Press Release

# GenSight Biologics Granted Six-Month Extension in LUMEVOQ® European Regulatory Review

- New submission date for Day 120 responses: October 2022
- Restart of validation batches in Q3 2022
- Committee for Medicinal Products for Human Use (CHMP) opinion expected by Q3 2023

**Paris, France, April 14, 2022, 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 announced that the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA) has granted the Company a six-month extension for submitting its responses to the Day 120 questions in the regulatory review of LUMEVOQ®, GenSight's gene therapy for the treatment of Leber Hereditary Optic Neuropathy (LHON).

The Company requested the extension in order to implement process adjustments in the manufacturing of the validation (PPQ) batches required for marketing approval (GenSight Biologics Provides Update on LUMEVOQ® Manufacturing Timeline – GenSight Biologics (gensight-biologics.com). The Company is working with its manufacturing partner to implement targeted corrections around enhanced process control and more rigorous supervision inside the manufacturing suites. In addition, smaller engineering lots will be used to confirm the robustness of the corrective actions.

GenSight targets the restart of the PPQ campaign in Q3 2022. In the meantime, the Company has already finalized the responses to the D120 questions that were not related to the validation batches.

Responses to the Day 120 questions are now due in October 2022, after which regulatory review of LUMEVOQ®'s Marketing Authorisation Application will resume. 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.

"*We are highly appreciative and grateful for the flexibility that the CAT has shown during the review of LUMEVOQ's regulatory filing,*" commented **Bernard Gilly**, Chief Executive Officer and Co-Founder of GenSight Biologics. *"The additional time granted allows us to implement the necessary adjustments with our manufacturing partner to ensure that LUMEVOQ is reliably and consistently produced at the scale needed for the upcoming commercial launch. These measures are part of our commitment to providing LHON patients with access to our innovative treatment as soon as possible."*

"*It is worth reiterating that the necessary adjustments are not related to any efficiency or safety issue linked to our gene therapy",* added Bernard*. "The soundness of the manufacturing process itself was never in doubt, as it had already generated product at the highest quality and safety needed for our clinical trials and compassionate use."*

In parallel, GenSight is continuing to work on making its product available in the United States. In line with recent announcements (e.g., GenSight Biologics Reports Cash Position as of December 31, 2021, and Provides Operational Update – GenSight Biologics (gensight-biologics.com), the Company is preparing to move forward quickly with a new clinical trial when product from the validation runs becomes available.

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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.

### 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.