



**GENOSCIENCE PHARMA**  
Innovative Therapy  
Targetting Cancer Stem Cells

## **Genoscience Pharma receives FDA approval for Phase Ib/IIa study of GNS561 in liver cancer**

**This new first-in-class molecule, with a new mechanism of action, will go through an IND clinical trial involving up to 50 patients**

**Marseilles, France, December 6, 2017** — Genoscience Pharma, a clinical-stage biotechnology company dedicated to discovering and developing cancer treatment drugs, announces today that its most advanced compound, GNS561, has received approval from the Food and Drug Administration (FDA) to initiate a Phase Ib/IIa study in patients with advanced hepatocarcinoma (HCC).

This is the First-In-Human study to be conducted under the Investigational New Drug (IND) protocol approved by the FDA. The phase Ib/IIa study will evaluate the safety, activity and pharmacokinetics of escalating doses of GNS561. Up to 36 patients will be enrolled in six cohorts during the dose escalation phase. Additional patients will be enrolled in the continuation phase to obtain a total of 20 evaluable subjects at the recommended dose.

“The FDA approval of our first IND application is a major milestone for Genoscience Pharma,” said Philippe Halfon, chief executive officer. “This strengthens our position as a drug discovery and development company focused on the development of innovative anti-cancer drugs for the betterment of patients. We believe that GNS561, acting through a novel mechanism of action, has the potential to change the treatment paradigm of HCC.”

“We value our collaboration with the FDA as well as other government authorities that reviewed our submission. We look forward to sharing the details of our upcoming Phase Ib/IIa trial,” he added.

### **About liver cancer**

With more than 780,000 new cases diagnosed each year, liver cancer is the fifth most common cancer worldwide. It is the second leading cause of cancer-related deaths globally, accounting for approximately 746,000 deaths annually. The majority of liver cancers are detected in advanced stage disease. New treatment options are urgently needed for these

patients. HCC is the most common form of liver cancer; it accounts for 90 percent of the total liver cancer burden worldwide.

### **About GNS561**

GNS561 is a novel Solute Carrier Transporter (SLCT) inhibitor demonstrating potent antitumor activity against a panel of human cancer cell lines, including HCC. GNS561 also shows activity in cell lines resistant to current standard-of-care treatment options for HCC.

GNS561 is an orally bioavailable compound initially being developed for the treatment of primary liver cancer, including advanced HCC. GNS561 is also being investigated pre-clinically in other solid tumors.

### **About Genoscience Pharma**

Genoscience Pharma is a clinical-stage biotechnology company, focused on the discovery and development of novel small molecule anti-cancer therapeutics, including novel Solute Carrier Transporter inhibitors, to improve cancer treatment and clinical outcomes for patients. [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 expectation 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 therapeutics will receive regulatory approval for any indication or prove to be commercially successful. While these 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 made as of the date hereof. Genoscience does not undertake any obligation to update such statements to reflect subsequent events or circumstances.

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