

*Source: GENFIT S.A.*

*September 19, 2022 01:30 ET*

## **GENFIT to Acquire Clinical-stage Biopharmaceutical Company Versantis, expanding its Portfolio in Liver Diseases**

- Further consolidates GENFIT's position as a leader in acute-on-chronic liver failure (ACLF)
- Significantly expands GENFIT's pipeline with VS-01-ACLF, a Phase 2 ready program based on first-in-class scavenging liposomes technology, VS-01-UCD, a pediatric program focused on urea cycle disorder (UCD), and VS-02-HE, an early-stage program focused on hepatic encephalopathy (HE)
- Combines Versantis' expertise with GENFIT's know-how in conducting complex development programs in liver diseases, to strengthen and accelerate research and development
- Deal terms include a payment of CHF40 million, an aggregate of CHF65 million of potential additional payments contingent on successful clinical and regulatory milestones, and one-third of the net proceeds from the potential sale of a Priority Review Voucher, if awarded by the FDA
- GENFIT will host a live conference call today, September 19, at 8:00am ET / 1:00pm GMT / 2:00pm CET in English and in French

**Lille, France; Cambridge, MA; September 19, 2022 - GENFIT (Nasdaq and Euronext: GNFT)**, a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases, today announced it has entered into an exclusivity agreement with a view to acquire all the share capital and voting rights of Versantis, a private Swiss-based clinical stage biotechnology company focused on addressing the growing unmet medical needs in liver diseases.

The acquisition of Versantis fits perfectly within GENFIT's strategic vision of becoming a global leader in ACLF (acute-on-chronic liver failure) and is another critical milestone in the execution of GENFIT's strategic plan. With this acquisition, GENFIT consolidates its position in ACLF via the integration of a clinically advanced asset presenting a solid scientific rationale supported by encouraging Phase 1b and preclinical data. GENFIT will also further expand its pipeline in other liver diseases characterized by high unmet medical needs with additional product candidates developed by Versantis. In addition, GENFIT's know-how in ACLF will broaden, with the integration of Versantis' team of experts, joining forces to accelerate both research and development.

ACLF is an underserved medical condition associated with short-term mortality (23% to 74% mortality at 28 days, depending on severity grade) and a significant cost of care. No drugs have been approved in this indication so far and incidence is growing at epidemic rates due to an aging population and a higher prevalence of diabetes, obesity, NASH, as well as alcohol and drug-induced liver injury. From a patient perspective, the ACLF syndrome is characterized by an abrupt life-threatening worsening of a pre-existing advanced chronic liver disease resulting in liver and extrahepatic organ failure (brain, kidneys, cardiovascular and respiratory). The cascade of multiple organ failures, including the development of a neuropsychiatric condition called hepatic encephalopathy (HE), together, lead to major complications in patients with ACLF, who can rapidly progress into coma and death. Every year, an estimated 137'000 patients are hospitalized in the US with ACLF, with very few therapeutic options. This represents an important unmet medical need.

As a pioneer in ACLF, Versantis has acquired a unique expertise, developing clinical-stage technology and assets aiming to improve ACLF patients' outcomes.

Its main asset, VS-01, is a first-in-class innovative liposomal-based therapeutic product candidate currently in clinical development as a potential first-line therapy for the timely recovery of ACLF and UCD. If approved, it would be the first drug to use the intraperitoneal route to simultaneously support the liver, kidney and brain, the organs that most often fail in cirrhotic patients. VS-01 operates to clear toxic metabolites from the body following paracentesis, by extracting them from the blood into the peritoneal (abdominal) cavity, where they are captured by proprietary scavenging liposomes which are then drained from the body. A planned 60-patient, randomized and controlled Phase 2 Proof-of-concept trial of VS-01 in ACLF is expected to launch in the fourth quarter 2022. Efficacy and safety interim data are expected as early as the first half of 2024. The US Food and Drug Administration (FDA) granted VS-01 with the Orphan Drug Designation (ODD) in ACLF and in UCD and with the Rare Pediatric Diseases Designation (RPDD) for the acute treatment of UCD. The European Medicines Agency

(EMA) also granted VS-01 with ODD in acute liver failure. Given the unmet medical need and the current standard of care, GENFIT intends to seek approval of these candidates via expedited regulatory pathways.

VS-02 is a pre-clinical oral, small molecule drug candidate being developed for the chronic management of HE, considered an endemic disease worldwide. HE is a nervous system disorder brought on by advanced chronic liver disease. VS-02 will be developed as a unique colon-active formulation designed to minimize systemic absorption of ammonia and act where ammonia is primarily produced, while reducing glutamine levels in the brain.

GENFIT will also be able to develop TS-01, a unique point-of-care diagnostic device in prototype development for the at-home measurement of ammonia in the blood, the primary cause of HE.

The deal should be completed during the fourth quarter 2022, following completion of the consultation of GENFIT's employees representative bodies.

In parallel, GENFIT continues the development of its other program evaluating NTZ in ACLF, with a pre-IND meeting scheduled with the FDA in the coming weeks, following encouraging Phase 1 data.

**Pascal Prigent, Chief Executive Officer of GENFIT**, commented: *"Versantis has an exciting portfolio that is complementary to GENFIT's. We are also thrilled to welcome a talented team that has developed a strong scientific expertise in ACLF. We believe that significant synergies exist and that this acquisition will accelerate the development of several promising drug candidates in areas of high unmet needs."* **Jean-François Mouney, Co-founder and Chairman of the Board of GENFIT**, added: *"This agreement is a new chapter in the implementation of GENFIT's strategy, which expands and diversifies our portfolio with assets presenting a significant market potential."* **Vincent Forster, PhD, Chief Scientific Officer and Meriam Kabbaj, PhD, Chief Operations Officer, both Board Members and Co-founders of Versantis**, concluded: *"We are enthusiastic to be part of GENFIT, considering their experience in exploring severe and underserved conditions. We think that GENFIT's knowledge and experience in the development of programs targeting complex liver diseases will be invaluable to accelerate and maximize the probability of success of our programs. We also are excited by the new opportunities offered by GENFIT's research capabilities."*

## Financials

The deal includes an initial consideration of CHF40 million due at closing, with contingent consideration of up to CHF65 million upon positive Phase 2 results for VS-01 and VS-02 and regulatory approval of VS-01. In addition, Versantis is eligible to receive 1/3 of the net proceeds resulting from the potential sale of the Pediatric Review Voucher of VS-01's pediatric application by GENFIT to a third party, or 1/3 of the fair market value of this Voucher if GENFIT opts to apply it to one of its own programs. GENFIT will finance the base acquisition consideration from its current cash and cash equivalents. Based on our development plan for our current programs and for Versantis' programs, the revenue expected from our partnership agreements, and accounting for transaction costs, we anticipate that funding of the Group's corporate development is secured for approximately 2 years.

## GENFIT will host a conference call on September 19, 2022 at 08:00am ET / 1.00pm GMT / 2.00pm CET in English and in French

Both the English and French conference calls will be accessible on the investor page of our website, under the events section at <https://ir.genfit.com/> or by calling 888-394-8218 (toll-free US and Canada), 0800 358 6377 (toll-free UK) or 0805 101 219 (France toll-free) five minutes prior to the start time (confirmation code: **3338254**). A replay will be available shortly after the call.

## Upcoming calls and events

- Live conference call today, September 19, at 8:00am ET / 1:00pm GMT / 2:00pm CET in English and in French
- Half-year financial results (press release) on September 28, 2022
- Pipeline days on October 5 (French session in Paris, France) and October 19 (English session in NYC, United States)

## ABOUT GENFIT

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases characterized by high unmet medical needs. GENFIT is a pioneer in liver disease research and development with a rich history and strong scientific heritage spanning more than two decades. Thanks to its expertise in bringing early-stage assets with high potential to late development and pre-commercialization stages, today GENFIT boasts a growing and diversified pipeline of innovative therapeutic and diagnostic solutions.

Its R&D is focused on three franchises: cholestatic diseases, Acute on Chronic Liver Failure (ACLF) and NASH diagnostics. In its cholestatic diseases franchise, ELATIVE™, a Phase 3 global trial evaluating elafibranor<sup>1</sup> in patients with Primary Biliary Cholangitis (PBC) is well underway following [a successful Phase 2 clinical trial](#). Topline data is expected to be announced in the second quarter 2023. In 2021, GENFIT signed an exclusive licensing agreement with IPSEN to develop, manufacture and commercialize elafibranor in PBC and other indications.<sup>2</sup> GENFIT is also developing GNS561<sup>1</sup> in cholangiocarcinoma following the acquisition of exclusive rights in this indication from Genoscience Pharma in 2021<sup>3</sup>. In ACLF, a Phase 1 clinical program with nitazoxanide has been initiated in 2021, and GENFIT further expanded its ACLF pipeline in 2022 via the acquisition of Swiss-based clinical-stage company Versantis, with a Phase 2 ready program evaluating liposomes technology and a preclinical stage small molecule. As part of its diagnostic solutions franchise, the Company entered into an agreement with Labcorp in 2021 to commercialize NASHnext®, powered by GENFIT's proprietary diagnostic technology NIS4® in identifying at-risk NASH.

GENFIT has facilities in Lille and Paris, France, and Cambridge, MA, USA. GENFIT is a publicly traded company listed on the Nasdaq Global Select Market and on compartment B of Euronext's regulated market in Paris (Nasdaq and Euronext: GNFT). In 2021, IPSEN became one of GENFIT's largest shareholders and holds 8% of the company's share capital. [www.genfit.com](http://www.genfit.com)

## ABOUT VERSANTIS

Versantis is a clinical stage biotechnology company focused on addressing the growing, unmet medical need in liver diseases. It was co-founded by Vincent Forster, PhD, Chief Scientific Officer, Board Member, Meriam Kabbaj, PhD, Chief Operations Officer, also Board Member, and Professor Jean-Christophe Leroux, PhD, Scientific Advisor. With a pipeline of drug and diagnostic product candidates to potentially address chronic and orphan acute indications, Versantis believes it can revolutionize the current standard of care for patients suffering from acquired and genetic hepatic deficiencies. Founded by scientists from ETH Zurich with entrepreneurial drive, Versantis has built a team and Board of seasoned industry executives with a proven ability to advance novel therapies from the idea stage into clinical development, regulatory approval, and commercial launch. The company is headquartered in Zurich, Switzerland, with an established wholly-owned U.S. subsidiary, Versantis, Inc. For additional information, visit: [www.versantis.com](http://www.versantis.com).

## GENFIT FORWARD LOOKING STATEMENTS

This press release contains certain forward-looking statements with respect to GENFIT, including those within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding GENFIT's corporate strategy and objectives, the potential sizes of the ACLF market for ACLF, commercial certainty within this market, potential synergies related to the future acquisition of Versantis and the outcome of the ELATIVE™ phase 3 trial of elafibranor in PBC, timelines for completion of the ELATIVE™ trial and receipt of market authorization if the results are positive, timing for completion of the acquisition of Versantis and our capacity to integrate Versantis and to develop its programs, including timelines for development and the ability to obtain regulatory authorizations and pathways, and our ability to fund our programs and projected cash runway. The use of certain words, including "consider", "contemplate", "think", "aim", "expect", "understand", "should", "aspire", "estimate", "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, progression of, and results from, its ongoing and planned clinical trials, review and approvals by regulatory authorities of its drug and diagnostic candidates, the impact of the COVID-19 pandemic, exchange rate fluctuations and the Company's continued ability to raise capital to fund its development, as well as those risks and uncertainties discussed or identified in the Company's public filings with the French *Autorité des Marchés Financiers* ("AMF"), including those listed in Chapter 2 "Main Risks and Uncertainties" of the Company's 2021 Universal Registration Document filed with the AMF on 29 April 2022 under n° D.22-0400, 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 2021 Annual Report on Form 20-F filed with the SEC on April 29, 2022. 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.

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1 Elafibranor and GNS561 are investigational compounds that have not been reviewed nor been approved by a regulatory authority

2 With the exception of China, Hong Kong, Taiwan, and Macau where Terns Pharmaceuticals holds the exclusive license to develop and commercialize elafibranor

3 Agreement includes commercialization and development in the United States, Canada and Europe, including the United Kingdom and Switzerland

#### **Attachment**

- [GENFIT to Acquire Clinical-stage Biopharmaceutical Company Versantis, expanding its Portfolio in Liver Diseases](#)