

Winter  
2026

N°19

# SHAREHOLDERS & INVESTORS NEWSLETTER

February 9, 2026

I. 2026: A Promising Start to the year

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II. GNS561: A Major Milestone in  
the Fight Against  
Hard to Treat Cancers

## 1. A strategy built on three pillars

The positive progress achieved at the end of 2025 provides a solid foundation on which GENFIT will build in the coming months. This will include:

**1** Continuing the clinical development of **G1090N across the ACLF continuum**, building on the strong Phase 1 results and the anti-inflammatory activity signals announced in early January.<sup>1</sup>



“The safety profile observed in Phase 1 and the consistent biological activity evidenced in ex vivo assays represent a meaningful step in development. These findings position G1090N as a promising candidate for patients with acute decompensation and for patients with ACLF, a life-threatening condition with no approved therapies and significant unmet medical need. We are eager to see more patient data as the program moves forward, to confirm G1090N's safety and strengthen the case for its activity in patients with organ failure.”

**Dr. Jacqueline O'Leary, Chief Medical Officer at UT Southwestern Medical Center, Dallas, Texas (United States)**

[Click here to read the press release](#)

**2** Strengthening an already solid financial foundation by capitalizing on the excellent **sales trajectory of Iqirvo® in primary biliary cholangitis (PBC)**, which reflects the outstanding work of our commercial partner Ipsen and highlights the quality of the molecule developed by GENFIT.

Full Prescribing Information | Important Safety Information | Healthcare Professionals Site > [Email Sign-Up](#)

About PBC | About Iqirvo | Iqirvo Stories | Support & Resources

**IQIRVO®**  
elafibranor  
500 mg tablets

**The Iqirvo Effect**  
Transforming your PBC treatment journey

If you aren't responding well enough to ursodiol (ursodeoxycholic acid, also known as UDCA), adding once-daily Iqirvo® may reduce and even normalize alkaline phosphatase (ALP).

[Click here to go to the website](#)

**3** Continuing the clinical development of **GNS561 in oncology**, capitalizing on the excellent preliminary results obtained (see page 5 for more details) in December to refine and strengthen the development plan: doses, target populations, combination agent, regulatory endpoints, and exploration in other cancer types.<sup>2</sup>

<sup>1</sup>Press release GENFIT - 01.06.26

<sup>2</sup>Press release GENFIT - 12.10.25

## 2. Presence in San Francisco during the J.P. Morgan conference

Members of GENFIT's management team attended the J.P. Morgan Annual Healthcare Conference in San Francisco and held around 30 strategic discussions with major pharmaceutical companies, innovative biotech firms, institutional investors, and other key industry stakeholders.

### Key takeaways:

- Growing appreciation for the commercial results of Iqirvo® and the excellent work of our partner Ipsen.
- Strong interest in the potential of GNS561 in oncology, particularly following the preliminary Phase 1 results released in December, which confirmed the molecule's favorable safety profile and provided very clear early signs of activity on tumor progression.
- Clear interest for G1090N in ACLF, whose potential was further reinforced by the results announced in early January, confirming a favorable safety profile and showing highly encouraging anti-inflammatory activity signals.
- Renewed confidence in the ability of French biotech companies to leverage their innovations

## 3. Upcoming events

### February 12, 2026: 2025 results from our partner Ipsen

The IPSEN conference, which will take place from 2:00 to 3:00 p.m. CET, will be accessible via [this link](#).



#### Ipsen FY 2025 Results Call

The Ipsen FY 2025 Results Call will take place on February 12th, from 2:00 to 3:00pm CET.

> [Webcast link](#)

> [Analyst Q&A \(by Phone Only\)](#)

### March 2026: newsletter video

In a few weeks, we will take the time to answer key questions from our individual shareholders in a video newsletter. Whether you are already a shareholder or are considering becoming one, we invite you to send us your questions now to [investors@genfit.com](mailto:investors@genfit.com).

The aim will be to answer your questions, providing useful information for everyone to gain a better understanding of our challenges, our strategy, and our progress. The video will be available on the website [www.genfit.com](http://www.genfit.com) in the investors section, and shared via the company's [LinkedIn](#) account, which we encourage you to follow.

Individual  
shareholder  
dialogue

### Other key dates to keep in mind in the first half of 2026:

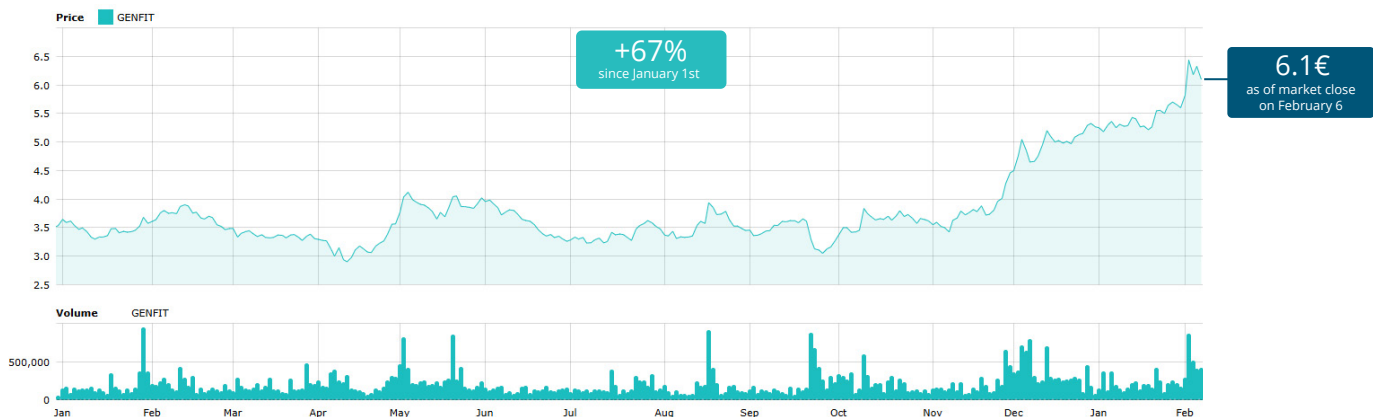
- February 26, 2026: Publication of revenue and cash position as of December 31, 2025
- March 9–11, 2026: Leerink Partners Global Healthcare Conference 2026 Miami
- April 2, 2026: Full-year 2025 financial results and update on the company's activities
- April 15–16, 2026: Kempen Healthcare Conference
- May 21, 2026: Publication of revenue and cash position as of March 31, 2026
- May 27–30, 2026: EASL Congress in Barcelona
- June 15, 2026: Annual General Meeting of Shareholders

## 4. Stock market environment and financing

### Shareholding Structure: Crossing of the 5% Threshold by a U.S. Fund

Following the announcement of the preliminary data in cholangiocarcinoma, the 5% threshold was crossed by a U.S. institutional investor — [AMF source, December 24, 2025](#): The company 683 Capital Partners, LP (New York, United States) declared that on December 22, 2025, it had exceeded the 5% threshold of GENFIT's share capital. After this crossing, it holds 2,576,702 GENFIT shares, representing 5.15% of the share capital and 4.57% of the voting rights. This threshold crossing resulted from an acquisition of GENFIT shares on the market.

### Evolution of the Share Price Since January 1, 2025



Source : <https://live.euronext.com/en/product/equities/FR0004163111-XPAP>  
Date : 06 February 2026

### Financial results

As communicated in November 2025, GENFIT's cash and cash equivalents amounted to €119.0 million as of September 30, 2025 (compared with €107.5 million as of June 30, 2025, and €81.8 million as of December 31, 2024).



Financial information for the fourth quarter of 2025 will be released on February 26, 2026, in line with the financial calendar shared earlier this year.

In the meantime, on February 12, 2026, our commercial partner Ipsen will publish its full-year 2025 financial results. This disclosure will be important for GENFIT, as the commercial performance of Iqirvo® directly influences the amount of royalties to which GENFIT is entitled under the 2021 agreement, as well as the expected timing for the completion of our commitment with HCRx under the 2025 Royalty Financing agreement.





# GNS561: A Major Milestone in the Fight Against Hard to Treat Cancers

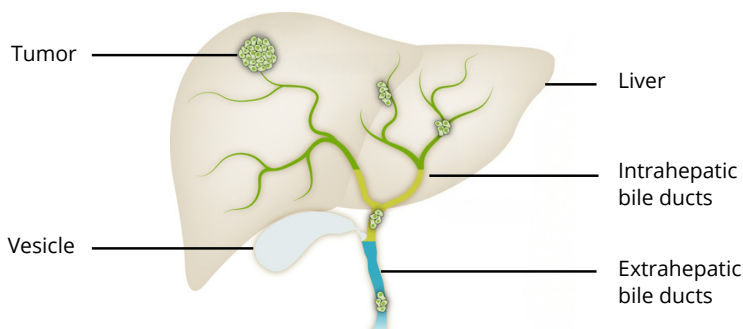
On December 10, 2025, GENFIT released highly encouraging preliminary data from its Phase 1b clinical trial in cholangiocarcinoma, a rare and aggressive cancer of the bile ducts. The study evaluates our investigational drug candidate GNS561 in combination therapy. These data give us an opportunity to share a few key points about this still little-known program, in order to put the announced results into better perspective.

Oncology is a complex field of exploration due to the heterogeneity of tumours, the multiple biological mechanisms involved, and the highly variable responses to treatment from one patient to another. It is also a relatively new field for many of our individual shareholders, who may not always have access to the resources needed to objectively interpret such data.

## 1. The medical need

### What is cholangiocarcinoma?

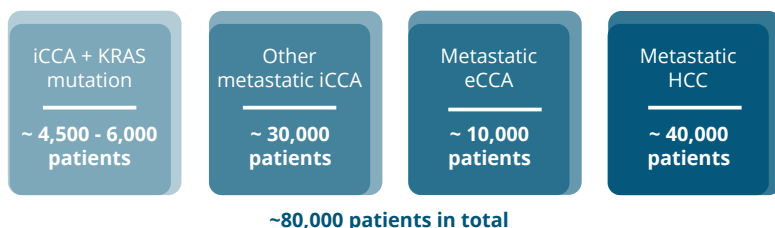
Cholangiocarcinoma, or CCA, is a rare and very aggressive cancer of the bile ducts. These ducts play an essential role in draining bile produced by the liver to the small intestine, in order to facilitate the digestion of fats. This cancer can affect the bile ducts inside the liver (intrahepatic ducts) or outside the liver (extrahepatic ducts). In both cases, the prognosis is extremely poor.



From Banales JM et al. Cholangiocarcinoma 2020: the next horizon in mechanisms and management. Nat Rev Gastroenterol Hepatol. 2020 Sep;17(9):557-588. doi: 10.1038/s41575-020-0310-z.

### How many patients are affected by this type of liver cancer?

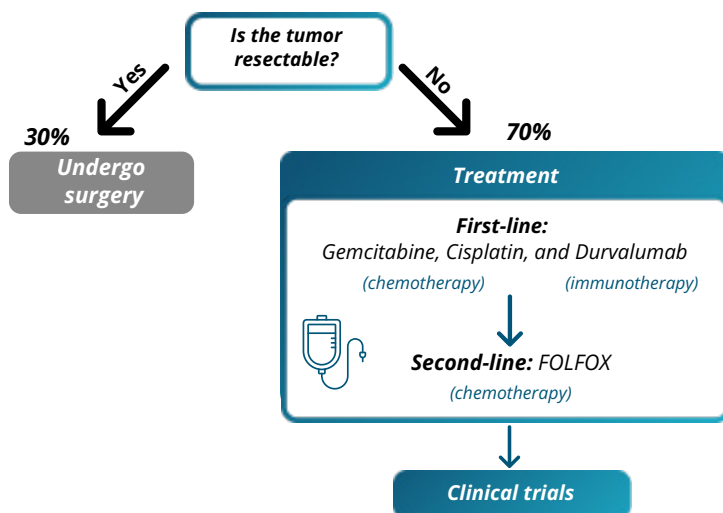
Intrahepatic cholangiocarcinoma (iCCA) with KRAS mutation represents 4,500-6,000<sup>1</sup> patients in second-line treatment. When extended to other metastatic iCCA, an additional 30,000 patients are added. Extrahepatic cholangiocarcinoma (eCCA) accounts for another 10,000 patients, and hepatocellular carcinomas for approximately 40,000 more patients.



### How is this cancer currently treated?

Patient care is highly challenging. Surgery is the only curative treatment, but only around 30% of patients have resectable tumors. For the others, first line treatment consists of a triplet therapy (gemcitabine, cisplatin, durvalumab). Despite this approach, average survival rarely exceeds 12 months.

In case of treatment failure, second line therapy with FOLFOX<sup>2</sup> may be offered, with very limited benefits (a few additional months). Beyond that, patients have no options other than clinical trials. This highlights the urgent need for new therapeutic approaches capable of significantly improving survival and quality of life.



<sup>1</sup> IQVIA data covering the United States, the United Kingdom, France, Germany, Spain, Italy, China, and Japan

<sup>2</sup> FOLFOX: Folinic acid, Fluorouracil, Oxaliplatin

## 2. Preliminary results and next steps for the program

GENFIT has kept to its planned schedule announced beginning 2025, with an initial communication of the results at the end of 2025, thanks to the unwavering commitment of its teams. We also extend our gratitude to the patients, their families, and all healthcare professionals involved on a daily basis.



Advanced KRAS-mutated cholangiocarcinoma remains a formidable clinical challenge, and the emerging activity seen in this initial study is encouraging. Because MEK inhibition alone has historically shown limited efficacy in this setting, the early signs of benefit with dual targeting of autophagy and MAPK signaling provide meaningful rationale for continued evaluation of this combination strategy.

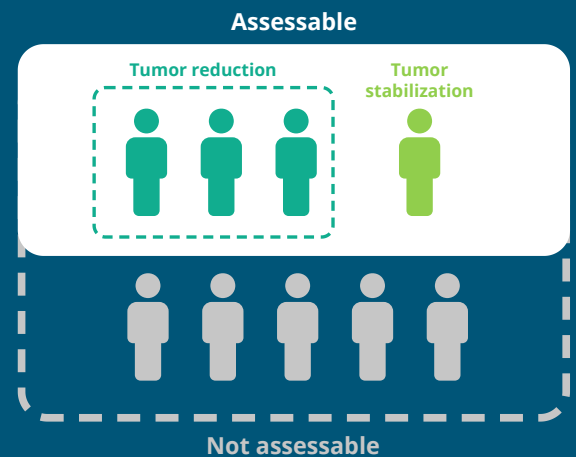
**Dr. Mark Yarchoan. Associate Professor of Oncology, Johns Hopkins Medicine (Baltimore, MD, USA), Principal Investigator of the program.**

[Click here to read the press release](#)

### Key takeaways from the results announced in December 2025

Nine patients participated in this part of the Phase 1b study. The health status of four of them could be assessed after 6 weeks. The first reason of satisfaction comes from the confirmation of the safety and tolerability profile of the combination of a MEK inhibitor (MEKi) with GNS561 (*the primary objective at this early stage of development*). The second reason of satisfaction comes from the highly encouraging efficacy signal, unexpected both for its early onset and its consistency across all evaluated patients: all four patients showed disease stabilization, and three of them even experienced tumor reduction.

This result is remarkable, especially in patients whose tumors continued to grow despite prior treatments. These data, obtained within the first few weeks and at limited doses, confirm the relevance of our strategy and justify continuing clinical development.



### What are the next steps in clinical development?

We are continuing the dose-escalation phase in Phase 1 in order to identify the most promising balance between safety, tolerability, and efficacy. Our current objective is to finalize, by the end of the year, the recommended Phase 2 doses: one for GNS561 and one for the MEKi. Once the analyses are completed and validated with clinical development and regulatory experts, our priority will be to initiate Phase 2 as quickly as possible. Between now and the start of Phase 2, we will share significant results from upcoming patient cohorts, including the one currently undergoing treatment. If the clinical signals continue to be confirmed, recruitment for Phase 2 could be significantly faster than for Phase 1.

### Patient testimonials



*This cancer is silent but devastating. Many patients are no longer here five years after the diagnosis. The tests take time, but the disease doesn't wait. The doctors talked about a "tumor," never about "cancer." I had to ask the questions myself to understand. My first question was: "How long do I have to live?" The word "palliative" really scared me.<sup>1</sup>*

<sup>1</sup> Patient Testimony - Espoir Voies Biliaires

## Dr. Eric Raymond, Head of the Oncology Department at Saint Joseph Hospital in Paris, answers a few questions



There is a phase 1/2 in CCA that was supposed to recruit 74 patients, but after two years of recruitment, only 9 patients have been analyzed and we are given evaluations based on 4 patients.

Four patients evaluated in two years is not credible, and they are going to launch a Phase 2 study with that?

What is the value of positive signals in 4 patients—is this really scientific?

If 74 patients were to be recruited for phase 1/2, it is probably because phase 1 (dose escalation) was to include 24 and the extension phase 50. As with VS01, there is a very serious recruitment issue in CCA.

*In early clinical development in oncology, it is essential to interpret results within the proper analytical frameworks. In Phase I, limited sample sizes and a gradual dose escalation are not only expected but necessary to identify biologically and clinically consistent signals in heavily pretreated patients. What gives these initial data their scientific value is not the raw number of patients, but the convergence of clinical observations—especially in complex indications such as cholangiocarcinoma, where treatment options remain limited. Experienced clinicians also know how to recognize emerging efficacy signals, often subtle yet pivotal for subsequent development.*



*In the AOF press release... It should report the good results in the current phase. I don't much like the term "cohort" used to refer to human beings who are ill and who, albeit as volunteers, will serve as guinea pigs. Shame on the person who wrote this press release.*

Indeed, cohort is not really respectful, even if the scientific context may justify it. The same goes for "escalation" of doses, from the English word "escalation," which simply means increase. Some will argue that form is not important (grumpy people!). Well, it does: it is the image the company projects to the investor community, which implies a minimum of respect—at the very least, proofreading the latest press release, which contains several grammatical errors that would have meant immediate elimination in the now-defunct "Certificat d'études primaires". I am not a French teacher but a finance professional and a professional evaluator of companies. As for the fundamentals? I remain positive on this stock, the third line in my portfolio. Confident.

*The vocabulary used—cohort, escalation, phase—belongs to a precise medical and regulatory language shared by all stakeholders in the field and is essential to ensure rigor, comparability, and safety. Major advances in oncology are never achieved in a single leap: they always begin with these methodical and demanding early steps, the quality of which makes it possible to identify the molecules that may become tomorrow's medicines.*

## Interview: Pascal Prigent, CEO of GENFIT, in the Journal des Biotechs (December 12, 2025)



💬 *The feedback from leading oncology experts is that we may be holding something with truly significant potential.* 💬

GENFIT | [investors@genfit.com](mailto:investors@genfit.com) | <https://ir.genfit.com/fr/>

This Shareholders' Letter contains forward-looking statements about GENFIT and, in particular, forward-looking statements relating to the commercial potential of Iqirvo® (elafibranor); the completion of Phase 1b and the initiation of Phase 2 of the ongoing clinical trial evaluating GNS561 in CCA; the potential of GNS561 in combination with MEK1 to deliver meaningful clinical benefit and represent a therapeutic advance for patients with advanced solid tumors; the possibility of improving response rates through dose optimization and patient selection; plans for additional studies that would evaluate GNS561 in combination with other agents and in other tumor types; GENFIT's commitment to advancing treatment options in CCA; the number of patients affected by CCA; the future development of G1090N and its potential therapeutic benefits across the ACLF continuum; and the timing of publication of financial information by the Company and by its partner Ipsen. The use of certain words, such as "believe," "potential," "hope," "should," "could," "if," and similar expressions or variations thereof, is intended to identify these forward-looking statements. Although the Company believes that its projections are based on reasonable assumptions and expectations of its Executive Management, such forward-looking statements may be challenged by a number of known or unknown risks and uncertainties that could cause actual results to differ materially from those described, implied or anticipated in such forward-looking statements. These risks and uncertainties include, among others, the uncertainties inherent in research and development, including those related to nonclinical and preclinical programs, the reproducibility of preclinical results, the translation of data from animal models to human biology, the safety of drug candidates, the progress, costs and results of planned and ongoing clinical trials, the reviews and approvals by regulatory authorities in the United States, Europe and worldwide concerning drug candidates and diagnostic solutions, the price, approval and commercial success of elafibranor in the relevant countries, fluctuations in exchange rates, and the Company's ability to continue to raise funds for its development. These risks and uncertainties also include those discussed in chapter 2 "Risk Factors and Internal Control" of the Company's 2024 Universal Registration Document filed on April 29, 2025 (No. D.25-0331) with the Autorité des marchés financiers ("AMF"), which is available on GENFIT's website ([www.genfit.fr](http://www.genfit.fr)) and the AMF's website ([www.amf.org](http://www.amf.org)), and those discussed in the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Form 20-F filed with the SEC on the same date and in subsequent documents and reports filed with the AMF and the SEC, including the Half-Year Activity and Financial Report as of June 30, 2025, or otherwise made public by the Company. Moreover, even if the Company's results, performance, financial position 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 future results or developments. These forward-looking statements speak only as of the date of publication of this Shareholders' Letter. Subject to applicable regulations, the Company undertakes no obligation to update or revise the information contained in this Shareholders' Letter, whether as a result of new information, future events or otherwise.