Press Release

GenSight Biologics Reports Cash Position as of December 31, 2023, and Provides Business Update

- Current cash runway to mid-February 2024; ongoing discussions for €14 million financing to bridge to French Compassionate Use resumption in Q3 2024
- FDA confirms acceptability of two-arm design for RECOVER to show efficacy while reiterating the need for a placebo control arm
- LUMEVOQ® Drug Product batch expected to be fully released in Q3 2024
- Discussions ongoing on strategic options, including M&A and licensing

Paris, France, January 25, 2024, 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 reported its cash position as of December 31, 2023, and provided a business update.

"*We begin 2024 energized by the solid progress we have made on achieving our ultimate goal of making LUMEVOQ® commercially available to LHON patients in Europe and the US,"* commented **Laurence Rodriguez**, Chief Executive Officer of GenSight Biologics. *"We have enjoyed positive interactions with regulatory authorities in the EU, UK and the US on the way forward, including encouraging advice from the MHRA on basing a regulatory submission on the extensive clinical evidence we already have. In parallel, we have significantly reduced our financial needs and are actively pursuing new financing options with existing and potential investors to extend our cash runway."*

Cash position as of December 31, 2023

GenSight Biologics' cash and cash equivalents totalled €2.1 million as of December 31, 2023, compared to €2.4 million as of September 30, 2023.

The Company completed a successful offering on November 21, 2023, through (i) a private placement reserved to specialist investors and (ii) a public offering to retail investors via the PrimaryBid platform, for a total gross amount of approximately €4.7 million. Since then, GenSight has continued to work on cash preservation measures, notably additional savings and other means to optimize short-term cash management, extending the cash runway from mid-January to mid-February 2024. These new measures include several ongoing discussions with business partners and creditors.

As a result of the Compassionate Use program (AAC - *autorisation d'accès compassionnel*, formerly known as ATU - *autorisation temporaire d'utilisation*) in France now being expected to resume in Q3 2024, and including the aforementioned cash preservation measures, the Company estimates it will require approximately €14 million to finance its activities until the Compassionate Use program can resume. Once the Compassionate Use program re-starts, the Company estimates that the cash runway would be extended to the end of Q1 2025. The Company is therefore actively discussing with existing and potential new shareholders to finance its activities from mid-February to Q3 2024.

In parallel, the Company is also advancing on a number of discussions with potential partners on strategic opportunities, including a possible merger, acquisition or licensing deal, assessed as one of the relevant options to move forward.

Manufacturing Update

In September and November 2023, GenSight announced the successful manufacturing of two Drug Substance (DS) batches of LUMEVOQ® under conditions compliant with Good Manufacturing Practice (GMP) standards, as confirmed by a vg titer within the expected range.

Given the need to set aside a specific number of vials per manufacturing batch for archives and quality control samples, the Company decided to mix the two manufactured DS batches into one single Drug Product (DP) batch to increase the number of vials available to patients. The FDA confirmed in writing that they agree in principle with the mixing step. Performing the mixing step means that LUMEVOQ® vials will be released for clinical use in Q3 2024.

Regulatory Update

On January 12, 2024, GenSight received written feedback from the US Food and Drug Administration (FDA) on the proposed design for the Phase III trial RECOVER. This protocol had been previously shared with the European Medicines Agency (EMA) and the UK Medicines and Healthcare products Agency (MHRA).

The FDA advised the Company that replacing the double sham injection control arm with a double placebo injection control arm "*would help make the study an adequate and well-controlled clinical study designed to provide the primary evidence of effectiveness to support a future marketing application*." The agency also had "*no objection to using best corrected visual acuity (BCVA) as the primary endpoint*" and made additional recommendations for the Company to consider.

The Company plans to revise the RECOVER study design to incorporate the feedback received from the three regulatory agencies, aiming at launching a single global Phase III study that will support marketing authorization applications in the US and EU. GenSight Biologics may schedule further consultations with the FDA and other agencies to reach alignment on the final RECOVER study design.

As previously announced, the current data package, not necessarily including data from the RECOVER trial, could support a marketing authorization application in the UK. The Company plans further discussions with the MHRA to clarify the quickest path towards a regulatory submission.

Number of outstanding shares

As of December 31, 2023, GenSight Biologics' number of outstanding shares was 65,309,073 ordinary shares.

Change in Management

Thomas Gidoin, Chief Financial Officer since 2015, has resigned, effective January 26, 2024. An interim CFO was appointed until a permanent replacement is recruited.

"*Thomas has been an invaluable member of the GenSight team over the years,"* said CEO **Laurence Rodriguez**. *"We are all very grateful to him for his leadership, collaboration and support throughout his time with us and warmly wish him the best for the future."*

Contacts

GenSight Biologics
Chief Financial Officer
Thomas Gidoin
tgidoin@gensight-biologics.com

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

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.