

## What to expect in 2023 as a GENFIT Shareholder?

Editorial by the CEO  
of GENFIT



Dear Shareholders,

2022 was a turning point for GENFIT. We continued to execute the strategy initially presented at the end of 2020, and then reinforced in 2021. You will be familiar with the three components of our strategic action plan:

- Maintain good **financial visibility**;
- Accelerate our flagship program in **Primary Biliary Cholangitis (PBC)**, for which Phase 3 data is imminent;
- Build a dense and diversified **portfolio of drug candidates** in the therapeutic areas in which we have expertise and representing significant market potential.

→ **At the end of 2020**, our main achievement was **the improvement of our financial position**, thanks to the restructuring of our convertible bond (OCEANE), which allowed us to rebuild a solid foundation for the coming years.

→ **At the end of 2021**, we signed **a strategic partnership agreement with Ipsen**, made possible thanks to the excellent results of our Phase 2 trial in PBC, and the good execution of our Phase 3 trial, despite the constraints engendered by the Covid pandemic.

→ **At the end of 2022**, we completed **the acquisition of Versantis AG**, a Swiss biotech company, which considerably strengthened our leadership in the field of rare and serious liver diseases, in particular in Acute on-Chronic Liver Failure (ACLF). Beyond ACLF, this acquisition has expanded our R&D portfolio, which now includes 4 clinical programs and 2 preclinical programs in several indications.

As a reminder, our strategic positioning consists of developing innovative compounds to fight liver diseases that are **rare**, **serious**, and for which there remains a **significant unmet medical need**, either because of the lack of available treatment, because existing therapeutic approaches are limited in terms of effectiveness, or because they generate undesirable side effects. In all cases, the goal is to **address the public health priorities set by health authorities**.

Pascal Prigent

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# 1.

## Financially: a solid foundation and short-term prospects

Our cash position at the end of 2022 is healthy, with **€140 million cash and cash equivalents** expected to fund all of our current programs through the third quarter of 2024.

Our financial situation will be **further reinforced if the results of our Phase 3 trial in PBC are positive**, because under our agreement with Ipsen, we are eligible for milestone payments, with a potential first milestone payment as early as 2023 and an additional potential milestone payment in 2024. As a reminder, if successful, GENFIT is eligible for:

- Regulatory, commercial and sales-based milestone payments of **up to €360 million**;
- Double-digit royalties of **up to 20% of total elafibranor sales**, knowing that elafibranor's "first-in-class" status combined with Ipsen's well-established global commercial footprint will be an important driver of commercial success.

# 2.

## Phase 3 ELATIVE® in PBC: upcoming results and a strong scientific rationale

Topline data for this pivotal study are expected **at the end of the second quarter**, in other words, in the next few months.

The Phase 2 results were particularly promising, which supported elafibranor receiving FDA's **Breakthrough Therapy designation**, the scientific publication in the **Journal of Hepatology** and the **collaboration agreement** signed with Ipsen. The results showed the following:

### Efficacy

➔ the primary endpoint was met with statistical significance as well as a significant response rate on the composite endpoint used for the Phase 3 trial;

### Quality of life

➔ a positive trend was observed on pruritus, a primary symptom in PBC;

### Safety and tolerability

➔ a favorable profile confirming previous observations on the >1000 patients with nonalcoholic steatohepatitis (NASH) in the

RESOLVE-IT® trial.

Note that the results for elafibranor in NASH do not impact the probability of scientific success in PBC.

PBC is a very different illness from NASH and the regulatory context is more stable for the following reasons:

- The evaluation of **patient response** is not subject to biopsy-related inter-reader variability;
- **Regulatory demands** are known given that a product has previously been approved for second-line treatment.

Further, the fundamentals of the commercial approach are well defined:

- Patients are **easily identified**;
- **Clear indicators exist** on the potential level of pricing or the size of the market for second-line therapy estimated at \$1.5bn in the coming years.

[See the ELATIVE® study on Clinicaltrial.gov](#)

### 3.

## Other programs in development: several advances expected in Phase 2 studies

As part of a coherent strategic approach, the therapeutic areas we are focusing on share common characteristics: a focus on rare and severe conditions for which there are no or limited therapeutic options, with medical needs which could allow most of our programs to be eligible for **expedited regulatory pathways** provided by health authorities.

Despite these therapeutic areas being rare, they represent (as a whole and not including PBC) a market opportunity of an estimated **\$11bn by 2030** in the US and the major European markets).

GENFIT has 3 programs in clinical development, details of which you can find in our previous communications (see [Pipeline Day](#) and [annual results press release](#)). The next steps are the following:

#### In ACLF

- **Second quarter 2023:** screening of a first patient in a Phase 2 clinical trial evaluating VS-01-ACLF, an innovative first-in-class drug which became part of GENFIT's drug candidate portfolio following the acquisition of Versantis;
- **Second quarter 2023:** conclusions on two Phase 1 clinical trials evaluating NTZ;
- **Second half of 2023:** expected initiation of a Phase 2a trial with NTZ, depending on the outcome of upcoming discussions with regulatory agencies.

#### In Cholangiocarcinoma (or CCA)

- **Towards the end of the second quarter 2023:** screening of a first patient in a Phase 1b/2 trial evaluating GNS561, an innovative drug which

was integrated in our drug candidate portfolio following the in-licensing of rights for GNS561 in this indication.

#### See Pascal Prigent's latest interview

On April 20, 2023, Pascal Prigent, GENFIT's CEO, was invited on the « **Journal des Biotechs** » presented by Laurent Grassin, Editorial Director at Boursorama.



The interview starts on the 11<sup>th</sup> minute in the video (french) which you can watch by clicking the image.



#### Next GENFIT event: May 24<sup>th</sup> Combined Shareholders Meeting

As you can see, 2023 could be a year with a new dynamic for GENFIT. This is why it is important for you to vote at the Combined Shareholders Meeting.

Your past support at our Shareholders meetings helped us bring value to the PBC program with Ipsen in 2021, and prepare the future with the Versantis acquisition in 2022.

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Disclaimer | This Shareholders' Letter contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995 in relation to timelines for topline data readout for our ELATIVE<sup>®</sup> Phase 3 trial, potential for positive ELATIVE<sup>®</sup> Phase 3 results, eligibility to meet milestones and receive payments from Ipsen, timelines for data readout in NTZ in ACLF Phase 1 trials, timelines for patient screening and enrollment in our VS-01 ACLF and GNS561 in CCA programs, timelines for the initiation of a Phase 2a proof of concept study evaluating NTZ in patients with ACLF grades 1 and 2, commercial perspectives for eldibrator in PBC and its potential as a therapeutic option for patients, potential market sizes in the disease areas where we develop our product candidates, our ability to qualify for and obtain specific regulatory pathways, our financial outlook including cash flow and cash burn projections and business activity projections for 2023 and beyond. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "targeted", "anticipated", "believe", "wish", "may", "could", "allow", "seek", "encourage" or "have confidence" or (as the case may be) the negative forms of such terms or any other variant of such terms or other terms similar to them in meaning is intended to identify forward-looking statements. Although the Company believes its projections are based on reasonable expectations and 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 in relation to safety, biomarkers, cost of, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, exchange rate fluctuations, potential synergies related to the acquisition of Versantis, our capacity to integrate its assets, develop its programs and our continued ability to raise capital to fund our development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the AMF, including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2022 Universal Registration Document filed with the AMF on April 18, 2023 under n° D.23-0304, which is available on the Company'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)) and public filings and reports filed with the U.S. Securities and Exchange Commission ("SEC") including the Company's 2022 Annual Report on Form 20-F filed with the SEC on April 18, 2023. 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.