Press Release

GenSight Biologics Reports Cash Position as of March 31, 2024, and Provides Business Update

- Advanced discussions ongoing to secure financing until resumption of early access program (AAC/AAP) expected in Q3 2024
- Full alignment sought with regulatory agencies prior to launch of a global Phase III trial supporting both US and EU regulatory submissions for registration of LUMEVOQ®
- Discussions ongoing on strategic options, including M&A and out-licensing

Paris, France, April 4, 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 March 31, 2024 and provided a business update.

"*We are currently fully engaged in active discussions to secure funding for our operations until the resumption of our early access program, whose supply is our main immediate-term priority,*" commented Laurence Rodriguez, CEO of GenSight Biologics. "*Simultaneously, we are actively working on refining the design of the RECOVER PIII study, in order to both fulfil regulatory requirements and support marketing authorization in both the United States and Europe.*"

Cash position as of March 31, 2024

GenSight Biologics' cash and cash equivalents totalled €2.2 million as of March 31, 2024, compared to €2.1 million as of December 31, 2023.

The Company completed a successful offering in February 2024 for a total gross amount of €5 million and has continued to work on cash preservation measures, notably additional savings and obtaining waivers from existing creditors[1].

The Company does not have sufficient net working capital to meet its obligations over the next 12 months but only until end of April 2024.

The Company is currently engaged in active discussions to secure financing for its activities from the end of April 2024 to Q3 2024, when the early access program in France (AAC - *autorisation d'accès compassionnel*, formerly known as ATU - *autorisation temporaire d'utilisation*) is expected to resume. Once the AAC/AAP program resumes, the Company estimates that the cash runway would be extended to the end of Q1 2025.

The net funding requirement for the next 12 months is estimated at €9 million (including the anticipated income from the resumption of the AAC/AAP program in France in Q3 2024), in view of the Company's need to finance its ongoing activities.

[1] https://www.gensight-biologics.com/2024/02/08/gensight-biologics-announces-completion-of-a-e5-million-capital-increase-with-sofinnova-partners-invus-upmc-enterprises-and-heights-capital/

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.

Business update

GenSight successfully manufactured two Drug Substance (DS) batches of LUMEVOQ® meeting Good Manufacturing Practice (GMP) standards in September and November 2023. To optimize vial availability for patients, the decision was made to mix these batches into one Drug Product (DP) batch, slated for release and inclusion in the EAP resumption in Q3 2024. In January 2024, GenSight received constructive feedback from the FDA regarding the design of the Phase III trial RECOVER, which had been previously shared with EMA (European Medicine Agency) and UK's MHRA (Medicines and Healthcare products Regulatory Agency).

The Company is currently refining the RECOVER study design to incorporate feedback from regulatory agencies prior to the launch of the study, in order to both fulfil regulatory requirements and then support both US and EU regulatory submissions for registration. Additional consultations with regulatory agencies may be necessary to finalize the study design.

RECOVER will be able to begin recruiting once the design is finalized; the product is released for human use; and approval is obtained from local competent authorities and ethics committees. With the Company prioritizing the allocation of the next available LUMEVOQ® vials to supply of the AAP/AAC program and considering the need of refining the RECOVER study design, the inclusion of the first patient in the trial is expected in H2 2025. The duration of the trial will depend on its final design currently being determined.

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

Starting Q3 2024, the Company expects to provide treatment to patients in France through the AAC program.

Number of outstanding shares

As of March 31, 2024, GenSight Biologics' number of outstanding shares was 78,370,724 ordinary shares.

Detailed information regarding the Company, including its business, financial information, results, perspectives and related risk factors are contained (i) in the Company's 2022 Universal Registration Document filed with the AMF on May 10, 2023 under number D.23-0406 (the "**2022 URD**"), and (ii) the amendment to the 2022 URD filed with the AMF on November 21, 2023 under number D.23-0406-A01 (the "**Amendment to the 2022 URD**"). These documents, 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). Your attention is drawn to the risk factors related to the Company and its activities presented in chapter 3 of its 2022 URD and in chapter 2 of the Amendment to the 2022 URD, in particular the liquidity risk presented in the chapter 2.2.1 of the Amendment to the 2022 URD.

Contacts

GenSight Biologics
Chief Financial Officer
Ivan Tortet
itortet@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, developed 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.