Press Release

GenSight Biologics Reports Cash Position as of September 30, 2024, and Provides Business Update

- Cash position amounts to €3.4 million as of September 30, 2024.
- LUMEVOQ® drug product has passed all quality control tests; submission to ANSM supporting AAC resumption now scheduled for mid-November and first patient injection expected by end of December, with first payment expected between late December 2024 and early January 2025.
- Advanced discussions ongoing to secure financing until resumption of early access program (AAC).

Paris, France, Thursday October 24, 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 reported its cash position as of September 30, 2024, and provided a business update.

Cash Position and Outlook

GenSight Biologics' cash and cash equivalents totalled €3.4 million as of September 30, 2024, compared to €6.9 million as of June 30, 2024.

The Company does not have sufficient net working capital to meet its obligations over the next 12 months but only until mid-November 2024. The Company expects to begin receiving indemnities from the resumption of the Early Access Program (AAC) between late December 2024 and early January 2025 (vs. November 2024 as previously announced). This will extend the cash runway to Q4 2026.

To manage the impact of the delayed resumption of AAC program and to account for the time until receipt of the first compensation payments, the Company is currently engaged in active discussions to secure financing for its activities from mid-November until it begins to receive AAC payments.

GenSight Biologics has obtained waivers from its existing creditors, the European Investment Bank and Heights Capital Management, enabling the Company to pursue additional financing options.

"*The small amount of bridge financing that we are trying to raise from existing and new investors will extend our cash runway to early January 2025, sufficient to overcome the delay we have experienced in the resumption of the French Early Access Program.*" noted **Jan Eryk Umiastowski**, Chief Financial Officer of GenSight Biologics. "*We are in an excellent position to resume the Early Access Program in the coming weeks, which should extend our cash runway to Q4 2026. We continue work on optimizing our cash management and ensuring a sustainable future for the Company*."

LUMEVOQ® Update

LUMEVOQ® drug product manufacture, which included the mixing of the 2 GMP drug substance batches produced in 2023, is now fully complete, with more than 100 vials available. The drug product has successfully passed all quality control tests required to release the product for human use. Vials are stored in France, labelled and ready to be supplied once the release is documented and the regulatory green light is obtained.

GenSight Biologics is currently preparing the Good Manufacturing Practice (GMP) documentation and anticipates submitting the dossier to support the AAC resumption to the *Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM) by mid-November 2024, in accordance with the requirements formulated by the ANSM.

Requests for compassionate treatment could subsequently be sent again to the ANSM by healthcare professionals. The Company anticipates a review period for these applications and will work closely with the ANSM to optimize the assessment timeline.

GenSight Biologics will be ready to initiate the supply of the drug to the treatment center in mid-December, rather than in mid-November as previously announced. The first patient injections are expected by end of December 2024, as envisaged with the administrative and medical teams of the Quinze-Vingts hospital in Paris.

"The successful production of a new GMP batch of LUMEVOQ® marks a significant milestone in our journey to bring this innovative therapy once again to patients," commented **Laurence Rodriguez**, Chief Executive Officer of GenSight Biologics. *"We know that many patients are waiting for this treatment. We are ready to answer any questions from the ANSM and share their commitment to treat these patients as quickly as possible."*

The Company did not initiate requests for compassionate treatment in Italy. Such requests are the responsibility of Italian physicians who seek to obtain the authorization, which is only rarely granted by the Italian medicines agency AIFA (*Agenzia Italiana del Farmaco*). The requests from Italian physicians signal a high unmet medical need in Leber Hereditary Optic Neuropathy (LHON). The paid compassionate access program AAC is unique to France and has no bearing on programs in other countries.

Share Information

As of September 30, 2024, GenSight Biologics had 107,686,349 outstanding 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.