Press Release

GenSight Biologics Reports Cash Position as of September 30, 2020 and Provides Operational Update

Paris, France, October 15, 2020, 7:30 am CEST – 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 September 30, 2020, and provided an operational update.

"Following the filing of the Market Authorization 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. *"GenSight is committed to provide LUMEVOQ to LHON patients as early as possible in various geographic areas."*

Cash position and financing runway

GenSight Biologics' cash and cash equivalents totaled €18.1 million as of September 30, 2020, compared to €16.8 million as of June 30, 2020.

The operating cash burn in the third 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 receipt of the €2.1 million balance of the €6.8 million State-guaranteed loan (*Prêt Garanti par l'Etat* or PGE), the second tranche of the bond financing from Kreos amounting to €4.0 million, as well as the final tranche of €1.1 million of the conditional advance and a €0.3 million subsidy from the Sight Again financing from Bpifrance.

The Company also recorded revenues from the sale of LUMEVOQ® under a Temporary Authorization for Use (ATU) in France amounting to €2.8 million in the third quarter of 2020, due to be received in the fourth quarter.

"We have been able to secure significant financing this year to fund the last mile of LUMEVOQ with minimal dilution to shareholders to at least mid- 2021," 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."*

Temporary Authorization for Use (ATU) of LUMEVOQ®

Additional patients were treated with LUMEVOQ® in the third 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 and granted to the CHNO of the Quinze-Vingts in Paris. Patients have been scheduled for treatment in October.

GenSight Biologics has committed to provide the drug, limited to available stock. These 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 is 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.

European Submission of LUMEVOQ® on time & Indirect Comparison to Natural History

GenSight Biologics submitted the Marketing Authorisation Application (MAA) for its lead product LUMEVOQ® to the European Medicines Agency in September 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 MAA is based on the benefit-risk balance established by results from a Phase I/IIa study (CLIN-01), two pivotal Phase III efficacy studies (CLIN-03A: RESCUE, and CLIN-03B: REVERSE) and the long-term follow up study of RESCUE and REVERSE (CLIN 06 - readout at Year 3 post injection). To demonstrate the efficacy of LUMEVOQ® in the context of a contralateral effect, the Company used a statistics-based indirect comparison methodology to assess the visual outcomes in LUMEVOQ®-treated patients (from LUMEVOQ® efficacy studies) against those in untreated patients from Natural History studies and GenSight's REALITY Natural History Registry.

The Natural History studies were identified from an extensive review of the scientific literature and selected based on specific inclusion criteria for their patient-level data. In all, the visual outcomes in 76 treated patients could be compared to the visual outcomes of 208 untreated patients. The meta-analysis demonstrated a statistically significant and clinically meaningful difference between the visual outcomes in LUMEVOQ®-treated patients and untreated patients.

Number of outstanding shares

As of September 30, 2020, GenSight Biologics' number of outstanding shares was 33,738,362 ordinary shares.

GenSight Biologics will report its cash position as of December 31, 2020 on January 19, 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. GenSight Biologics' lead product candidate, LUMEVOQ® (GS010; lenadogene nolparvovec), has been submitted for marketing approval in Europe for the treatment of Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease affecting primarily teens and young adults that leads to irreversible blindness. 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.