
LETTER TO SHAREHOLDERS

N° 9 - July 2019



Dear shareholder,

The 2019 newsflow has been particularly intense for GENFIT, therefore we believed it useful to reiterate some of the more important milestones and progress achieved. Also, this letter serves as a thank you to those who attended and supported GENFIT at the shareholders' meeting in June.

The agenda for the upcoming months is expected to be dense, with our Phase 3 data read-out for elafibranor in NASH fast approaching and eagerly awaited by all of the GENFIT team, who are relentlessly working to achieve success, but also all the stakeholders in the NASH space. The few months until the readout will likely seem endless, however for our dedicated team and long-term supporters it will only represent a fraction of the years spent in R&D, which have made of GENFIT one of the pioneers in the NASH field.

To continue, the main objective for the company is to achieve its profound and ongoing evolution and ensure we are well equipped to tackle the next milestone as a commercial organization.

TABLE OF CONTENTS

2019: Six months marked by significant scientific advances.....	2-4
The close of a twenty year chapter and the unveiling of a new era	5
Conclusion.....	6

2019: Six months marked by significant scientific advances

The first-half of 2019 has proven fruitful on the scientific, strategic and commercial fronts, reflecting GENFIT's commitment to excellence.

PBC: Compelling Phase 2 results



In December 2018, GENFIT announced successful topline results from our Phase 2 trial evaluating elafibranor in Primary Biliary Cholangitis (PBC), a severe liver disease. Additional data were presented at EASL in April in Vienna, Austria. These positive results are clear, with an efficacy three times that of competitor, Ocaliva, on the composite endpoint used for Phase 3 approval¹. Elafibranor's potential in PBC is indisputable and beyond the demonstrated efficacy, the Phase 2 data also suggest a potential beneficial effect on pruritus, one of the landmark symptoms of PBC. Elafibranor's successful data have also demonstrated positive signals in multiple blood markers that are closely monitored and associated with NASH.

The medical and scientific communities have commended the Phase 2 trial results in PBC and the FDA (U.S. Food and Drug Administration) has awarded elafibranor Breakthrough Therapy Designation. These achievements and recognition support our ongoing confidence in elafibranor's potential in PBC and NASH, and represent an opportunity to broaden GENFIT's therapeutic pipeline.

NIS4: The first licensing agreement paving the path for commercialization

GENFIT's strategy for NASH is comprised of three essential pillars: Diagnosis, Treatment, and Awareness. Diagnosis remains the main challenge for NASH patients and is only achieved with a liver biopsy - a long, invasive, and costly procedure. This is a major limitation that needs to be overcome. In addition, biopsy is not easily accessible, as it can only be performed by hepatologists, of whom there are too few to tackle this public health issue that affects up to 10% of the global adult population, and increasingly children and adolescents.



The initial commercialization of NASH therapies will only be successful if physicians can efficiently identify patients eligible for treatment, of which biopsy will be prohibitive. As of now, biopsy does not allow large scale identification. The FDA's 2018 guidance reiterated the need for a simple, reliable, quick, non-invasive diagnostic test. As a pioneer in the field, GENFIT had predicted this need by leveraging its rich databank and expertise in biostatistics to develop a non-invasive diagnostic test, NIS4.

With the timely FDA guidance at the end of 2018, in early 2019 GENFIT signed its first non-exclusive licensing agreement with LabCorp-Covance. This partnership, which validates NIS4 as an effective diagnostic tool also serves as the strategic rollout phase or pre-commercialization. Functionally, this agreement enables utilization of NIS4 in the clinical research field, however the key benefit

1. Hirshfield et al. 2015 *Gastroenterology* 148:751-761

will be familiarity and support of NIS4 amongst future prescribers in the NASH field.

The larger scale commercial rollout (expected in 2020 – 2021) will achieve two main objectives:

- To potentially garner a higher market share for elafibranor with the identification of a large number of patients eligible for treatment;
- The potential to create a revenue stream complementary and independent of elafibranor, should the Phase 3 be successful.

NASDAQ: A successful prerequisite for U.S. expansion



On March 27th, 2019, GENFIT successfully completed its dual-listing on the Nasdaq Global Select Market.

The Nasdaq listing is an integral part of GENFIT's U.S. expansion from a commercial standpoint. The U.S. NASH patient population will be GENFIT's primary market, representing the largest market opportunity and typically the fastest market access. In addition, the Nasdaq IPO – a platform acknowledging the innovative and promising nature of GENFIT – contributes to the rationale for our U.S. expansion:

- Exposure: A wider network of American research analysts and media outlets;
- Credibility: Greater access to specialized, healthcare-only investment funds with deep pools of active capital surpassing the AUMs of every other country combined (Orbimed, Great Point Partners, Lord Abbett, Healthcor, BackRock, etc...)
- Attractiveness: Recruiting top talent from big pharmaceutical companies and renowned consulting firms, with essential expertise necessary for a growing a commercial organization in the U.S.

In addition, the IPO strengthened our cash position, the foundation for long-term company stability, and even-more fundamental for one in the biotech sector. Financial leverage enables optionality for independent thought regarding research and development and negotiation power.



The successful operation was characterized by:

- An oversubscription reaching \$155M with a full and quick exercise of the greenshoe option bringing the cash balance of the company to over \$300M;
- A favorable post-IPO stock performance, outperforming the index NBI, S&P500, NextBiotech and CAC40;
- Increased U.S. analysts coverage with a consensus well above current stock price;
- New and extensive media coverage.

More recently, the financial markets have been experiencing substantial headwinds due to changes in U.S. healthcare policy. These challenges, coupled with negative readouts in the NASH field, have caused pressure on the biotech sector overall, with GNFT as no exception.

TERNS : first commercial partnership

GENFIT steadily continues to build the foundation necessary to maximize the company's future value.



GENFIT et Terns Pharmaceuticals annoncent un partenariat stratégique de 228MM\$ pour le développement et la commercialisation d'elafibranor en Chine

With this objective in mind, GENFIT signed a partnership with Terns Pharmaceuticals, an American-Chinese company, for the development and commercialization of elafibranor in Mainland China, Hong-Kong, Macau and Taiwan.

This agreement was signed at a strategic time for GENFIT. Compared to other Chinese partnerships in the healthcare field, this is a high-value financial transaction. Terns Pharmaceuticals is a partner with a strong reputation and is acknowledged by experts in the field.

The ongoing regulatory reforms of the CFDA (Chinese FDA) will facilitate and expedite market access for innovative compounds like elafibranor. Therefore it is an important and strategic time for GENFIT to proactively position itself as a leader in this region.

Terns Pharmaceutical has received the support of some of the most renowned financial and pharmaceutical stakeholders, including Lilly Asia Ventures, Orbimed and Vivo Capital. Terns is a very well respected company due to its history as a spin-off of Eli Lilly, one of the leading global pharmaceutical companies in the metabolic disease field. Today, Terns has a proven management team, with experience from leading pharmaceutical companies such as Gilead or Novartis.

Our decision to enter into an agreement with Terns was motivated by their deep knowledge of NASH, experience with the Chinese regulatory framework, and their ability to deploy and target commercial forces in the appropriate territory. Additionally, given its background, Terns clearly understand the complexity of innovation.

The value of the deal reflects a high level of confidence in the potential of elafibranor, with an upfront of \$35MM payable immediately, and up to \$193MM in milestones and royalties related to drug sales that can be added. This agreement is one of the larger deals ever signed over the last years for a single product with only Chinese rights. It is also important to note that the size of the Chinese market in NASH will be smaller than the U.S., European, and Japanese markets. Therefore, progress calls for other partnerships on a larger scale in the near and/or long-term.

Additionally...

Upcoming newsflow reflect the dynamic and motivated GNFT team. Recently, the FDA approved the protocol trial design for the clinical study of elafibranor in pediatric NASH, making elafibranor the only compound used in both an adult Phase 3 study for NASH and a pediatric study.

GENFIT is also launching a combination study to evaluate the association of elafibranor with commercialized molecules from the GLP1 and SGLT2 classes. This program aims to obtain clinical evidence and increase foundational knowledge of elafibranor among diabetologists and endocrinologists, and eventually facilitate prescription, should the compound be approved in NASH.

Finally, GENFIT announced the launch of a clinical study to evaluate the hepatic lipid composition of NAFLD patients. This would provide us with a better understanding of the mechanisms of action of elafibranor in toxic lipids.

The close of a twenty year chapter and the unveiling of a new era

GENFIT's 20-year history has been punctuated by many successful achievements and milestones. This coming year will mark the culmination of 20 years of research, development, and clinical trials of elafibranor in NASH and validate the work of our internal teams and external collaborations, transforming GENFIT into the next corporate phase.

RESOLVE-IT: The first clinical data from a Phase 3 trial



Our most anticipated milestone will come at the end of the year with the announcement of the RESOLVE-it results, a Phase 3 trial evaluating elafibranor for NASH resolution. Without a doubt, this will be an extremely important development for patients, doctors, our employees, our investors, our partners, and all stakeholders working in the NASH field.

The RESOLVE-IT study protocol was optimized based on the criteria required by regulatory authorities (FDA, EMA) for the Phase 3 clinical trials in NASH. These criteria include the definition of «NASH resolution without worsening of fibrosis,” the target population (inclusion of only the most seriously affected patients to limit the placebo effect), the duration of the study (extended to 72 weeks to better understand the histological changes, which are slow in nature), the recruitment of patients by block, and stratification of patients in order to have balanced representation.

This is a very exciting time for GENFIT, given the disappointing readouts from some of our competitors in the NASH space. However, the main objective remains positioning elafibranor for the next 10 to 15 years. Elafibranor's potential is based on its strong clinical profile: statistical efficacy, successful clinical data demonstrating a positive cardiometabolic benefit and a good safety profile, characteristics in line with our goal to position elafibranor as a first-line treatment and a backbone for future combination therapies.

From biotech to biopharma

The RESOLVE-it data readout is just one part of our recent transformation. Over the past year, we have grown our market access, marketing, and commercialization teams, particularly in the U.S. As a pioneer in NASH, we have conducted intense research to better realize the potential NASH market and the future interplay of prescribers, patients, and payers. Our market research studies have been encouraging thus far, and show strong support for GENFIT, elafibranor and NIS4, validating our initial hypotheses.

This proactive approach puts GENFIT in an ideal position in conversations and negotiations with major players in the pharmaceutical industry. Our market access work will surely place GENFIT in a competitive position, allowing for informed discussions based on a deep understanding of the market and its subtleties. This proactive effort could facilitate and accelerate commercialization and therefore create value for the company.

The pipeline continued...

We expect 2019 to be a groundbreaking year for GENFIT. Aside from RESOLVE-it, there are many additional programs underway: the soon-to-come commercialization and deployment of NIS4 in the clinical research setting, the launch of a Phase 3 clinical trial in PBC, the approval of our protocol to launch our first combination therapy study in NASH, and the progress of our clinical trial evaluating NTZ in fibrosis. As part of our multi-tiered approach, we also plan to submit scientific publications to known research journals for further validation of our ongoing research and development.

Conclusion

The successes of the first half of 2019, as well as the upcoming milestones, validate the strategic expansion plan our leadership team has put in place. However, it is important to remain focused and remind ourselves that major efforts are still underway. With an internal and external commitment stronger today than ever before, we are dedicated to accomplish and deliver on our priorities, understanding the high stakes.

To conclude, although stock markets are volatile, we remain committed to our strategic and operational priorities and are dedicated to building the greatest long-term value for you, our shareholders, our collaborators, our teams, and to the millions of patients suffering from NASH.

Thank you for your continued support of GENFIT.

Sincerely,

The General Direction

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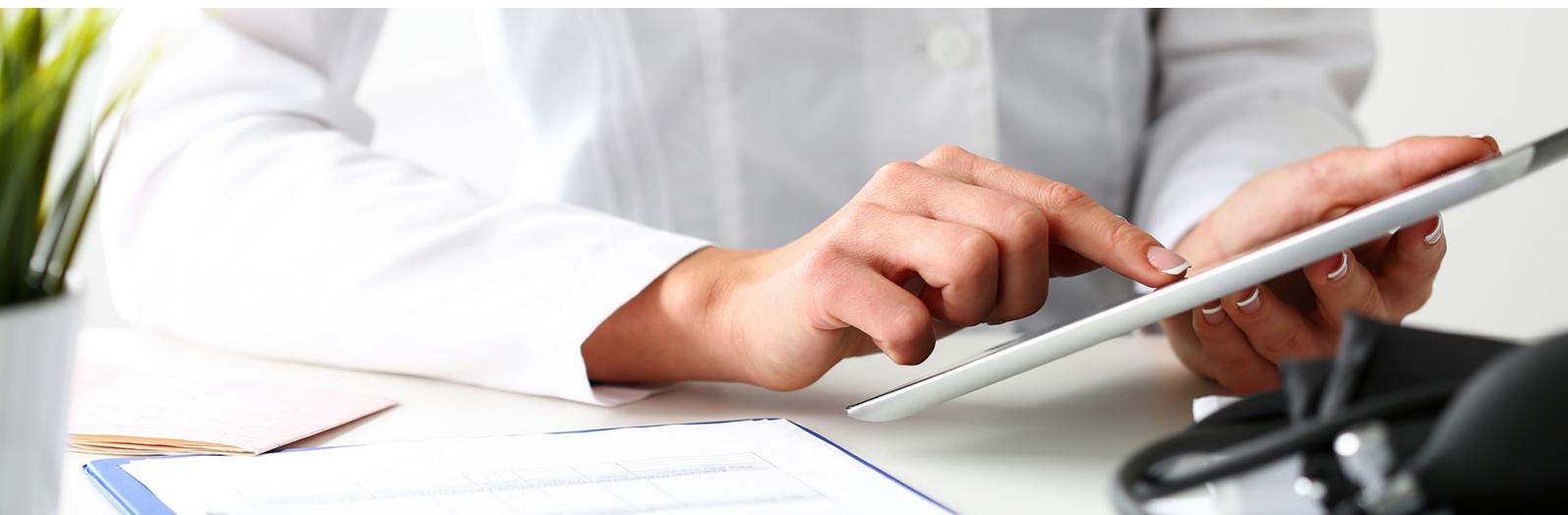
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AVERTISSEMENT - This letter contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995, with respect to GENFIT, including statements related to the belief that elafibranor may be a safe and effective treatment for NASH and PBC, to the development timelines for elafibranor in NASH and PBC, to ongoing and planned clinical trials in NASH, PBC and fibrosis, to the potential benefits of combination therapy with elafibranor or NTZ in addressing NASH and fibrosis, to the review and approvals by regulatory authorities, such as the FDA or the EMA, of its drug candidates and diagnostic tools and the timing thereof by regulatory authorities, the potential to and success of commercialization of elafibranor in Greater China and the effect of new regulations in China to accelerate and facilitate drug approvals, to the potential size of the NASH market in the United States, Europe and Japan, to elafibranor's and NIS4's commercial potential, and to potential negotiations and agreements with other companies. The use of certain words, including "believe," "potential," "expect" and "will" and similar expressions, is intended to identify forward-looking statements. Although the Company believes its expectations are based on the current expectations and reasonable assumptions of the Company's management, these forward-looking statements are subject to numerous known and unknown 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 safety, biomarkers, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French Autorité des marchés financiers ("AMF"), including those listed in Section 4 "Main Risks and Uncertainties" of the Company's 2018 Registration Document filed with the AMF on February 27, 2019 under n° D.19-0078, which is available on GENFIT's website (www.genfit.com) and on the website of the AMF (www.amf-france.org) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's final prospectus dated March 26, 2019, and subsequent filings and reports filed with the AMF or SEC, or otherwise made public, by the Company. In addition, even if the Company's results, performance, financial condition and liquidity, and the development of the industry in which it operates are consistent with such forward-looking statements, they may not be predictive of results or developments in future periods. These forward-looking statements speak only as of the date of publication of this document. Other than as required by applicable law, the Company does not undertake any obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise.