Press Release

The 15-20 National Hospital and GenSight Biologics announce the treatment of the first patient in the GS010/LUMEVOQ® REVISE Study

- First of 14 planned patients for the dose-ranging study approved by the ANSM in December 2025
- Clinical study marks continuing partnership between the 15-20 Hospital and GenSight Biologics to develop transformative treatments for rare diseases

Paris, France, February 10, 7.30 am CET – The 15-20 National Hospital (*l'Hôpital national des 15*-20) in Paris and 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 the treatment of the first patient enrolled in the REVISE dose-ranging study. The open-label, single center study aims to enroll 14 patients in France.

With REVISE now underway, the hospital is currently the only institution in Europe with a clinical study involving GS010/LUMEVOQ®, GenSight Biologics' candidate gene therapy being developed as a treatment for Leber Hereditary Optic Neuropathy (LHON) caused by a mutated *ND4* mitochondrial gene[1]. The hospital is also the sole institution in Europe authorized to perform named patient early access (AAC) treatments with GS010.

"*As a leading hospital specialized in the treatment of vision disorders, 15-20 National Hospital is committed to supporting the most promising scientific advances rigorously and in the service of patients affected by rare diseases,*" said **Nicolas Péju**, Chief Executive Officer of the 15-20 National Hospital*. "The start of the REVISE study testifies to this drive and to the trust given to our clinical and research teams."*

The REVISE study will investigate two doses of GS010 for the treatment of *ND4*-LHON. The study was requested by the French medicines agency ANSM (*Agence nationale de sécurité du medicaments et des produits de santé*) during the review of the application for a named patient early access program (AAC) for GS010 and was authorized in December 2025.

Reviewed in parallel with the REVISE study, the AAC program received the authorization from the ANSM later in December 2025 and is potentially open to patients from outside of France depending on regulatory requirements in their home country. In accordance with regulations, the first named patient requests for AAC were submitted to the ANSM last week. The named patient requests, each of which resulted from a multidisciplinary consultation, will be individually evaluated by the agency. Enrollment into REVISE is prioritized for patients eligible for both programs.

"*We at GenSight are gratified that two avenues are now available for patients to be treated with GS010 in France*," said **Dr. Magali Taiel**, Chief Medical Officer of GenSight Biologics. "*The unmet medical need among ND4-LHON patients and the urgency to treat the condition continue to animate our efforts to*

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

advance the clinical development of the gene therapy, *including our push to begin a new Phase III clinical study by the end of this year.*"

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

The 15-20 National Hospital
Doriane Allain
Communications Director
dallain@15-20.fr
+33 (0)6 30 71 02 40

GenSight Biologics
Chief Financial Officer
Jan Eryk Umiastowski
jeumiastowski@gensight-biologics.com

About the *Hôpital national des 15-20* (the 15-20 National Hospital)

The 15-20 National Hospital is the leading French hospital in ophthalmology and the fight against vision pathologies. A hospital with national standing and university teaching, the 15-20 National Hospital brings together the best medical and care teams and provides dedicated care for visual diseases. In 2018, the hospital founded, with the Institut de la vision, the University Hospital Institute (IHU) FOReSIGHT, whose mission is to promote fundamental research to develop tomorrow's ophthalmology care and provide access to therapeutic innovations through international partnerships and the development of companies involved in preventing and treating eye diseases.
www.15-20.fr

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.