Press Release

GenSight Biologics Reports Cash Position and Revenues as of September 30, 2022

- EMA D120 Responses submitted in October as planned
- Two successful engineering batches of LUMEVOQ® validate actions taken to correct low yields in previous runs
- €13.9 million of cash as of September 30, 2022; runway confirmed to early Q1 2023
- The Company is finalizing a minimally dilutive financing and expects to communicate in the coming days

Paris, France, Friday October 28, 2022, 5:45 pm 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 and revenues as of September 30, 2022.

Cash position as of September 30, 2022

GenSight Biologics' cash and cash equivalents totaled €13.9 million as of September 30, 2022, compared to €24.1 million as of June 30, 2022.

The operating cash burn in the third quarter of 2022 mainly reflected 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 engineering and validation batches. In addition, the Company continued to conduct the REFLECT and RESTORE (long-term follow-up of REVERSE and RESCUE patients) Phase III clinical trials 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.

GenSight Biologics has been assessing several financing options over the past few months and is now finalizing a minimally dilutive financing to be announced in the coming days.

Revenues as of September 30, 2022

In the first nine months of 2022, the Company recorded revenues from the sale of LUMEVOQ® under a Temporary Authorization for Use ("*ATU nominative*", or ATU) granted by the French National Drug Safety Agency (Agence Nationale de Sécurité du Médicament or ANSM) in France amounting to €3.1 million. These revenues represent a single quarter of ATUs in 2022, following manufacturing issues at the Company's partner leading to available vials being used up in March 2022. The Company expects to resume ATUs in early 2023 as soon as the product becomes available again.

Regulatory Pathway of LUMEVOQ®

As agreed with the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA) in April 2022, the Company submitted its responses to the Day 120 questions in the regulatory review of LUMEVOQ® in October 2022. The review process has therefore resumed, and GenSight Biologics is now expecting the Day 180 questions in December 2022. The Company expects the opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) by Q3 2023, to be followed by commercial launch by the end of 2023.

In parallel, GenSight is continuing to work on making its product available in the United States. The Company is preparing to move forward quickly with a new clinical trial when product from GMP batches becomes available.

Manufacturing of LUMEVOQ®

GenSight Biologics announced in September 2022 the successful completion of the first engineering batch incorporating refinements in the manufacturing process of LUMEVOQ®. The batch was the first to implement a set of targeted corrective measures around enhanced process control and strengthened on-site supervision that were identified by the Company and its manufacturing partner in the United States in April this year.

The second engineering run was successfully completed at the end of September with a similar yield.

The two successful engineering runs generated drug substance whose viral genome titer achieved the acceptance threshold, thereby confirming that the manufacturing process of LUMEVOQ® is sound at the defined batch size. In addition, the results demonstrate that corrective actions have successfully fixed issues in the filtration steps of the downstream process, resulting in a significantly improved product yield that had not been achieved previously.

Number of outstanding shares

As of September 30, 2022, GenSight Biologics' number of outstanding shares was 46,335,591 ordinary shares.

GenSight Biologics will report its cash position as of December 31, 2022, on January 26, 2023.

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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.