Press Release

GenSight Biologics Announces Regulatory Approval for GS010/LUMEVOQ® REVISE Dose-Ranging Study in France

- French medicines agency ANSM and Ethics Committee authorize the dose-ranging study investigating two doses of candidate product for the treatment of *ND4*-LHON.
- Approval of the study protocol will support the ongoing review of the named patient early access program (AAC) in France.
- The Phase II study is expected to start in January 2026.

Paris, France, December 2, 2025, 5:00 pm 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 the French medicines safety agency ANSM (*Agence nationale de sécurité du médicament et des produits de santé*) has authorized the dose-ranging study REVISE, which will investigate the efficacy and safety of two dose levels of the Company's candidate gene therapy GS010/LUMEVOQ®.

The study had been requested by the agency during discussions with the Company about a named patient early access program for the candidate product, which is in clinical development for the treatment of vision loss due to Leber Hereditary Optic Neuropathy (LHON) caused by a mutated *ND4* mitochondrial gene.[1] Regulatory approval was granted after the ANSM assessed the GS010/LUMEVOQ® quality dossier and clinical aspects of REVISE. The study also received approval from the Ethics Committee. The regulatory approval of REVISE will support the ongoing review of GenSight Biologics' application for the French named patient early access program (AAC) by the ANSM.

REVISE is an open-label, single center, Phase II study with a target enrollment of 14 patients. The patients must all have confirmed mutations in the *ND4* gene and must have 6 months to 1.5 years of vision loss at the date of treatment. Two (2) clinical doses will be investigated in the trial, with patients distributed equally over the two doses. Efficacy, as measured by the change in Best Corrected Visual Acuity (BCVA), 1.5 years post-treatment versus baseline, is the primary endpoint in REVISE. The study is expected to begin in January 2026.

Company Prepares for Strategic Priorities in 2026

While the AAC application is under review, GenSight Biologics is moving forward according to target timelines with the final stages of the technology transfer to its new manufacturing partner and with the preparations to finalize the protocol for the Phase III study.

In parallel, the Company is pursuing opportunities to out-license GS010 in markets outside the USA and Europe, while exploring paid Early Access Programs worldwide.

About Leber Hereditary Optic Neuropathy (LHON)

LHON is a rare, maternally inherited mitochondrial genetic disease, characterized by the degeneration of retinal ganglion cells, which results in precipitous and usually irreversible vision loss and typically leads to

[1] GS010/LUMEVOQ® has not been granted marketing authorization in any country and is not commercially available.

legal blindness. The *ND4* mitochondrial mutation is the most common of the mutations that cause LHON and is associated with the worst prognosis among the leading mutations.

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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, GS010 (lenadogene nolparvovec) is in Phase III in Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible blindness in teens and young adults. GS010 is currently in clinical development, has not to date been granted marketing authorization in France or any other jurisdiction, and is therefore not available commercially. 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 GS010/LUMEVOQ® (lenadogene nolparvovec)

GS010/LUMEVOQ® (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 is then shuttled to the mitochondria through specific nucleotidic sequences in order to restore the missing or deficient mitochondrial function. GS010/LUMEVOQ® (lenadogene nolparvovec) is in Phase III of its clinical development. It has not been granted marketing authorization in any country and is not available commercially.