Press Release

GenSight Biologics Reaches Agreement with ANSM for Opening of LUMEVOQ® Named Early Access Program (AAC) in France

- Agreement to consider opening the French Early Access Program expeditiously after approval of a dose-ranging study
- Design for dose-ranging study submitted, with clinical trial application targeted for Q3 2025
- Opening of AAC targeted for Q4 2025 at the latest
- Multiple near-term value catalysts expected over next 12 months

Paris, France, June 12, 2025, 7:00 pm CET – 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 announced that it has reached agreement with the French medicines safety agency ANSM to consider expeditiously opening the French named early access program (AAC) for LUMEVOQ® upon approval of a dose-ranging clinical study.

Clear Path Forward for LUMEVOQ® AAC Program in France

Following extensive discussions, GenSight reached alignment with ANSM on a plan to open the LUMEVOQ® AAC program. The agency has agreed that the authorization of a focused dose-ranging study could enable the opening of the early access program. The Company has submitted a preliminary design of the study to the agency and aims to finalize the protocol of a dose-ranging study in Q3 2025.

In parallel, the Company will work with the agency to find a solution for patients who may not be included in the study but who may benefit from the AAC program. The AAC program is targeted to open in Q4 2025 at the latest.

"In the interest of clearing the way for patients to be treated with LUMEVOQ, we are pleased to have achieved this important agreement with ANSM on a clear path forward for opening patient access to LUMEVOQ in France" said **Laurence Rodriguez**, Chief Executive Officer of GenSight Biologics. *"We are thankful for the ANSM's ongoing engagement and openness to discussion, as we work towards the shared goal of providing access to LHON patients who urgently need a safe and effective treatment."*

Financing Strategy to Support Regulatory Milestones

GenSight is implementing a financing strategy to bridge operations through the opening of the AAC program and prepare for the new global Phase III clinical trial. The Company is actively pursuing various funding initiatives to support these critical regulatory milestones.

"We are working on our financing strategy to manage the bridge between now and the opening of the AAC program and the initiation of the Phase III study," commented **Jan Eryk Umiastowski**, CFO of GenSight Biologics. *"Our focus remains on securing the resources needed to execute our regulatory strategy while exploring additional funding opportunities. "*

Advancing Core Marketing Authorization Strategy

In parallel with the French AAC program developments, GenSight will continue 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 to secure reliable clinical and commercial supply
- Advancing preparations for MHRA submission in the United Kingdom

During this period, the Company will actively pursue additional non-dilutive funding opportunities, including licensing arrangements outside North America and Europe and potential M&A activities.

Multiple Value Catalysts

GenSight anticipates a number of significant value-creating events in 2025-2026:

- **Q3 2025:** Clinical trial application for focused dose-ranging study
- **Q4 2025:** Completion of manufacturing tech transfer
- **Q4 2025:** Opening of the AAC program
- **Q2 2026:** Completion of Phase III trial preparations
- **Early H2 2026:** Initiation of global Phase III clinical trial
- **Early H2 2026:** pre-submission meeting with MHRA

Financial Position

The Company received €0.7 million of its Research Tax Credit (CIR) end of May, with the remaining €0.4 million to be paid in July 2025. Based on current operations and projections, GenSight's cash will support operations until mid-July 2025.

The Company acknowledges that current funds are insufficient to cover operational requirements for the next 12 months. The planned financing initiatives are designed to extend the cash runway and enable the initiation of the Phase III clinical trial and UK MHRA marketing application for LUMEVOQ®.

As of June 12, 2025, the number of outstanding GenSight Biologics shares was 131,466,495 ordinary shares.

Risk factors

Detailed information regarding the Company, including its business, financial information, results, perspectives and related risk factors are contained (i) in the Company's 2024 Universal Registration Document filed with the AMF on April 8, 2025 under number D.25-0234. This document, as well as other regulated information and all of the Company's press releases, can be accessed on the Company's website (www.gensight-biologics.com) and/or AMF (www.amf-france.org). The reader's attention is drawn to the risk factors related to the Company and its activities presented in chapter 3 of its 2024 URD in particular the liquidity risk presented in the chapter 3.1.1.

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.

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. **While the Company is actively pursuing financing solutions, regulatory requirements necessitate disclosure that material uncertainty exists regarding the Company's ability to continue as a going concern if sufficient funding cannot be secured**. 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.