

Press Release

The 15-20 National Hospital and GenSight Biologics Announce the First Treatments in the French Named Patient Early Access Program (AAC) for GS010/LUMEVOQ®

- The first group of patients in the GS010 AAC program were treated at the 15-20 National Hospital in Paris on March 19.
- The REVISE dose-ranging study is proceeding according to the planned timeline.

Paris, France, March 20, 2026, 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 that the first patients have been treated in the French Named Patient Early Access Program (AAC) for GS010/LUMEVOQ®.¹ The REVISE dose-ranging study, which is being conducted in parallel, has enrolled the next three patients.

First patients treated in the GS010 AAC program

Following [the recent authorization of the first named patient requests](#), an initial group of patients in the GS010 AAC program were treated at the 15-20 National Hospital in Paris on March 19. More treatments are scheduled in the coming weeks.

GS010 is a candidate gene therapy in clinical development for the treatment of Leber Hereditary Optic Neuropathy (LHON) caused by a mutation in the *ND4* mitochondrial gene. LHON patients suffer precipitous, usually irreversible vision loss caused by the rapid degeneration of their retinal ganglion cells (RGCs), cells that are essential to vision. Recognizing the urgency to treat the disease in the face of the progressive loss of these cells, the ANSM authorized, under the AAC program, the treatment of patients presenting with vision loss related to *ND4*-LHON. The *ND4* mitochondrial mutation is the most common of the mutations that cause LHON and is associated with the worst visual prognosis among the three most prevalent mutations.

“The 15-20 National Hospital provides LHON patients with access to GS010 within a rigorous regulatory framework,” said **Nicolas Péju**, Chief Executive Officer of the 15-20 National Hospital. *“Our clinical teams are fully mobilized to care for these patients, whether through the REVISE study or the AAC program.”*

REVISE study update

The REVISE dose-ranging study, [authorized by the ANSM and the Ethics Committee in December 2025](#), is proceeding according to plan. The first patient was [treated in February 2026](#), and three additional patients have since been enrolled in the study. French patients eligible for both the REVISE study and the AAC program are prioritized for the clinical study, in accordance with applicable regulations.

*“The treatment of the first patients under the AAC program makes access to GS010 a reality for many LHON patients with the *ND4* mutation, patients who would otherwise have no appropriate treatment*

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

option,” said **Dr. Magali Taiel**, Chief Medical Officer of GenSight Biologics. “With both the REVISE study and the AAC program running, two avenues have now become available in France for these patients.”

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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) FOrReSIGHT, 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.