> These results echo the phase 2b results announced a few weeks ago by Allergan, with cenicriviroc (CCR2 / 5), which were not extensively discussed at the 2017 Liver Meeting<sup>®</sup>.

As a reminder, at 2 years-out, efficacy has not been demonstrated for either the resolution of NASH or fibrosis.

Many observers seem to interpret this as an indicator that NASH - the underlying cause of disease progression - is a primary target to be

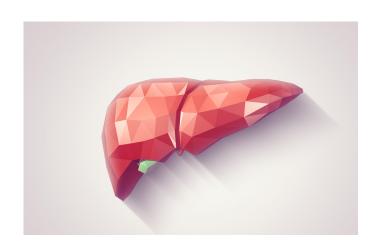
tackled head-on, otherwise, any one-time benefit on fibrosis does not seem to be sufficient to compensate for the worsening of NASH, characterized by inflammation and degeneration of liver cells.

> Lastly, Ocaliva, a compound developed by Intercept, has received particular attention in the wake of the warning letter issued by the FDA following safety issues observed in PBC.

Note that precautions had already been taken when PBC was first marketed (incremental doses, and dosing frequency, for example). Increased LDL and pruritus (55% in the CONTROL trial in NASH) remain important issues.

Other lesser known players announced encouraging results in preclinical or earlier-stage clinical stages:

- > Keep in mind, for example, the preclinical results of Madrigal with MGL-3196, targeting the thyroid hormone receptor (THR  $\beta$ -selective agonist), and seeming to indicate a reversal and/or a slowing down of the progression of lipid-related markers, inflammation and fibrosis.
- > Enanta has also reported interesting preclinical results with EDP-305, a FXR agonist, in animal models of hepatic fibrosis, as well as metabolic and bile duct diseases.





#### SIGNIFICANT INTEREST IN "DISEASE AWARENESS" ACTIONS

Beyond the traditional scientific data, disease awareness efforts have also clearly emerged as some of the most useful vectors for ensuring the future optimal management of NASH patients.

This specific dimension of clinical practice was mentioned many times, especially during the session chaired by Dr. Younossi and Dr. Vos, entitled "The Global Burden of NAFLD".



GENFIT's work in this field has been commended by important actors such as the Global Liver Institute and ELPA, which are very active patient advocacy groups. We met with them at the conference, and they expressed interest in the initiatives launched by our endowment fund, The NASH Education Program $^{TM}$ .

They particularly appreciated the publication of the results of the <u>first US survey</u> conducted for the NASH Global Health Observatory™, and the <u>educational videos</u> featuring world-class doctors in NASH.



Many would like to get involved directly with the First International NASH Information Day, organized by The NASH Education Program™, which is scheduled for June 12, 2018.

Events are expected to take place concurrently in some twenty European and American cities, and will be widely publicized in the press and on social media.

#### SAVE THE DATE!

JOIN US!

JUNE 12 **2018** 





#### MEETING OF INVESTIGATORS INVOLVED IN THE RESOLVE-IT PHASE 3 TRIAL

The numerous investigators involved in the RESOLVE-IT trial, evaluating elafibranor in NASH, met at the AASLD on invitation from GENFIT and expressed their satisfaction with the ramping up of patient recruitment, including the sharp increase experienced over the last few months, in order to meet the recruitment objective of ~1000 patients by the end of Q1 2018.



762 patients have already been randomized, and the first patient in the study has already completed treatment.

As a reminder, we must continue to scrupulously monitor balance between genders, between diabetic and non-diabetic patients, and among ethnic origins. The main priority is to stay as close as possible to the initial protocol, which was defined with the regulatory agencies in order to respect the proportions observed in real life.

The balance between the centers and the number of patients per center are also monitored.

The purpose of this careful attention is to ensure the relevance of the results of the clinical trial.

All these precautions should also make it possible to quickly evaluate the data, and thus limit the time leading up to the marketing authorization, in a context that will already benefit from an accelerated approval process.





#### OPEN HOUSE FOR RETAIL INVESTORS

In line with its culture of transparency and its desire for openness, GENFIT will invite retail investors who wish to participate in an open house at the company's headquarters in Lille,

# On Friday, December 1st from 3PM.

More details on how to participate in this event will be communicated at a later date.



In conclusion, the information from the recent weeks and the recent AASLD conference lead us to believe now more than ever in the potential of elafibranor as a future first-line treatment of NASH and fibrosis, particularly thanks to its unique profile combining, in the phase 2b trial, multiple benefits for NASH patients: (i) a significant efficacy on the histological criteria of «resolution of NASH» as it will be applied to the Phase 3 trial (ii) a histological benefit on fibrosis for patients having resolved their NASH (iii) a significant benefit on cardiometabolic risk parameters, an essential element for a chronic condition such as NASH and (iv) a particularly favorable safety and tolerability profile in the treatment of a silent disease such as NASH, where compliance will be crucial for both patients and payers.

I would also like to remind you that in addition to the Phase 3 trial in NASH, GENFIT continues the intense work undertaken in *in vitro* diagnostics, pediatric NAFLD/NASH, fibrosis (with NTZ) and PBC (Primary Biliary Cholangitis). We will provide information on these important programs in later announcements.

Lastly, I would like again to thank all of those who remain committed, often with tremendous conviction and patience, to this great medical and entrepreneurial adventure. I share with you, day after day, the disappointment of not yet seeing the market capitalization really represent the potential offered by GENFIT.

Our priorities, however, remain the commercialization of therapeutic and diagnostic solutions for the millions of patients affected by NASH. Providing strong financial resources for our company is one of the key requirements.

I look forward to continuing this discussion on December 1st.

Jean-François Mouney, GENFIT CEO







#### MARKET INFORMATION

Stock exchange: Euronext Paris, Compartiment B Mnemonic code: GNFT - ISIN code: FR0004163111

#### **CONTACT US**

#### **EUROPE**

Lille - 885, avenue Eugène Avinée - 59120 Loos - France Paris - 19, rue du Général Foy - 75008 Paris

Phone: +33 (0)3 2016 4000 - Contact: investors@genfit.com

#### **USA**

--

**Boston** - 185 Alewife Brook Parkway, Suite 401, 4th floor Cambridge, MA 02138 - USA Phone: +1 (617) 714 5252 - www.genfit.com



AVERTISSEMENT - This shareholders' letter 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 and the trial of elafibranor in PBC, 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 drug candidates in other indications and biomarkers candidates, the success 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 in Chapter 7 of the 2017 Half Year Business and Financial Report and under Section 4 "Main Risks and Uncertainties" of the Company's 2016 Registration Document registered with the French Autorité des marchés financiers on April 28, 2017 under n° R.17-034, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (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 letter 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 letter has been prepared in both French and English. In the event of any differences between the two texts, the French language version shall supersede.

