Press Release

GenSight Biologics Announces Preliminary Assay Indicating Successful Manufacture of Second LUMEVOQ® GMP Batch

- Vg titer results to be confirmed by an independent laboratory in the next few days
- The latest batch is the second one to confirm successful implementation of corrections identified in remediation plan
- Batch may provide product supply in the beginning of Q2 2024 for potential resumption of early access program and initiation of the new RECOVER clinical trial, as well as additional data for planned regulatory submission
- Preparations underway for manufacture of third planned GMP batch

Paris, France, November 13, 2023, 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 announced that a preliminary assay of the viral genome (vg) titer indicates the successful manufacture of a second batch of drug substance (DS) for LUMEVOQ®, the Company's gene therapy for Leber Hereditary Optic Neuropathy (LHON), compliant with Good Manufacturing Practice (GMP) standards.

The assay, while preliminary, is known to be predictive of the final result at the independent laboratory used for the official release assay. Because the batch was manufactured according to GMP manufacturing protocols, which are the required standards for commercial batches, the gene therapy from the drug substance of this batch may be eligible for use with patients after passing all quality control tests and pending discussions with regulatory bodies.

"*We are delighted that the actions we took in collaboration with our manufacturing partner, including enhanced training and supervision for the manufacturing team, have contributed to these two successful batches*," commented **Scott Jeffers**, Chief Technology Officer of GenSight Biologics. "*The streamlined batch records and work instructions, coupled with the training and our presence on the manufacturing floor for every critical operation, have significantly reduced process deviations. We are excited to take this level of execution quality into our future campaigns, so that GS010 can be made available to LHON patients who have an urgent need for a treatment*."

Preparations are underway for the third GMP batch of the campaign planned by the Company. As with the two batches successfully manufactured so far, all of which are outside the context of a validation campaign[1], the third batch will generate more process data for a future Marketing Authorisation Application (MAA) submission, provide more experience of the manufacturing process to the operating teams, and help fulfill the immediate requirement of supplying product for the new RECOVER clinical trial and for the

[1] A validation campaign, or Process Performance Qualification (PPQ) campaign, consists of at least 3 successful GMP (Good Manufacturing Practice, required standards for human use outside of a clinical trial) batches manufactured sequentially to demonstrate and document the robustness, control, consistency and reproducibility of the commercial manufacturing process at the designated commercial facility. This exercise is required only as part of a Marketing Authorisation Application with the EMA and a Biologics License Application (BLA) with the FDA.

potential resumption of an early access program for patients in the beginning of the second quarter of 2024.

GenSight Biologics will communicate further in the next few days when the vg titer results are confirmed by the independent laboratory. Upon this confirmation, the Company would be eligible to drawdown the second tranche of €4 million from the bridge financing signed in August 2023 with Sofinnova Partners, Invus and UPMC Enterprises (the "**Bridge Financing**").

The cash runway would be extended to mid-December 2023 with the drawdown of the second tranche of the Bridge Financing for an amount of €4 million. Following the drawdown of the second tranche, GenSight Biologics needs to seek other sources of debt, other non-dilutive or equity financing beyond that date in order to supplement its working capital requirements and fund its operating expenses until the resumption of the early access program in France (*Autorisation d'Accès Compassionnel* or AAC) expected in the beginning of the second quarter of 2024. GenSight Biologics estimates that, in addition to the second tranche of the Bridge Financing, it will need approximately €10 million to finance its activities until that date.

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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), is an investigational compound and has not been registered in any country at this stage; a marketing authorization application is currently under review by the EMA 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.

About LUMEVOQ® (GS010; lenadogene nolparvovec)

LUMEVOQ® (GS010; lenadogene nolparvovec) targets Leber Hereditary Optic Neuropathy (LHON) by leveraging a mitochondrial targeting sequence (MTS) proprietary technology platform, arising from research conducted at the Institut de la Vision in Paris, which, when associated with the gene of interest, allows the platform to specifically address defects inside the mitochondria using an AAV vector (Adeno-Associated Virus). The gene of interest is transferred into the cell to be expressed and produces the functional protein, which will then be shuttled to the mitochondria through specific nucleotidic sequences in order to restore the missing or deficient mitochondrial function. "LUMEVOQ" was accepted as the invented name for GS010 (lenadogene nolparvovec) by the European Medicines Agency (EMA) in October 2018. LUMEVOQ® (GS010; lenadogene nolparvovec), is an investigational compound and has not been registered in any country at this stage.