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## GENFIT to receive US$20M milestone after Ipsen's Iqirvo® exceeds the US$200M threshold in its first full year of net sales

- **Ipsen reported US$88M of Iqirvo® net sales in PBC for 4Q25, bringing 2025 sales to US$208M, triggering the first commercial milestone payment to GENFIT ahead of schedule[1]**
- **Ipsen confirmed its commitment to launch a Phase 3 in PSC, creating a new avenue for potential future upside for GENFIT**
- **GENFIT's CCA Phase 1b study progressing as planned:**
  - **New dose-escalation cohort fully enrolled with no dose-limiting toxicities reported at the 21-day timepoint**
  - **Phase 1b data readout and recommended Phase 2 doses remain on track for 1H26**

**Lille (France), Cambridge (Massachusetts, United States), Zurich (Switzerland), February 12, 2026** - **GENFIT (Euronext: GNFT)**, a biopharmaceutical company dedicated to improving the lives of patients with rare and life-threatening liver diseases, today announced that the strong commercial performance of Iqirvo® in its first full year on the primary biliary cholangitis (PBC) market has triggered a US$20M milestone payment from Ipsen under the companies' licensing agreement.

The commercial success of Iqirvo® in 2025 underscores the strength of our partnership with Ipsen and exceeded our initial expectations with first-year net sales reaching US$208M. This performance activated a US$20M milestone payment ahead of plan, reinforcing GENFIT's financial position. This momentum also led to the receipt of an additional €30M tranche under GENFIT's royalty-financing agreement with HCRx, enhancing financial flexibility in a non-dilutive way.

In parallel, Ipsen confirmed the initiation of the first and only global Phase 3 clinical trial in primary sclerosing cholangitis (PSC), addressing a significant unmet medical need, as no approved therapies currently exist for this severe and progressive disease. PSC represents a substantial untapped market opportunity, comparable in size to second line PBC. Should Iqirvo® ultimately receive regulatory approval for this indication, GENFIT would be eligible for additional milestone payments as well as additional double-digit royalties.

Beyond Iqirvo®, GENFIT continues to advance its oncology program. The ongoing Phase 1b study in cholangiocarcinoma (CCA), evaluating GNS561 in combination with a MEK inhibitor, is progressing in line with expectations. As communicated in December 2025, early positive activity was observed in the first evaluable patients at Week 6. Enrollment for a the next escalated-dose cohort has now been completed, with no dose-limiting toxicities (DLTs) reported to date. Recruitment for the following one will now proceed, consistent with the predefined dose-escalation process. Multi-cohort readouts on safety, tolerability and

[1] Based on contractual change rates (€76,6M sales in 4Q25 and €184M annual sales in 2025)

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activity along with the determination of the recommended Phase 2 doses remain expected by the end of the first half of 2026.

**Pascal Prigent, CEO of GENFIT** declared: *"We are pleased with Ipsen's continued success with Iqirvo®. Net sales have surpassed US$200M in 2025 and this remarkable performance has allowed us to get the first commercial milestone a year earlier than anticipated. We believe that this commercial trajectory has the potential to be transformative for our business model. We are also pleased with the progress of our GNS561 program, with a new cohort fully recruited. This program might bring significant hope for patients with a devastating disease, and we are eagerly awaiting new data. As we are also anticipating the first ACLF patients to be included in a phase 2 evaluating G1090N in the second half of the year we believe 2026 will be a landmark year for GENFIT."*

GENFIT will publish its 4Q25 revenue and cash position on February 26, 2026.

All details from Ipsen's communication are available here: www.ipsen.com/event/fy-results

**END**

## 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 focuses on Acute on-chronic Liver Failure (ACLF) and associated conditions such as acute decompensation (AD) and hepatic encephalopathy (HE). It develops therapeutic assets which have complementary mechanisms of action, selected to address key pathophysiological pathways. GENFIT also targets other serious diseases, such as cholangiocarcinoma (CCA), urea cycle disorders (UCD) and organic acidemia (OA). Its R&D portfolio, covering several stages of development, ensures a constant news flow. GENFIT's expertise in developing high-potential molecules – from early to advanced pre-commercialization stages – culminated in 2024 with the accelerated approval of Iqirvo® (elafibranor) by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom for the treatment of Primary Biliary Cholangitis (PBC). Iqirvo® is now marketed in several countries.[2] Beyond therapies, GENFIT also has a diagnostic franchise including NIS2+® for the detection of Metabolic dysfunction-associated steatohepatitis (MASH, formerly known as NASH for non-alcoholic steatohepatitis). GENFIT, a BCorp™ certified company since 2025, is headquartered in Lille, France and has offices in Paris (France), Zurich (Switzerland) and Cambridge, MA (USA). The Company is listed on the Euronext regulated market in Paris, Compartment B (Euronext: GNFT). In 2021, Ipsen became one of GENFIT's largest shareholders, acquiring an 8% stake in the Company's capital. www.genfit.com

[2] Elafibranor is marketed and commercialized, notably in the U.S and Europe, by Ipsen under the trademark Iqirvo® .

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## FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including, but not limited to, statements about the future commercial trajectory of Iqirvo® in PBC, the ability to obtain marketing authorization for elafibranor in PSC, the potential to receive future milestone payments and royalties under the Ipsen agreement, the timing, progression and expected data readouts of GENFIT's ongoing clinical programs such as the Phase 1b study in cholangiocarcinoma and the planned Phase 2 study of G1090N in ACLF, and more generally GENFIT's expectations regarding its financial position, strategic outlook and prospects for 2026 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 non-clinical and pre-clinical programs, reproducibility of preclinical results, the translation of animal model data to human biology, 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 2024 Universal Registration Document filed on April 29, 2025 (no. 25-0331) 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 2024 Annual Report on Form 20-F filed with the SEC on April 29, 2025 and subsequent filings and reports filed with the AMF or SEC, including the Half-Year Business and Financial Report at June 30, 2025, 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.

## CONTACTS

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