Press Release

GenSight Biologics Reports Cash Position as of December 31, 2022, FY 2022 Revenues and Provides Business Update

Paris, France, Thursday January 26, 2023, 7:30 am CET – GenSight Biologics (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, 2022, revenues for the full year 2022 and provided a business update.

"With both the €35 million conditional loan from the EIB and the €12 million premium convertible notes with Heights Capital, we have been able to secure important funding with minimal dilution for our shareholders, despite particularly challenging capital market conditions in 2022," said **Thomas Gidoin**, Chief Financial Officer of GenSight. *" With the EIB Tranche B expected in Q2, our cash runway would be extended from May 2023 to early 2024. We are now focusing our resources towards an expected commercial launch of LUMEVOQ in Europe by the end of the year."*

Cash position as of December 31, 2022

GenSight Biologics' cash and cash equivalents totalled €10.6 million as of December 31, 2022, compared to €13.9 million as of September 30, 2022.

The Company completed a €35 million conditional loan from the European Investment Bank (EIB) in October (press release), as well as a €12 million premium convertible notes with Heights Capital in December (press release).

Following the imminent request to draw down the €8.0 million Tranche A of the EIB loan as previously announced, and which is not included in the cash position as of December 31, 2022, the Company will have sufficient net working capital to meet its financial obligations until May 2023. With the addition of €12 million from the EIB Tranche B, expected in Q2 2023, the Company would extend its financial visibility to early 2024. The Company expects to seek other sources of debt or equity financing starting in 2023 to supplement its working capital needs and finance its operating expenses for 2024.

The operating cash burn in the last quarter of 2022 mainly reflected the final pharmaceutical development steps for LUMEVOQ® (lenadogene nolparvovec) to support the Marketing Authorisation Application currently being reviewed by the European Medicines Agency (EMA). These were mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) and notably the production of engineering and validation batches. In addition, the Company continued to follow patients over the long term in the REFLECT Phase III clinical trial of LUMEVOQ® in the treatment of Leber Hereditary Optic Neuropathy. GenSight Biologics also continued to build up its commercial infrastructure and prepare for a possible launch of LUMEVOQ® in Europe by the end of 2023.

In addition, the Company continued the PIONEER Phase I/II trial of GS030 in the treatment of Retinitis Pigmentosa.

Revenues for the Full Year of 2022

In 2022, the Company recorded revenues from the sale of LUMEVOQ® to supply a Temporary Authorization for Use ("*ATU nominative*", or ATU) granted by the French National Drug Safety Agency (Agence Nationale de Sécurité du Médicament or ANSM) in France amounting to €3.1 million. These revenues represent a single quarter of supply of ATUs in Q1 2022, as the stock of vials was fully used up by the end of March 2022, following manufacturing issues at the Company's partner. The Company expects to resume the supply for named patient use in France as AAC (*Autorisation d'Accès Compassionnel* or Compassionate use authorisation, previously ATU) in the second quarter of 2023 as soon as GenSight is able to supply the product.

Regulatory Pathway of LUMEVOQ®

As anticipated, GenSight received the D180 questions from the European Medicines Agency (EMA) in December 2022. The Company must now submit its responses in March 2023.

The Company anticipates the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA in Q3 2023. Commercial launch could follow by the end of 2023.

In parallel, GenSight continues to interact with the U.S. Food and Drug Administration (FDA) to secure a regulatory pathway in the United States and the design of a possible additional Phase III clinical trial.

Manufacturing of LUMEVOQ®

Following the successful production in September of two Engineering batches incorporating adjustments to the LUMEVOQ® manufacturing process, GenSight initiated in December the production of a GMP (Good Manufacturing Practices) batch, identical and under the same conditions as the validation campaign (3 consecutive PPQ batches) required to complete the registration of LUMEVOQ® in Europe. The results of this GMP production, whose products could be used to treat patients, and specifically the supply of AAC in France, are expected at the end of Q1 2023. In parallel, the Company is due to launch the validation campaign in Q1 2023, with results expected in Q2 2023.

Number of outstanding shares

As of December 31, 2022, GenSight Biologics' number of outstanding shares was 46,335,591 ordinary shares.

GenSight Biologics will soon release its financial calendar for 2023.

Contacts

GenSight Biologics
Corporate Communications Director
Clothilde Caillet
ccaillet@gensight-biologics.com

RooneyPartners
Media Relations
Jeanene Timberlake
jtimberlake@rooneypartners.com
+1 646-770-8858

LifeSci Advisors
Investor Relations

Orpheon Finance
Retail Investors

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

James Palmer
j.palmer@orpheonfinance.com
+33 (0)7 60 92 77 74

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.