Press Release

GenSight Biologics Provides Update on Operations in the Context of COVID-19

Paris, France, April 6, 2020, 7.30 am CET – GenSight Biologics (Euronext : SIGHT, ISIN : FR0013183985, PEA-PME eligible), a biopharma company focused on discovering and developing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders, today provides an update on the impact of COVID-19 on its operations.

"The current pandemic is affecting all of us, and it is our number one priority to protect our patients and staff, while facilitating the redirection of any necessary healthcare resources to combat COVID-19. Currently, the impact on our operations is very limited, and while we are hopeful it will remain so, we are preparing for all scenarios. GenSight Biologics is funded through the rest of this year and we are also exploring options to reduce costs and to access non-dilutive sources of financing in order to extend our cash runway into next year. We are actively preparing for a rapid return to full operations both internally and at clinical trial sites as soon as the public health situation supports it," said **Bernard Gilly**, Co-founder and Chief Executive Officer of GenSight Biologics.

The **REVERSE and RESCUE** Phase III trials of LUMEVOQ® (GS010) for the treatment of Leber Hereditary Optic Neuropathy (LHON) are completed, and patients have been transferred to long-term follow-up for an additional 3-year period. As of today, 10 out of 61 patients are due to attend their first annual follow-up visit (at Year 3 after injection) in the coming weeks and months. Given the follow-up nature of these visits and the stability of patients with no safety concern, delaying some of these visits is an acceptable precautionary measure, which should have no impact on the conduct of the trial, and will be properly documented and reported to regulators.

The **strategic manufacturing partner (CDMO)** for LUMEVOQ® is maintaining its operations and has indicated that no delay is currently expected in the planned activities to support the filing to the European Medicines Agency (EMA) in Europe. The Company is actively working with its partner to complete this key part of the regulatory dossier.

GenSight Biologics held a **pre-submission meeting with the EMA** on March 19, 2020, as planned, in the form of a teleconference. Official minutes of the meeting are expected by the end of April, and the Company remains on track for regulatory filing in Europe (MAA filing with EMA) in Q3 2020, with potential approval in H2 2021.

The **REFLECT** Phase III trial of LUMEVOQ® is fully recruited with a primary endpoint at 78 weeks. Although some on-site visits are being postponed, the Company is closely partnering with clinical sites, and investigators continue to assess the safety of all patients remotely, in accordance with regulators' guidelines. Safety monitoring is an absolute priority and will not be disrupted. Most patients are due to make their 78-week visit in the near future, and some may be delayed as a result. This will be properly documented and reported to regulators, as well as pre-specified in the Statistical Analysis Plan (SAP), in agreement with biostatisticians, before database lock. Accordingly, GenSight Biologics foresees limited impact on the trial and no consequence on the primary endpoint other than a possible delay in data availability from Q1 to Q2 2021, which will be confirmed as soon as possible. The regulatory filing target with the FDA in the US remains H2 2021.

The **PIONEER** Phase I/II clinical trial of GS030, combining gene therapy and optogenetics for the treatment of retinitis pigmentosa (RP), has fully completed recruitment of the second cohort. The Data

Safety Monitoring Board (DSMB) is expected to make a recommendation in a few days about proceeding to the third cohort with a higher dose, based on an interim look at the safety database. The use of corticosteroids pre and post gene therapy injection, performed as part of the protocol to minimize inflammatory response, was deemed by GenSight Biologics and investigators to expose patients to a higher risk of COVID-19 infection. In order to protect patients, the Company and investigators have together decided to delay recruiting new patients into the third cohort until the COVID-19 situation has improved, as RP is a chronic disease, and does not require an urgent treatment. In the interim, the six patients in the first two cohorts are being remotely monitored for safety aspects by investigators. Consequently, recruitment may take longer than expected; this limited impact will be more precisely assessed as soon as possible.

A patient was treated with LUMEVOQ® under a first **Temporary Authorization for Use (*ATU*)** granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) in December 2019. A second patient was treated early 2020, and several additional ATUs have been requested and are being reviewed by the ANSM. Hospitals focusing their resources on the current COVID-19 situation may delay requesting additional ATUs as well as the treatment of patients in the next few weeks. GenSight Biologics expects any delay to be overcome as soon as patients can get normal access to treatment sites, with no material impact on the related revenues expected in 2020; this will be more precisely assessed as soon as the situation improves. In addition, the Company is currently discussing with the ANSM the possibility to broaden individual named patient ATUs to a cohort ATU as soon as feasible to further facilitate access to LUMEVOQ® for patients in Europe.

GenSight Biologics has implemented measures to protect its staff against COVID-19 by putting in place remote working for all employees.

The Company is financed until the end of 2020 and is investigating other financing options through debt or equity, seeking in priority several non-dilutive financing initiatives promoted by the French government and Bpifrance in addition to existing commitments from Kreos Capital, in order to increase cash available for operations and ensure that the Company is able to face any evolution of the COVID-19 situation with as much flexibility and foresight as possible.

Contacts

GenSight Biologics
Thomas Gidoin
Chief Financial Officer
tgidoin@gensight-biologics.com
+33 (0)1 76 21 72 20

RooneyPartners
Media Relations
Marion Janic
mjanic@rooneyco.com
+1-212-223-4017

LifeSci Advisors
Investor Relations
Guillaume van Renterghem
gvanrenterghem@lifesciadvisors.com
+33 (0)6 69 99 37 83

James Palmer
Retail Investors
j.palmer@orpheonfinance.com
+33 (0) 7 60 92 77 74

About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biopharma company focused on discovering and developing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders. GenSight Biologics' pipeline leverages two core technology platforms, the Mitochondrial Targeting Sequence (MTS) and optogenetics to help preserve or restore vision in patients suffering from blinding retinal diseases. GenSight Biologics' lead product candidate, LUMEVOQ® (GS010), is in Phase III trials in Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible blindness in teens and young adults. Using its gene therapy-based approach, GenSight Biologics' product candidates are designed to be administered in a single treatment to each eye by intravitreal injection to offer patients a sustainable functional visual recovery.