Press Release

GenSight Biologics Announces Regulatory Authorization for Early Access Treatment with GS010/LUMEVOQ® in Israel

- Israel's Ministry of Health authorizes individual patients early access treatment with GS010/LUMEVOQ®, a candidate gene therapy for the treatment of *ND4*-LHON.
- Bilateral injection expected to be performed in Q1 2026.

Paris, France, December 22, 2025, 6:00 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 Israel's Ministry of Health Pharmaceutical Division has authorized the use of the candidate gene therapy GS010/LUMEVOQ®[1] for the early access treatment of individual patients in the country.

Early access treatment in Israel is potentially available to patients with a life-threatening or seriously debilitating disease who cannot be properly treated with a registered and approved medicinal product in Israel or abroad and who cannot be included in an appropriate clinical trial. As in many countries, the decision to treat must be initiated by a patient's physician, after which the treating hospital's ethics committee (Helsinki Committee) and Ministry of Health must both approve treatment. The application for early access treatment includes the scientific rationale for the treatment and evidence from non-clinical and clinical studies as well as professional literature that support the benefit-risk assessment for the patient. The Company is working with SK-Pharma, its partner of choice in Israel, to ensure access to GS010/LUMEVOQ for patients with unmet medical needs in the country.

"*We are very pleased that we are able to provide limited quantities of GS010/LUMEVOQ for early access treatment worldwide, after authorization by relevant competent authorities,*" commented **Laurence Rodriguez**, Chief Executive Officer of GenSight Biologics. "*At the same time, we are gratified that the evidence that we could make available, regarding the clinical data on GS010, could support the compassionate treatment application."*

"*For now, the company is giving the highest priority to ensuring sufficient supply for the REVISE dose-ranging study and named patient Early Access Program (AAC) recently authorized in France,"* explained Ms. Rodriguez. *"These programs represent essential steps towards our ultimate goal of maximizing patient access to GS010/LUMEVOQ through full market authorizations in key markets of the world.*"

Business Update

The Company is currently completing the technology transfer to its new manufacturing partner, Catalent, which is expected to be finalized by year-end 2025. The transition will enable the production of new batches in 2026 to fully address the projected clinical needs.

In parallel, the Company is preparing to resume discussions with global regulatory agencies to pave the way for the launch of the pivotal GS010/LUMEVOQ® Phase III study RECOVER in H2 2026 and in anticipation of a submission in the UK.

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

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

Financial Calendar 2026

Q4 2025 Cash position	January 8, 2026
EGM to renew financial authorization for future potential fundraising	January 28, 2026
FY 2025 Financial statement	March 26, 2026
Q1 2026 Cash position	April 7, 2026
AGM	May 19, 2026
Q2 2026 Cash position	July 8, 2026
First half year 2026 Financial Statement	September 29, 2026
Q3 2026 Cash position	October 8, 2026

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 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.

Contacts

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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 being investigated as a treatment for 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 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 clinical development. It has not been granted marketing authorization in any country and is not available commercially.