GenSight Biologics Announces Significant Milestone in New Manufacturing Partnership with Catalent

- Upstream phase of LUMEVOQ® manufacturing process successfully transferred
- Milestone follows successful manufacture of drug product batch to be used for named early access program (AAC) and dose-ranging study in France
- Partnership expected to improve yield and upgrade analytical methods ahead of clinical use and regulatory submissions

Paris, France, June 26, 2025, 7:30 am 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 the successful transfer of the upstream phase of the manufacturing process for LUMEVOQ®, the Company's gene therapy candidate product for the rare mitochondrial disease Leber Hereditary Optic Neuropathy (LHON), to its new manufacturing partner, Catalent, Inc.

"*This outstanding result is a significant milestone in GenSight's strategy for securing the supply of LUMEVOQ for clinical use and for supporting the planned regulatory submissions*," commented **Scott Jeffers**, Chief Technical Officer of GenSight Biologics. "*Our new partnership is proving to be highly effective, not just in completing the tech transfer process successfully, but also in improving the yield and upgrading the analytical methods used to reinforce control over the safety and quality of each batch. The level of collaboration and coordination between our teams has been truly impressive.*"

Catalent, Inc. is a leading global contract development and manufacturing organization (CDMO) whose mission is to develop, manufacture, and supply products that help people live better and healthier lives. It is the only CDMO with a successfully commercialized gene therapy produced in their facility. Catalent offers gene therapy companies both production and in-house testing capabilities, and the GMP capacity at the facility used for LUMEVOQ® will provide GenSight Biologics greater flexibility in the manufacture of the gene therapy.

Catalent successfully manufactured the drug product batch that was released as safe for human use in November 2024 and which will be the source of product supply for the named patient early access program (AAC) and dose-ranging study in France. After the tech transfer is completed, Catalent will also manufacture the drug for the planned global Phase III trial RECOVER and the regulatory submissions.

The Partnership as a Critical Element of GenSight Biologics' Strategy

Following agreement with the French agency ANSM to consider opening the AAC program expeditiously after approval of a dose-ranging study, the Company is currently implementing a financing strategy, as it continues to advance its global marketing authorization strategy:

- Preparation for regulatory consultations in the US and EU
- Planning for the global Phase III trial scheduled to begin in 2026, designed to meet FDA and EMA requirements
- Completing the transition to a new manufacturing partner (Catalent) to secure reliable clinical and commercial supply
- Advancing preparations for MHRA submission in the United Kingdom

"*Our partnership with a manufacturing powerhouse like Catalent is a critical enabler of our global strategy*," explained **Laurence Rodriguez**, CEO of GenSight Biologics. "*The outputs from their work with our team*

will allow us to reassure regulators that we have surmounted the challenges we faced in the past and, ultimately, to fulfill our mission to provide LHON patients a safe and effective treatment for their urgent unmet need."

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 in Phase III in Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible blindness in teens and young adults. 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 Leber Hereditary Optic Neuropathy (LHON)

Leber Hereditary Optic Neuropathy (LHON) is a rare maternally inherited mitochondrial genetic disease, characterized by the degeneration of retinal ganglion cells that results in brutal and irreversible vision loss that can lead to legal blindness, and mainly affects adolescents and young adults. LHON is associated with painless, sudden loss of central vision in the 1st eye, with the 2nd eye sequentially impaired. It is a symmetric disease with poor functional visual recovery. 97% of subjects have bilateral involvement at less than one year of onset of vision loss, and in 25% of cases, vision loss occurs in both eyes simultaneously.

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. LUMEVOQ® (GS010; lenadogene nolparvovec) has not been registered in any country at this stage.