



## **Genoscience Pharma licences GNS561, its PPT-1 inhibitor, to GENFIT in cholangiocarcinoma indication in US/Canada and Europe**

- **Exclusive rights for novel early stage asset in cholangiocarcinoma have been acquired by GENFIT in these territories**
- **Phase 2 clinical program in cholangiocarcinoma expected to start first half of 2022**
- **Genoscience Pharma pursues the development with GNS561 in other oncology indications; will start phase 2 in hepatocarcinoma in 2022**

**Marseille, France, December 17, 2021** – Genoscience Pharma, a clinical stage biotechnology company developing unique lysosomotropic drug candidates for the treatment of cancer, auto-immune and infectious diseases through autophagy modulation, announces today the licencing of its PPT-1 inhibitor, GNS561, in cholangiocarcinoma indication, to GENFIT (Nasdaq and Euronext: GNFT), a late-stage biopharmaceutical company dedicated to improving the lives of patients with metabolic and chronic liver diseases. GENFIT will develop and commercialize investigational treatment with GNS561 in cholangiocarcinoma, in the United States, Canada and Europe, including the United Kingdom and Switzerland.

Under the agreement, GENFIT is committed to taking a €3 million (\$3.4M) equity stake in Genoscience Pharma through the subscription of new ordinary shares. GENFIT will also contribute clinical and regulatory milestone payments and tiered royalties (financial terms not disclosed). The first payable milestone is contingent on positive results from the phase 2 clinical trial in cholangiocarcinoma, which is expected to start in the first half of 2022.

GNS561 is a novel clinical-stage autophagy/PPT1 inhibitor developed by Genoscience Pharma in cholangiocarcinoma indication, which is an orphan disease. The inhibitor has completed preclinical studies and a phase 1b trial confirming the rationale for targeting cholangiocarcinoma, a rare liver malignancy with high mortality and with limited treatment options.

“This is a great step for the development of GNS561 as a new potential treatment option in liver cancer, as it offers an innovative mechanism of action for patients with high unmet needs,” said Philippe Halfon, CEO of Genoscience Pharma. “We believe that GENFIT is a highly qualified partner for the development of GNS561 in cholangiocarcinoma and we will provide GENFIT with our expertise in oncology to support their development plan. On our side, we will pursue the development of GNS561 in other oncology indications as well as research in other therapeutic areas.”

“This decision fully aligns with our strategic roadmap by broadening our asset portfolio within our cholestatic disease franchise, through the addition of an innovative drug candidate with the potential to address considerable unmet needs for patients,” said Pascal Prigent, CEO of GENFIT. “The scientific rationale, together with preclinical and clinical evidence, supports further development of the asset, and our plan is to start the phase 2 program in the first half of 2022. We believe that GNS561’s mechanism of action is very promising. Given the current landscape, standard of care and lack of marketed options, and based on KOL opinions, we will interact with regulatory agencies to investigate accelerated paths to approval, post phase 2.”

### **About cholangiocarcinoma**

Cholangiocarcinoma is a type of cancer that forms in the slender tubes (bile ducts) that carry the digestive fluid bile. Cholangiocarcinoma occurs mostly in people over the age of 50. Cholangiocarcinoma is divided into intrahepatic and extrahepatic types based on where the disease occurs in the bile ducts. Cholangiocarcinoma is often diagnosed when it is advanced, making



successful treatment difficult to achieve. Several risk factors of chronic inflammatory damage and increased cellular turnover have been established, such as primary sclerosing cholangitis, a cholestatic liver disease, liver flukes, biliary tract cysts, hepatolithiasis and toxins. Treatment options for cholangiocarcinoma are limited and associated with high rates of tumor recurrence and short survival times.

### **About GNS561**

GNS561 is a PPT-1 (Palmitoyl Protein Thioesterase-1) inhibitor that blocks autophagy. Autophagy is activated in tumor cells in response to certain conditions, due to tumor cell growth in advanced cancers. One of the key organelles implicated in the autophagy process is the lysosome. By entering the lysosome and binding to its target, GNS561 has an important inhibiting activity on late-stage autophagy, which leads to tumor cell death. GNS561 is an investigational compound and has not been registered by any regulatory authority.

### **About GENFIT**

GENFIT is a late-stage biopharmaceutical company dedicated to improving the lives of patients with severe chronic liver diseases. GENFIT is a pioneer in the field of nuclear receptor-based drug discovery, with a rich history and strong scientific heritage spanning more than two decades. Today, GENFIT's pipeline is robust and diversified, using different compounds and technologies evaluated at different development stages and in different liver diseases.

Leveraging its internal assets and in-house expertise, GENFIT's R&D is focused on cholestatic diseases and Acute-on-Chronic Liver Failure (ACLF); two therapeutic areas with significant unmet medical needs. Currently, the ELATIVE™ phase 3 clinical trial is evaluating elafibranor (an investigational compound that has neither been reviewed nor approved by a regulatory authority) in patients with Primary Biliary Cholangitis (PBC) is being conducted following [a successful phase 2 clinical trial](#). Patient enrolment is anticipated to be completed in the first quarter of 2022 and topline data is expected to be announced between the end of the first quarter and the end of the second quarter 2023. In ACLF, a phase 1 clinical program with nitazoxanide has been initiated.

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).

[www.genfit.com](http://www.genfit.com)

### **About Genoscience Pharma**

Genoscience Pharma is a French clinical-stage biotechnology company developing novel lysomotropic therapeutics to establish a new standard of care in cancer, autoimmune and infectious diseases. Its lead candidate GNS561 is a phase 2-ready best-in-class drug candidate, tackling cancer cells through autophagy modulation. In addition, GNS561 has shown a synergistic effect with immunotherapies, eliciting striking tumor regression where single agent immunotherapy has had limited effect.

Genoscience Pharma is also entering a phase 2 trial in hepatocarcinoma with GNS561.

[www.genosciencepharma.com](http://www.genosciencepharma.com)

### **Forward-looking statements**

This press release may involve and contain forward-looking statements by the company about its product candidate GNS561, including its potential benefits. Such statements are based upon the current beliefs and expectations of Genoscience Pharma's management and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, but are not limited to: additional financing, the company's ability to implement its chosen strategy, dependence upon third parties, other risks and uncertainties inherent in research and development, including the possibility of unfavorable study results, changes in the competitive environment, changes in regulations, clinical or industrial risks and all risks linked to the company's growth. There are no guarantees that future clinical trials will be completed or successful or that any Genoscience Pharma therapeutics will receive regulatory approval for any indication or prove to be commercially successful. While those factors presented here are considered representative, no such list should be considered to be a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are



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made as of the date hereof; Genoscience Pharma does not undertake any obligation to update such statements to reflect subsequent events or circumstances.

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