GENOSCIENCE PHARMA
Innovative Therapy
Targetting Cancer Stem Cells

GENOSCIENCE PHARMA ANNOUNCES IMPORTANT ADVANCES IN NOVEL COVID-19 ANTIVIRAL PROGRAM

Genoscience Pharma Starts a phase 2 multicenter study using GNS561, a super potent chloroquine analog, in patients with advanced or metastatic cancer and SARS-CoV-2 (COVID-19) in France

Marseille, France, April 6, 2020 —

- **Genoscience is the only company worldwide to develop a clinical stage chloroquine derivative, GNS561, which shows at least 10-fold superior antiviral activity against SARS-CoV-2**
- **GNS561 completed a Phase Ib study, showing excellent tolerability**
- **Genoscience is now starting phase II in SARS-CoV-2 (COVID-19) patients with advanced or metastatic cancer**

In order to meet the pressing public health need, Genoscience Pharma, a clinical-stage biotechnology company developing new potent autophagy inhibitors for cancer indications, announced today the beginning of a Phase II clinical study testing Genoscience Pharma's lead candidate, GNS561, in SARS-CoV-2 (COVID-19) patients with advanced or metastatic cancer. The first patients are already being tested.

Based on outstanding in-vitro results against SARS-Cov2 and a strong scientific rationale involving the replication mechanism of SARS-CoV-2, which seems to exploit autophagy for its own replication, the company decided to move forward in a randomized clinical trial on cancers patients infected by SARS-CoV-2.

The clinical trial consists of a prospective, controlled, randomized, multicenter study to compare the efficacy of the company's chloroquine analogue (GNS561), an anti PD-1 (nivolumab) and an anti-interleukine-6 receptor (tocilizumab), versus standard of care in patients with advanced or metastatic cancer and SARS-CoV-2 (COVID-19) infection.

This multicenter clinical program includes a staging phase and 2 therapeutic cohorts that differ according to the patient's symptomatic profile. Patients with mild symptoms of COVID-19 will be included in Cohort 1; patients with moderate to severe symptoms will be included in cohort 2.

A total of 273 patients will be included in the IMMUNONCOVID-20 program. The trial is coordinated by Dr. Philippe CASSIER, Director of Innovation and Research at Centre Léon Bérard, Lyon and includes 10 centers in France

"Inhibiting autophagy appears to be a powerful way to deal with COVID-19 and we believe GNS561 may constitute a game changer in our fight against the current pandemic" said Pr. Philippe Halfon, Founder & CEO of Genoscience Pharma and Infectious Disease specialist at Hopital Europeen in Marseille, France. "Comparatively to hydroxychloroquine and to chloroquine, GNS 561 presents several advantages: no phototoxicity, no ECG modification, and minor manageable adverse events (mainly nausea, vomiting and diarrhea). Initial findings show GNS561 is 10- to 50-fold more potent than hydroxychloroquine".

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Autophagy is a fundamental cellular homeostasis process that deals with damaged, harmful or surplus cellular content. Autophagy usually restricts viral replication; however, coronaviruses have been shown to have the potent ability to hijack and subvert autophagy for their own replication.

"We are hopeful that this novel antiviral drug GNS561 against SARS-CoV-2 will prove to be a significant and effective weapon against COVID-19" said Pr. Jean Yves Blay, Director of the Centre Léon Bérard in Lyon and President of UNICANCER, the French hospital federation specialized in cancer.

About the COVID-19

Since December 2019, the novel coronavirus (SRAS-COV2, causing an emerging infectious disease called Covid-19) has spread quickly worldwide. As of April 6, 2020, more than 1,200,000 cases and 65,000 deaths have been reported in 181 countries (WHO data). The overall case-fatality rate is about 2.3% but reaches 8% in patients aged 70 to 79 years and 14.8% in those aged >80 years. Thus, there is an urgent need for an effective treatment to treat symptomatic patients but also to decrease the burden of the number of patients hospitalized.

About GNS561

GNS561 is an orally available chloroquine analog currently in development for oncology indications (ongoing human trial NCT03316222). GNS561 is a small basic lipophilic molecule binding PPT-1 that induces lysosomal dysregulation by inhibition of late-stage autophagy and induction of a dose-dependent build-up of enlarged lysosomes.

Coronaviruses are single-stranded, positive sense RNA viruses, which induce the rearrangement of cellular membranes upon infection of a host cell. This provides the virus a platform for the assembly of viral replication complexes, improving the efficiency of RNA synthesis. The membranes observed in coronavirus-infected cells include double membrane vesicles. By nature of their double membrane, these vesicles resemble cellular autophagosomes, generated in the cellular autophagy pathway. Several tudies evidenced that coronavirus infection resulted in endoplasmic reticulum stress and autophagy responses, that coronavirus regulated the autophagy pathway, that the autophagy machinery was required to initiate coronavirus replication. By affecting autophagy at a late stage, GNS561 inhibits the pH-dependent replication steps of several viruses, including members of the flaviviruses, retroviruses, and coronaviruses.

About Genoscience Pharma

Genoscience Pharma is a French clinical-stage biotechnology company developing novel therapeutics to establish new standard of care against cancers. Our lead candidate GNS561 is a Phase II best-in-class drug candidate, tackling cancer cells through lysosomal membrane permeabilization, which showed remarkable results during its preclinical development and first-in-human clinical trials (AbouAlfa G et al. Hepatology 2019). In addition to killing cancer cells, GNS561 has shown synergistic effect with immunotherapies, eliciting striking tumor regression where single agent immunotherapy had minor effect.

The company will begin in 2020 Phase II/III in unmet essential medical needs: primary and secondary liver cancers. Genoscience Pharma is collaborating with leading clinical investigators in both Europe and the US.

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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 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 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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