Press Release

GenSight Biologics Reports Cash Position as of December 31, 2020 and Provides Operational Update

Paris, France, January 19, 2021, 7.30 am CET – GenSight Biologics (Euronext: SIGHT, ISIN: FR0013183985, PEA-PME eligible), a biopharma company focused on developing and commercializing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders, today reported its cash position as of December 31, 2020, and provided an operational update.

"Following the filing of the Market Authorisation Application of LUMEVOQ with the European Medicines Agency, our team is focused on taking GenSight forward to a new chapter in our development and growth. The European sales and marketing infrastructure is being put in place to be ready for commercial launch as early as the beginning of 2022. At the same time, we continue to prepare for the filing of the Biologics License Application with the U.S. Food and Drug Administration during the second half of 2021," commented **Bernard Gilly**, Chief Executive Officer of GenSight Biologics.

Cash position and financing runway

GenSight Biologics' cash and cash equivalents totaled €37.9 million as of December 31, 2020, compared to €18.1 million as of September 30, 2020.

The operating cash burn in the fourth quarter of 2020 mainly reflects the conduct of the REFLECT Phase III clinical trial of LUMEVOQ® in the treatment of Leber Hereditary Optic Neuropathy, as well as the PIONEER Phase I/II trial of GS030 in the treatment of Retinitis Pigmentosa. The Company also focused on the final pharmaceutical development steps for LUMEVOQ® in preparation for the European marketing authorization filed in September 2020. These were mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP).

The operating cash burn was more than offset by the net proceeds from the €25 million private placement in October led by Arix Bioscience, Invus and Sofinnova Partners.

The Company also recorded revenues from the sale of LUMEVOQ® under a Temporary Authorization for Use (ATU) in France amounting to €2.1 million in the fourth quarter of 2020, and to a total of €5.6 million in 2020 despite a very limited access of patients to hospitals due to the COVID-19 crisis.

"We have been able to secure significant financing this year with minimal dilution to shareholders, in addition to revenues generated by ATUs in France, extending the runway to at least the end of Q1 2022," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"We will continue to be opportunistic and seek optimal conditions to finance the commercial launch of LUMEVOQ through 2022."*

Temporary Authorization for Use (ATU) of LUMEVOQ®

Additional patients were treated with LUMEVOQ® in the fourth quarter under a Temporary Authorization for Use (ATU) granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM). Additional ATUs have been requested by and granted to the CHNO of the Quinze-Vingts in Paris. Patients have been scheduled for treatment in January 2021.

GenSight Biologics has committed to providing the drug, limited to available stock. Bilateral injections are priced at €700,000 per patient and are expected to generate revenues prior to regulatory approval and reimbursement in France.

In addition, the Company has submitted to the ANSM an application for a cohort ATU to further facilitate access to LUMEVOQ® for patients in France and in Europe. The application is being reviewed and patients can benefit from nominative ATUs in the meantime.

Validation of LUMEVOQ® Marketing Authorisation Application by European Medicines Agency (EMA)

GenSight Biologics submitted the Marketing Authorisation Application (MAA) for its lead product LUMEVOQ® to the European Medicines Agency (EMA) in September 2020 as planned, seeking approval for the treatment of patients with vision loss due to Leber Hereditary Optic Neuropathy (LHON) caused by mutation in the *ND4* mitochondrial gene.

The dossier passed the validation checks required for submissions to the EMA, triggering the official start of the review procedure on October 29, 2020.

Number of outstanding shares

As of December 31, 2020, GenSight Biologics' number of outstanding shares was 40,875,965 ordinary shares.

GenSight Biologics will report its cash position as of March 31, 2021 on April 20, 2021.

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About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biopharma company focused on developing and commercializing 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. 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. Developed as a treatment for Leber Hereditary Optic Neuropathy (LHON), GenSight Biologics' lead product candidate, LUMEVOQ® (GS010; lenadogene nolparvovec), is currently in the review phase of its registration process in Europe, and in Phase III to move forward to a BLA filing in the U.S.