

## GenSight Biologics Provides Update on Regulatory Discussions and Financial Situation

- Ongoing communication with French medicines safety agency ANSM on early access dossier for LUMEVOQ®
- First injections expected in January 2025
- Advanced discussions to secure financing until first early access program (AAC) payment expected in late January 2025

**Paris, France, December 18, 2024, 6:00 pm CEST** – GenSight Biologics ("**GenSight Biologics**" or the "**Company**") (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 provided an update on its regulatory discussions with the French medicines safety agency (*Agence Nationale de Sécurité du Médicament et des Produits de Santé* or the ANSM) and on its financial strategy.

### Ongoing Discussions with the ANSM

The Company confirms the continuation of a constructive and collaborative communication with the ANSM on the updated regulatory file for LUMEVOQ® submitted in [November](#). These discussions demonstrate mutual commitment to advancing toward the resumption of the Early Access Program in France (*Autorisation d'Accès Compassionnel* or AAC) for the Company's gene therapy LUMEVOQ®.

### Operational Readiness

GenSight Biologics has completed all preparations to supply LUMEVOQ® to the treatment center at the 15-20 National Hospital in Paris, which will optimize the time to the first injections after receipt of regulatory acceptance from the ANSM. Both the Company and the 15-20 National Hospital are aware of the acute need for treatment among eligible Leber Hereditary Optic Neuropathy (LHON) patients who have been waiting for the AAC program to resume. The first patient injections are now expected in January 2025, instead of late December as previously announced.

### Financial Strategy

The Company does not have sufficient net working capital to meet its obligations over the next 12 months but only until early January 2025. The Company is currently engaged in advanced discussions to secure financing for its activities until the end of January 2025. The Company expects to receive the first payments from the resumption of the AAC Program at the end of January 2025, which would extend its cash runway beyond 12 months.

### Share Information

As of today, the share capital of GenSight Biologics is composed of 117,517,544 ordinary shares.



## 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, 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.

## Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding product development prospects and financial projections. These statements do not constitute guarantees of future performance and involve risks and uncertainties. A further list and description of risks and uncertainties that could cause actual results to differ materially from those set forth in the forward-looking statements in this press release can be found in GenSight Biologics' regulatory filings with the French *Autorité des Marchés Financiers*. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements and estimates, which speak only as of the date hereof. Other than as required by applicable law, GenSight Biologics undertakes no obligation to update or revise the information contained in this press release.