Press Release

# GenSight Biologics Provides Update on LUMEVOQ® Manufacturing and Commercialization Timelines

- PPQ campaign to start early May 2023 (previously end of March) with results expected in Q3 2023
- EMA CHMP opinion now expected in Q1 2024 (previously September 2023)

**Paris, France, March 7, 2023, 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 provides an update on the manufacturing and commercialization timelines of LUMEVOQ®, the Company's gene therapy for Leber Hereditary Optic Neuropathy (LHON).

Two engineering batches were successfully manufactured[1] as a result of close collaboration between the Engineering team (Manufacturing Sciences and Technology, MSAT) of Brammer Bio (a subsidiary of Thermo Fisher Scientific, or TFS), GenSight's manufacturing partner in the US and the Company's own manufacturing experts. Following these engineering batches, a GMP batch (Good Manufacturing Practices, which are the required standards for commercial batches) was scheduled before initiating the production of the validation campaign (3 consecutive GMP batches, or Process Performance Qualification [PPQ] campaign) necessary to complete the European regulatory dossier currently being reviewed by the European Medicines Agency (EMA). This GMP batch was executed under GMP standards by the Manufacturing Operations team at TFS.

Due to the occurrence of an operational issue at TFS in the handling of the downstream process, the batch has been terminated. The precise root cause is being investigated in collaboration with TFS before initiating the validation campaign. To prevent the reoccurrence of such an operational issue and secure a successful outcome, GenSight agreed with TFS to jointly involve the MSAT team and GenSight's own experts (including a person-in-plant at all times) real time in the conduct of the validation campaign.

*"Even if limited, I deeply regret this additional delay. However, given the successful production of two successive engineering batches under the help and supervision of GenSight's experts, we are confident that the measures being jointly implemented with our manufacturing partner will lead to a successful validation campaign,"* said **Bernard Gilly**, Chief Executive Officer and Co-Founder of GenSight Biologics. *"Together with our partner, we are committed to bringing LUMEVOQ to the market for LHON patients, and will devote all our efforts to ensure the success of the future batches production."*

GenSight now expects to initiate the validation campaign in May 2023, with results expected in Q3 2023 (previously Q2 2023). The reports from PPQ batches of the validation campaign will be submitted to the EMA as soon as they become available. They will also allow to resume supply of AAC (*Autorisation d'Accès Compassionnel*, or Early Access Authorisation, former ATU) in France in Q4 2023 and be used for the commercial launch. GenSight now expects to receive the opinion from the European Committee for Medicinal Products for Human Use (CHMP) by Q1 2024 (previously end of September 2023), to be followed shortly by the commercial launch of LUMEVOQ® in Europe. In parallel, GenSight will resume its

[1] https://www.gensight-biologics.com/2022/10/28/gensight-biologics-reports-cash-position-and-revenues-as-of-september-30-2022/

interactions with the U.S. Food and Drug Administration (FDA) to secure a regulatory pathway in the United States.

The Company is taking measures aimed at reducing its operating cash burn in 2023, thereby extending its current cash runway from May to June 2023, while actively discussing options with certain existing shareholders and financial partners with a view to bridge to the results of the validation campaign expected in Q3, which in turn would trigger the 12 million euros Tranche B of the EIB loan.

## Contacts


**GenSight Biologics**
Corporate Communications Director
Clothilde Caillet
ccaillet@gensight-biologics.com

**RooneyPartners**
Media Relations
Jeanene Timberlake
jtimberlake@rooneypartners.com
+1 646-770-8858

**LifeSci Advisors**
Investor Relations
Guillaume van Renterghem
gvanrenterghem@lifesciadvisors.com
+41 (0)76 735 01 31

**Orpheon Finance**
Retail Investors
James Palmer
j.palmer@orpheonfinance.com
+33 (0)7 60 92 77 74


### 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, LUMEVOQ® (GS010; lenadogene nolparvovec), is an investigational compound and has not been registered in any country at this stage; a marketing authorization application is currently under review by the EMA for the treatment of Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease affecting primarily teens and young adults that leads to irreversible blindness. 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 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), is an investigational compound and has not been registered in any country at this stage; a marketing authorization application is currently under review by the EMA.