Press Release

GenSight Biologics Reports Cash Position as of September 30, 2021 and Provides Operational Update

Paris, France, November 10, 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 September 30, 2021, and provided an operational update.

"With our current financial runway to mid-2023, we are able to maintain the momentum behind preparations for LUMEVOQ's commercial launch while setting up for the next stages in GS030's development as a pioneering optogenetics treatment," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"After further strengthening the commercial organization next year, we should be in an excellent position for LUMEVOQ's European launch in the first half of 2023."*

Cash position as of September 30, 2021

GenSight Biologics' cash and cash equivalents totaled €49.1 million as of September 30, 2021, compared to €54.3 million as of June 30, 2020.

The operating cash burn in the third quarter of 2021 mainly reflects the final pharmaceutical development steps for LUMEVOQ® supporting the Marketing Authorisation Application currently being reviewed by the European Medicines Agency (EMA). These were mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) and notably the production of validation batches. In addition, the Company continued to conduct 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.

Temporary Authorization for Use (ATU) of LUMEVOQ® in France

Additional patients were granted early access to treatment with LUMEVOQ® in the third quarter of 2021 under a Temporary Authorization for Use (ATU) approved by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM). Although these ATUs were requested and approved in Q3, patients were treated in October at the CHNO of the *Quinze-Vingts* in Paris. Related revenues will therefore be recorded accordingly in Q4.

In the first three quarters of 2021, the Company recorded revenues from the sale of LUMEVOQ® under a Temporary Authorization for Use (ATU) in France amounting to €5.6 million compared to €2.8 million for the same period in 2020, and to €4.4 million for the full year in 2020.[1]

GenSight Biologics is 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.

[1] The Company elected to account for a variable consideration in accordance with IFRS15 to reflect the uncertainty of the actual net commercial price that will be obtained after negotiation with the French public payer. Any difference with the initial ATU price would then have to be repaid. The variable consideration is assessed by using an expected value method based on a range of probability-weighted net prices and discounted at market rate. Further detail is provided in sections 7 and 18 of the 2020 Universal Registration Document.

Update on LUMEVOQ® EMA Regulatory Procedure in Europe

Following a technical issue in the manufacturing of the validation batches of LUMEVOQ®, the Company requested from the EMA a 9-month extension to the current D120 clock stop, as announced on November 4, 2021. The request was discussed by the Committee for Advanced Therapies (CAT) last week, and a decision is now expected to be ratified by the Committee for Medicinal Products for Human Use (CHMP) in the meeting scheduled November 8-11, 2021. The Company expects to provide an update early next week following the feedback from the Agency.

Number of outstanding shares

As of September 30, 2021, GenSight Biologics' number of outstanding shares was 46,011,756 ordinary shares.

GenSight Biologics will report its cash position as of December 31, 2021 on January 18, 2022.

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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.