Press Release

GenSight Biologics Reports Cash Position as of September 30, 2023, and Provides Business Update

- Current cash runway to mid-November 2023; August financing's 2nd tranche for €4m conditioned notably to 2nd batch successful manufacturing expected early November
- New RECOVER Phase III trial design endorsed overall by the EMA; trial expected to start in Q2 2024
- Successful 1st GMP batch manufactured in September; 2nd batch ongoing with results expected early November 2023
- Discussions on further financing and strategic options including M&A ongoing

Paris, France, Thursday October 26, 2023, 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, 2023, and provided a business update.

Cash position as of September 30, 2023

GenSight Biologics' cash and cash equivalents totalled €2.4 million as of September 30, 2023, compared to €1.0 million as of June 30, 2023.

In August 2023, GenSight Biologics signed a €10 million bridge financing with Sofinnova Partners, Invus and UPMC Enterprises[1] (the "**Bridge Financing**"), and drew down the first tranche of €6 million in the form of convertible bonds with a conversion price of 0.7122 euros (the "**Convertible Bonds 2023**").

In connection with the drawdown of this first tranche and following discussions in the recent weeks, GenSight Biologics has obtained from its existing creditors, subject to certain conditions:

- a waiver by the BNP Paribas, CIC, Bpifrance (together, the "**Banks**"), the European Investment Bank ("**EIB**") and Heights on any provision which could trigger early repayment of their debt until January 31, 2024;
- an agreement of the EIB and Heights on the *pari passu* treatment of the Convertible Bonds 2023 with the convertible bonds issued in 2022 to Heights (the "**Convertible Bonds 2022**");
- a deferral of principal payments due to the Banks until January 31, 2024;
- the suspension of Heights' conversion rights with respect to the Convertible Bonds 2022 until January 31, 2024;
- deferral of principal payments due to Heights in connection with the redemption of the Convertible Bonds 2022 until January 31, 2024[2]; and

[1] https://www.gensight-biologics.com/2023/08/03/gensight-biologics-obtains-funding-of-e10-million-from-sofinnova-partners-invus-and-upmc-enterprises/

[2] The conditions of the waiver from Heights (in particular the modification of the price limit and the insertion of additional amortization rights in the terms and conditions of the Convertible Bonds 2022) are described in the press release dated August 3rd, 2023:

- a waiver by the EIB of any adjustment right it has under the subscription agreement relating to the warrants issued in the context of the facility agreement signed by GenSight Biologics and the EIB on December 22, 2022, and in particular the anti-dilution provision contained in this subscription agreement.

The Company has agreed with its existing creditors that the drawdown of the second tranche of the Bridge Financing shall occur at the latest on November 15, 2023.

The second tranche is conditioned to either the successful production of at least two successive GMP (Good Manufacturing Practice) batches of LUMEVOQ® or unanimous approval of the three investors. No guarantee can be given that the Company will satisfy the conditions precedent for the second tranche of the Bridge Financing.

Sofinnova Partners, Invus, UPMC Enterprises and the Company agreed to extend the deadline until November 15, 2023, for the satisfaction of the condition precedents for the drawdown of the second tranche of the Bridge Financing to allow for the second GMP batch to be completed.

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

As of today, the Company is financed through mid-November 2023. If the Company is not able to raise additional funds or achieve M&A opportunities in the short term, there is substantial doubt regarding its ability to continue as a going concern as indicated in the limited report of the auditors relating to the 2023 half-year financial statements of the Company[3]. The cash runway would be extended to December 2023 with the drawdown of the second tranche of the Bridge Financing for an amount of €4 million. Following the drawdown of the second tranche, GenSight Biologics need to seek other sources of debt or equity financing beyond December 2023 in order to supplement its working capital requirements and fund its operating expenses until the resumption of the early access program in France (*Autorisation d'Accès Compassionnel* or AAC) expected at the end of the first quarter of 2024.

Manufacturing Update

GenSight Biologics is planning to manufacture at least 3 GMP batches at commercial scale outside the context of a validation campaign[4], to generate more process data for a future Marketing Authorisation Application (MAA) submission, to provide more experience of the manufacturing process to the operating teams, and to fulfil the immediate requirement of supplying product for a possible new clinical trial and for the potential resumption of an early access program for patients in Q1 2024.

The manufacturing of these batches started as planned in August 2023, and successful results of the first drug substance batch were announced in September 2023[5]. A second batch is currently being manufactured. The results of the second batch are now expected early November 2023 instead of October 2023 initially. Assuming the 2nd batch is successfully manufactured with a vg titer within the required range, full quality control tests would then be undertaken on the two successful batches, potentially leading to full release of the drug product for human use in Q1 2024.

---

https://www.gensight-biologics.com/2023/08/03/gensight-biologics-obtains-funding-of-e10-million-from-sofinnova-partners-invus-and-upmc-enterprises/. Sofinnova Partners and Invus have undertaken to vote in favour of the modification of the terms and conditions of the Convertible Bonds 2022 that will be proposed at the next shareholders' general meeting.

[3] https://www.gensight-biologics.com/wp-content/uploads/2023/09/GENSIGHT_RFS_2023_VDEF.pdf.

[4] A validation campaign, or Process Performance Qualification (PPQ) campaign, consists of at least 3 successful GMP (Good Manufacturing Practice, required standards for human use outside of a clinical trial) batches manufactured sequentially to demonstrate and document the robustness, control, consistency and reproducibility of the commercial manufacturing process at the designated commercial facility. This exercise is required only as part of a Marketing Authorisation Application with the EMA and a Biologics License Application (BLA) with the FDA.

[5] https://www.gensight-biologics.com/2023/09/18/gensight-biologics-announces-successful-manufacture-of-lumevoq-gmp-batch/

Regulatory Update

In July 2023, GenSight Biologics requested scientific advice from the European Medicines Agency (EMA) to discuss a new regulatory pathway for LUMEVOQ® in Europe, including the potential need for generating additional clinical data. The EMA provided its feedback in September[6] regarding the design of a new Phase III trial for LUMEVOQ®.

The new study, which will be called RECOVER, will be a randomized controlled trial with a two-arm design: a sham control arm, in which a sham procedure mimics an injection into each eye but no substance is injected into the eye, and a treatment arm, in which subjects will be given bilateral intravitreal injections of LUMEVOQ® (also known as GS010). The proposed study design also contains an open-label extension, in which subjects in the sham arm will be eligible to receive LUMEVOQ® bilateral injection if the primary endpoint is met.

The RECOVER study is designed to address the questions raised by the EMA's Committee for Advanced Therapies (CAT) when it reviewed the MAA filed in 2020. The Company decided to withdraw its application in April 2023 to be able to discuss EMA's concerns more fully. RECOVER will be able to begin recruiting once the design is finalized; the product is manufactured and released for human use; and approval is obtained from local competent authorities and ethics committees. GenSight Biologics expects to initiate the study in Q2 2024 and to have it completed by H2 2026, provided that the Company obtains the means to finance it.

GenSight also plans to share key aspects of RECOVER's design with other regulatory authorities such as the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and the U.S. Food and Drug Administration (FDA). An initial discussion with the MHRA is scheduled to take place in November 2023. The Company plans to engage with the FDA in the coming months, so that RECOVER results will be accepted by all major regulatory authorities.

Update on the PIONEER Phase I/II clinical trial of GS030

The clinical batch used to treat patients affected with Retinitis Pigmentosa in the PIONEER Phase I/II clinical trial of GS030 has now reached the end of its current shelf-life extension. The recruitment of the extension cohort has therefore been paused. Only one patient out of the planned 3 has been included in the extension cohort. GenSight Biologics will explore ways to supply the clinical trial and reopen the recruitment. The initiation of a possible Phase III trial of GS030 in the treatment of Retinitis Pigmentosa is still expected in 2026.

Number of outstanding shares

As of September 30, 2023, GenSight Biologics' number of outstanding shares was 46,335,591 ordinary shares.

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

6 https://www.gensight-biologics.com/2023/09/27/gensight-biologics-provides-update-on-european-medicines-agency-scientific-advice-for-lumevoq/

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.