

## **GENFIT Reports Full-Year 2024 Financial Results and Provides Corporate Update**

- Cash and cash equivalents totaled €81.8 million as of December 31, 2024. In addition, completion in early 2025 of: (i) a non-dilutive royalty financing agreement for up to €185 million including a first installment of €130 million and (ii) the debt repurchase offer
- Net profit of €1.5 million thanks to revenues amounting to €67.0 million for the period ended December 31, 2024, including a €48.7 million milestone payment and royalties
- In 2024, Iqirvo® received marketing approval in PBC in both the United States and Europe, and was subsequently commercially launched in the U.S. and in some European countries by Ipsen, who reported an acceleration in 1Q25 sales growth in line with expectations
- In ACLF, several new datasets highlighting the potential of our main assets and providing a strong rationale for further development have been produced and presented at various scientific meetings. Meanwhile, a major initiative based on analysis of Real-World data helped improve understanding of ACLF and its continuum. Key clinical data readouts expected by year-end.

Lille, France; Cambridge, MA; Zurich, Switzerland; April 24, 2025 - GENFIT (Nasdaq and Euronext: GNFT), a latestage biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced annual financial results for the year ended December 31, 2024. A summary of the consolidated financial statements is included below.

**Pascal Prigent, CEO of GENFIT commented**: "In 2024 the commercial launch of lqirvo® by Ipsen marked a major milestone in GENFIT's history as we evolved from a pure R&D company into a company with commercial revenues. This enabled us to considerably strengthen our financial visibility and eliminate our convertible debt overhang, as we pivot decisively towards the advancement of our innovative pipeline in ACLF. With five dedicated programs, GENFIT has positioned itself as a key player to address this deadly condition, for which there is no approved treatment. In 2024, major progress was achieved in our understanding of the ACLF continuum and patients with ACLF. Key insights generated will provide a solid foundation for the continued development of our programs in 2025."

### I. 2024 Highlights – including post-closing events

### Iqirvo® in Primary Biliary Cholangitis (PBC): regulatory approvals and commercial launch

In 2024, GENFIT and its partner Ipsen reported significant commercial and regulatory advances with Iqirvo®<sup>1</sup> (elafibranor) in the United States, Europe and the UK.

Ipsen's lqirvo $\mathbb{R}^2$  received accelerated approval from the U.S. Food and Drug Administration (FDA) on June 10, 2024 as a first-in-class treatment for PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults who are unable to tolerate UDCA. GENFIT received a milestone payment of €48.7 million upon the first sale of Iqirvo $\mathbb{R}$  in the US.

Ipsen also received conditional approval from the European Commission on September 20, 2024 for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as monotherapy in adults who are unable to tolerate UDCA, and from the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) on October 9, 2024, followed by reimbursement approval from the National Institute for Health and Care Excellence (NICE) on October 22, 2024.

<sup>&</sup>lt;sup>1</sup> Iqirvo®, NIS2+®, ELATIVE® and UNVEIL-IT® are registered trademarks of GENFIT SA

<sup>&</sup>lt;sup>2</sup> Elafibranor is marketed and commercialized by Ipsen under the trademark Iqirvo®



On April 16, 2025, Ipsen reported "accelerated sales growth in the U.S. based on increasing patient uptake from new patients, switch and market expansion, successful launches in Germany and the UK with additional launches expected in 2025".<sup>3</sup>

### Meaningful progress across ACLF programs

In 2024, we launched and executed a major Real-World data program designed to improve understanding of the ACLF syndrome and support more targeted, data-driven decision-making:

- Using a U.S. database including comprehensive information on patients, encompassing clinical characteristics, diagnosis, prescriptions, comorbidities, outcomes, and laboratory values. Data from ~270 000 patients provided a longitudinal perspective on patient profiles and disease progression.
- Development of a machine learning model to segment subgroups of patients with ACLF and those with Acute Decompensation (AD) of the liver, facilitating a deeper understanding of risk stratification across different patient profiles.
- The first key outcome of this project was an in-depth analysis of the disease continuum between patients with AD and ACLF, as well as a detailed characterization of subpopulations at varying levels of mortality risk. These insights served as a scientific foundation for updating GENFIT's 2025 strategic action plan, supporting the decision to expand our target population in upcoming trials to include a subset of patients with high-risk AD who are more likely to progress to ACLF.

**VS-01-ACLF** – The UNVEIL-IT®<sup>1</sup> Phase 2 trial for VS-01 continued to progress, with expanded geographic reach including new sites in the U.S. Following early recruitment challenges, protocol adjustments were implemented to better reflect patient care logistics and comorbidities. New data were also generated to give more flexibility to healthcare providers in the timing of administration of the drug. New datasets were showcased during international scientific congresses. New "blood and peritoneal metabolomics data suggesting that VS-01 actively captures metabolites associated with ACLF" were presented at EASL congress, and "VS-01 effects on ACLF-related toxins such as lipopolysaccharide and hydrophobic bile acids in vitro" were shared during AASLD The Liver Meeting®.

**NTZ** (nitazoxanide) – Data indicating that "NTZ directly protects from stress-induced cell death to alleviate liver damage in preclinical models of ACLF" were reported at EASL congress, and "NTZ efficacy in PAMPs-induced disease models" was showcased during AASLD The Liver Meeting®. These data reinforce the therapeutic potential of investigational drug NTZ to act on major pathological pathways of ACLF. In 2024, a program aimed to develop **G1090N** – a new formulation of NTZ – also initiated to optimize dose-response and permit sufficient dosing flexibility in patients with ACLF, who are known to have varying degrees of renal or hepatic impairment or failure.

**SRT-015** – As highlighted during AASLD The Liver Meeting®, preclinical analyses demonstrated that "intravenous administration of SRT-015 alleviates liver injury and systemic inflammation in disease models of liver failure", supporting further development. Additional positive data were also obtained in a gut leakage-induced sepsis model, where SRT-015 was shown to protect animals from mortality.

**CLM-022** – Significant progress was made, with new data positioning "CLM-022, a potent inhibitor of NLRP3 inflammasome-mediated pyroptosis, as a potential treatment for acute and chronic inflammatory liver diseases". First in-vivo data have shown that one oral administration of CLM-022 decreases inflammation and protects against liver injury in a model of acute liver injury in mice.

2024 also marked the start of a research collaboration between GENFIT and the European Foundation for the Study of Chronic Liver Failure (EF CLIF), reinforcing our leadership in advancing the understanding of ACLF. Other collaboration with learned societies included engagement with US KOLs from NACSELD<sup>4</sup>.

 $<sup>\</sup>label{eq:linear} {}^{3} https://www.ipsen.com/websites/ipsen_com_v2/wp-content/uploads/2025/04/16112235/Ipsen-Q1-2025-sales-presentation_VF.pdf$ 

<sup>&</sup>lt;sup>4</sup> North American Consortium for the Study of End-Stage Liver Disease



#### **Other R&D developments**

**Cholangiocarcinoma (CCA)** – Preliminary safety data analyzed end of 2024 from the patients treated in the first cohort of Phase 1b with the combination of GNS561 and trametinib were supportive of the continuation of the study. In early 2025, GENFIT completed the acquisition of the full intellectual property rights for GNS561 from Genoscience Pharma, replacing the more limited license agreement rights initially obtained at the end of 2021.

**Diagnostics** – NIS2+® was included in the European clinical practice guidelines for the management of metabolic dysfunction-associated steatotic liver disease (MASLD) as a key tool for detecting at-risk MASH. These new recommendations were presented at the EASL 2024 congress, and have been published in the *Journal of Hepatology*<sup>5</sup>.

#### Transformative royalty financing and debt overhang reduction

In 2024, GENFIT initiated a dual-transaction initiative to reinforce its financial outlook, that was successfully completed in March 2025:

- Completion of a non-dilutive royalty financing agreement for up to €185 million. This agreement triggered an initial payment of €130 million, with the possibility of receiving a further €55 million in two installments depending on the achievement of short-term net sales targets for Iqirvo® (elafibranor).
- Repurchase of 99% of the outstanding OCEANE convertible debt, effectively extinguishing the convertible debt burden without any dilution to shareholders.

The royalty financing signed with HCRx on January 30, 2025 has significantly extended GENFIT's cash runway, beyond the end of 2027, enabling the Company to further develop its pipeline focused on ACLF and support general corporate purposes. This estimation is based on current assumptions and programs and does not include exceptional events. This estimation assumes i) our expectation to receive significant future milestone revenue in 2025, including the €26.55 million milestone pending a third pricing and reimbursement approval of Iqirvo® (elafibranor) in a major European market and Ipsen meeting its sales-based thresholds, ii) drawing down all installments under the Royalty Financing, and iii) the Repurchase of the OCEANEs as described and the reimbursement at maturity in October 2025 of any OCEANEs not repurchased and cancelled.

#### Sustainability performance

In 2024, the sustainability roadmap validated at the beginning of the year by GENFIT's ESG Committee was executed according to plan. Furthermore, the company's work in this area was recognized by external stakeholders. Notably, GENFIT was ranked among the top 5 companies in its sector by Ethifinance (out of 222), retained its Gold Medal status (since 2023) while increasing its score from 74 to 82 in 2024 and its "Prime status" with ISS<sup>6</sup> (since 2022), and received additional forms of acknowledgment.

### Corporate governance updates

Following the death of Mr. Xavier Guille des Buttes in April 2024, Vice-Chairman of the Board of Directors, the composition of the Board of Directors of the Company changed. In accordance with the succession plan, Mr. Éric Baclet was appointed Vice-Chairman of the Board of Directors. He was also appointed Chairman of the Nomination and Compensation Committee. Mr. Jean-François Tiné joined the Audit Committee. In May, the Board of Directors appointed Ms. Katherine Kalin to the ESG Committee.

The Board of Directors will propose the renewal of Board members Mr. Éric Baclet and Ms. Katherine Kalin at the annual shareholders meeting scheduled on June 17, 2025. The Board of Directors will also propose the appointment

<sup>&</sup>lt;sup>5</sup> J Hepatol. 2024 Sep;81(3):492-542. DOI: https://doi.org/10.1016/j.jhep.2024.04.031

<sup>&</sup>lt;sup>6</sup> Institutional Shareholder Services



of Mr. Tristan Imbert as a new Director, in order to strengthen its composition and its expertise in financial and extra-financial matters.

### II. 2025 Outlook

#### ACLF programs – next steps

**VS-01-ACLF** – Data readout for UNVEIL-IT® Phase 2 is targeted for the second half of 2025. Leveraging the new insights gained in 2024 about patients with ACLF, a proof-of-concept study was initiated in 1Q25. The target population includes patients with AD or ACLF grade 1 having grades 2, 3, or 4 overt Hepatic Encephalopathy (HE) and ascites as a prerequisite for enrollment. The primary endpoint is time-to-improvement in overt HE. Data readout is also expected in the second half of 2025.

**G1090N** – A proof-of concept study with the new formulation of NTZ was initiated as planned in 1Q25. Following recent exchanges with the FDA, it was decided to optimize dose-selection for the planned proof-of-concept study in patients with ACLF, by first evaluating our new formulation in healthy volunteers, followed by hepatic and renal impairment studies. These studies will also generate additional safety data as well as provide data on early markers of efficacy-in-patients with compromised liver function. These data are expected by the end of the year and will serve to optimize the design of the proof-of-concept study now targeted to launch in early 2026.

**SRT-015** – Following the positive preclinical data generated up to and including in 1Q25, GENFIT will advance the program and work on an improved formulation aimed at increasing exposure. Pending positive development, the launch of a first-in-human trial could be initiated as early as the second half of 2026.

**CLM-022** – Next experiments will aim at confirming the therapeutic efficacy of CLM-022 using different disease models relevant for AD and ACLF as well as starting formulation development and first toxicological studies in 2025. Pending further positive developments, a first-in-human trial could be initiated as early as end of 2026 or beginning of 2027.

**VS-02-HE** – We intend to develop VS-02-HE as a unique oral formulation designed to act where ammonia is primarily produced, minimizing systemic absorption of ammonia while reducing glutamine levels in the brain. Investigational New Drug-enabling nonclinical studies and formulation development started in 2024 with completion expected in 2025. Pending further confirmation, a first-in-human trial could be initiated in 2027.

Several new datasets will be presented at the upcoming EASL Congress, presenting advancements across multiple programs and underscoring both recent progress and the potential of our pipeline assets.

#### Other life-threatening diseases – next steps

**GNS561 in CCA** – The Phase 1b/2a clinical trial is currently ongoing and results from Phase 1b are targeted by the end of 2025.

**VS-01-HAC (pediatric indication)** – Following feedback from FDA (U.S.) and PDCO<sup>7</sup> (Europe), we are in a situation to start a pivotal juvenile toxicology study in Göttingen Minipigs earlier than initially planned, potentially as early as 2H25, with data expected before the end of 2025. Pending further confirmation, a first-in-human trial could be initiated toward the end of 2026.

<sup>&</sup>lt;sup>7</sup> The Paediatric Committee (PDCO) is the European Medicines Agency's (EMA) scientific committee responsible for activities on medicines for children



### III. Financial results (\*)

(in € thousands, except earnings per share data)	31/12/2023	31/12/2024
Revenues and other income	38,176	70,939
Research and development expenses	(46,503)	(47,210)
General and administrative expenses	(17,741)	(19,497)
Marketing and market access expenses	(876)	(634)
Reorganization and restructuring expenses	505	0
Other operating income (expenses)	(141)	(316)
Operating income (loss)	(26,580)	3,281
Financial income	3,680	3,339
Financial expenses	(5,614)	(4,774)
Financial profit (loss)	(1,934)	(1,434)
Net profit (loss) before tax	(28,514)	1,847
Income tax benefit (expense)	(380)	(340)
Net profit (loss)	(28,894)	1,507
Basic/diluted earnings (loss) per share (€/share)	(0.58)	0.03
Diluted earnings (loss) per share (€/share)	(0.58)	0.03
Cash, cash equivalents and current financial assets	77,789	81,788

(\*) Audit procedures on the Consolidated Financial Statements have been substantially completed. The Report of Independent Registered Public Accounting Firm is forthcoming.

### **Revenues and other incomes**

Revenue and other operating income for 2024 amounted to €70.9 million compared to €38.2 million for 2023.

Revenue specifically amounted to €67.0 million in 2024 and is primarily composed of the following:

- €48.7 million was attributable to a milestone payment invoiced to Ipsen in June 2024 following the first commercial sale of Iqirvo®/elafibranor in the U.S.
- €15.3 million was attributable to previously deferred revenue of €40 million from 2021, in line with the progress in the ELATIVE® clinical study and related expenses incurred during the period, estimated remaining expenses, and the fact that the study was fully transferred in 2024.
- €2.7 million was attributable to royalty revenue from U.S. sales of Iqirvo®/elafibranor which commenced mid-June.
- €0.1 million in revenue was generated from the services rendered under the Transition Services Agreement and Part B Transition Services Agreement, signed in April 2022 and September 2023 respectively by GENFIT and Ipsen, in order to facilitate the transition of certain services related to the Phase 3 ELATIVE<sup>®</sup> clinical trial until the complete transfer of the responsibility of the trial to Ipsen.
- €0.2 million was attributable to other ancillary activities.

Other operating income specifically amounted to 3.9 million in 2024 and is primarily composed of the following:

• The research tax credit (CIR) amounting to €3.4 million. It is important to note that this amount includes:



i) the 2024 CIR of €3.9 million,

ii) a reduction of  ${\rm {\sc e0.7}}$  million following the conclusion of the tax audit relating to the 2019 and 2020 financial years, and

- iii) an increase of €0.2 million in late payment interest collected for the 2022 and 2023 CIRs.
- There were government grants and subsidies of €0.3 million and exchange gains on trade receivables of €0.2 million.

#### **Operating results and expenses**

Operating expenses for 2024 amounted to  $\in$ 67.7 million compared to  $\in$ 64.8 million for 2023. This is comprised of research and development expenses, general and administrative expenses, marketing and market access expenses, reorganization and restructuring expenses, and other operating expenses.

The increase is due to multiple factors:

- An increase in research and development costs of €0.7 million, explained by the sharp decrease related to ELATIVE® and GNS561 partially offset by costs related to new programs and product candidates, in particular VS-01, SRT-015, and CLM-022.
- An increase in general and administrative expenses of €1.8 million, explained by increased headcount.
- A decrease in marketing and market access expenses of €0.3 million.
- An increase in reorganization and restructuring charges of €0.5 million due solely to the reversal of €0.5 million recorded in 2023 as the RESOLVE-IT<sup>®</sup> study was complete.
- A decrease in other operating expenses of €0.2 million.

In 2024, GENFIT generated a consolidated operating income of €3.3 million, compared to an operating loss of €26.6 million in 2023.

### **Financial results**

2024 resulted in a financial loss of €1.4 million compared to a financial loss of €1.9 million in 2023.

Our net financial loss for 2024 consisted primarily of  $\notin 0.7$  million in foreign exchange gain on cash and cash equivalents,  $\notin 2.6$  million in interest income, offset by  $\notin 4.7$  million of interest expense.

#### Cash position

As of December 31, 2024, the Company's cash and cash equivalents amounted to €81.8 million compared with €77.8 million as of December 31, 2023.

This amount includes the receipt of a €48.7 million milestone in August 2024 which was attributable to a milestone payment invoiced to Ipsen in June 2024 following the first commercial sale of Iqirvo®/elafibranor in the U.S.

The overall increase in cash is offset by our continued research and development efforts, notably for:

- UNVEIL-IT<sup>®</sup>, our Phase 2 clinical trial evaluating VS-01 in ACLF;
- Our cholangiocarcinoma program evaluating GNS561;
- Our ACLF program evaluating NTZ;
- Our non-clinical trial of SRT-015 in ACLF; and
- Our preclinical work for CLM-022 in ACLF.



On March 20, 2025, GENFIT announced the closing of a royalty financing agreement (Royalty Financing) with HealthCare Royalty (HCRx) providing up to  $\in$ 185 million non-dilutive capital:  $\in$ 130 million upfront, with eligibility to receive up to  $\in$ 55 million in two additional installments based on near-term sales milestones for Iqirvo® (elafibranor), and can be exercised at the discretion of GENFIT upon achievement of such milestones. In return, HCRx will receive a portion of royalties on global sales of Iqirvo® (elafibranor) payable to GENFIT under its licensing agreement with Ipsen, up to an agreed upon cap after which all future royalties will revert back to GENFIT.

GENFIT retains rights to all future regulatory, commercial and sales-based milestone payments from Ipsen under the Ipsen agreement.

The royalty financing signed with HCRx in January 30, 2025 has significantly extended GENFIT's cash runway, beyond the end of 2027, enabling the Company to further develop its pipeline focused on ACLF and support general corporate purposes. This estimation is based on current assumptions and programs and does not include exceptional events. This estimation assumes i) our expectation to receive significant future milestone revenue in 2025, including the €26.55 million milestone pending a third pricing and reimbursement approval of Iqirvo® (elafibranor) in a major European market and Ipsen meeting its sales-based thresholds, ii) drawing down all installments under the Royalty Financing, and iii) the Repurchase of the OCEANEs as described below and the reimbursement at maturity in October 2025 of any OCEANEs not repurchased and cancelled.



## APPENDICES

## **Consolidated Statement of Operations\***

	Year ended	d
(in $\in$ thousands, except earnings per share data)	31/12/2023	31/12/2024
Revenues and other income		
Revenue	28,565	67,002
Other income	9,610	3,937
Revenues and other income	38,176	70,939
Operating expenses and other operating income (expenses)		
Research and development expenses	(46,503)	(47,210)
General and administrative expenses	(17,741)	(19,497)
Marketing and market access expenses	(876)	(634)
Reorganization and restructuring income (expenses)	505	0
Other operating expenses	(141)	(316)
Operating income (loss)	(26,580)	3,281
Financial income	3,680	3,339
Financial expenses	(5,614)	(4,774)
Financial profit (loss)	(1,934)	(1,434)
Net profit (loss) before tax	(28,514)	1,847
Income tax benefit (expense)	(380)	(340)
Net profit (loss)	(28,894)	1,507
Basic and diluted earnings (loss) per share		
Basic earnings (loss) per share (€/share)	(0.58)	0.03
Diluted earnings (loss) per share (€/share)	(0.58)	0.03



### **Consolidated Statement of Financial Position\***

### Assets

EENIE

(in € thousands)	As of	
	31/12/2023	31/12/2024
Current assets		
Cash and cash equivalents	77,789	81,788
Current trade and others receivables	32,707	7,564
Other current assets	2,615	3,409
Inventories	4	4
Total - Current assets	113,115	92,766
Non-current assets		
Intangible assets	48,761	47,998
Property, plant and equipment	7,872	7,595
Other non-current financial assets	4,125	3,065
Total - Non-current assets	60,758	58,659
Total - Assets	173,872	151,424



Appendices

#### Liabilities

EENIE

	As of	As of	
(in € thousands)	31/12/2023	31/12/2024	
Current liabilities			
Current convertible loans	415	54,572	
Other current loans and borrowings	7,510	2,009	
Current trade and other payables	18,799	18,387	
Current deferred income and revenue	11,692	0	
Current provisions	40	40	
Other current tax liabilities	23	155	
Total - Current liabilities	38,480	75,162	
Non-current liabilities			
Non-current convertible loans	52,206	0	
Other non-current loans and borrowings	10,047	5,552	
Non-current deferred income and revenue	3,755	0	
Non-current employee benefits	978	1,341	
Deferred tax liabilities	455	145	
Total - Non-current liabilities	67,441	7,038	
Shareholders' equity			
Share capital	12,459	12,499	
Share premium	445,261	446,948	
Retained earnings (accumulated deficit)	(361,870)	(392,077)	
Currency translation adjustment	996	347	
Net profit (loss)	(28,894)	1,507	
Total - Shareholders' equity	67,951	69,224	
Total - Shareholders' equity & liabilities	173,872	151,424	



Appendices

#### **Statement of Cash Flows\***

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	For the periods ended	
(in € thousands)	31/12/2023	31/12/2024
Cash flows from operating activities		
+ Net profit (loss)	(28,894)	1,507
Reconciliation of net loss to net cash used in operating activities		
Adjustments for:		
+ Depreciation and amortization on tangible and intangible assets	1,654	1,724
+ Impairment and provisions	(392)	169
+ Expenses related to share-based compensation	578	610
- Loss (gain) on disposal of property, plant and equipment	(81)	(56)
+ Net finance expenses (revenue)	485	346
+ Income tax expense (benefit)	380	340
+ Other non-cash items	(878)	2,549
Operating cash flows before change in working capital	(27,148)	7,189
Decrease (increase) in trade receivables and other assets	(17,418)	23,965
(Decrease) increase in trade payables and other liabilities	(10,397)	(15,531)
Change in working capital	(27,815)	8,433
Income tax paid	(465)	(74)
Net cash flows provided by (used in) in operating activities	(55,429)	15,548
Cash flows from investment activities		
- Acquisition of other intangible assets	(2,074)	0
- Acquisition of property, plant and equipment	(414)	(979)
+ Proceeds from disposal of / reimbursement of property, plant and equipment	172	80
- Acquisition of financial instruments	(12)	(140)
+ Proceeds from disposal of financial instruments	4,562	0
Net cash flows provided by (used in ) investment activities	2,234	(1,039)
Cash flows from financing activities		
+ Proceeds from issue of share capital (net)	0	61
+ Proceeds from new loans and borrowings net of issue costs	89	0
- Repayments of loans and borrowings	(3,619)	(9,170)
- Payments on lease debts	(1,075)	(1,113)
- Financial interests paid (including finance lease)	(2,201)	(2,134)
+ Financial interests received	1,709	1,786
Net cash flows provided by (used in ) financing activities	(5,098)	(10,570)
Increase (decrease) in cash and cash equivalents	(58,292)	3,939
Cash and cash equivalents at the beginning of the period	136,001	77,789
Effects of exchange rate changes on cash	80	60
Cash and cash equivalents at the end of the period	77,789	81,788

**Appendices** 

#### **ABOUT GENFIT**

GENFIT is a biopharmaceutical company committed to improving the lives of patients with rare, life-threatening liver diseases whose medical needs remain largely unmet. GENFIT is a pioneer in liver disease research and development with a rich history and a solid scientific heritage spanning more than two decades. Today, GENFIT has built up a diversified and rapidly expanding R&D portfolio of programs at various stages of development. The Company focuses on Acute-on-Chronic Liver Failure (ACLF). Its ACLF franchise includes five assets under development: VS-01, NTZ, SRT-015, CLM-022 and VS-02-HE, based on complementary mechanisms of action using different routes of administration. Other assets target other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorder (UCD) and organic acidemia (OA). GENFIT's expertise in the development of high-potential molecules from early to advanced stages, and in pre-commercialization, was demonstrated in the accelerated approval of Iqirvo® (elafibranor1) by the U.S. Food and Drug Administration, the European Medicines Agency and the Medicines and Healthcare Regulatory Agency in the UK for Primary Biliary Cholangitis (PBC). Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® in Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis) and TS-01 focusing on blood ammonia levels. GENFIT is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Nasdaq Global Select Market and on the Euronext regulated market in Paris, Compartment B (Nasdaq and Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. For more information, visit .www.genfit.com

#### **GENFIT FORWARD LOOKING STATEMENTS**

This press release contains certain forward-looking statements, including those within the meaning of the Private Securities Litigation Reform Act of 1995 with respect to GENFIT, including, but not limited to statements about the launch and/or availability of results for preclinical studies and clinical trials relating to VS-01, G1090N, SRT-015, CLM-022, VS-02 and GNS561, regulatory approval and pricing and reimbursement for Igirvo® (élafibranor) for PBC in other countries, expectations to receive milestones and royalty payments subject to Ipsen's sales of Iqirvo® (elafibranor), the achievement of the necessary targets enabling the additional €55 million to be obtained under the royalty financing, and our financial outlook including our cash horizon, our cash flow and cash burn projections and business activity projections for 2025 and beyond. The use of certain words, such as "believe", "potential", "expect", "target", "may", "will", "should", "could", "if" 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 others, the uncertainties inherent in research and development, including in relation to safety of drug candidates, cost of, progression of, and results from, our ongoing and planned clinical trials, patient recruitment, review and approvals by regulatory authorities in the United States, Europe and worldwide, of our drug and diagnostic candidates, pricing, approval and commercial success of elafibranor in the relevant jurisdictions, exchange rate fluctuations, 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 "Risk Factors and Internal Control" of the Company's 2023 Universal Registration Document filed on April 5, 2024 (no. D.24-0246) with the Autorité des marchés financiers ("AMF"), which is available on GENFIT's website (www.genfit.fr) and the AMF's website (www.amf.org), and those discussed in the public documents and reports filed with the U.S. Securities and Exchange Commission ("SEC"), including the Company's 2023 Annual Report on Form 20-F filed with the SEC on April 5, 2024, the Half-Year Business and Financial Report dated September 19, 2024 and subsequent filings and reports filed with the AMF or SEC or otherwise made public, by the Company. In addition, even if the results, performance, financial position and liquidity of the Company 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 press release. 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.



Appendices

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