GENFIT
TOWARDS BETTER MEDICINE

SHAREHOLDERS' LETTER

N° 14 - May 2023

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

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 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 11th minute in the video (french) which you can watch by clicking the image.

Next GENFIT event: May 24th 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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