Press Release

# GenSight Biologics Provides Financial and Operational Update

- Cash runway extended to end of July 2023 to pursue financing ongoing advanced discussions with a limited number of existing and new investors
- Operating cash burn significantly reduced going forward to limit financing needs in 2024
- Manufacturing of 3 GMP batches to start early August; results expected through September and October
- Scientific Advice meeting with EMA confirmed end of September
- Ongoing discussions on strategic options including potential M&A opportunities
- Reporting of Interim Financial Statements as of June 30 postponed to September 15, 2023

**Paris, France, Thursday July 20, 2023, 7:30 am CEST** – 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 provides an update on its financial and operational situation.

**Financial Update**

In the past two months, GenSight has instituted cash preservation measures, including a 40% headcount reduction mainly in Commercial teams, leading to a significant reduction equalling approximately 40% of its planned operating expenses in 2023. The Company was also able to retrieve its 2022 Research Tax Credit amounting to €2.2 million in July 2023, much faster than in normal operating conditions where it is usually received towards the end of the year. These measures have contributed to an extension of the cash runway from June to the end of July 2023, allowing the Company to advance discussions on a financing with a limited number of existing shareholders and new investors.

This significant reduction of cash burn will mostly benefit 2024 and the following years until the Company can reach European Medicines Agency (EMA) approval and launch LUMEVOQ® in Europe.

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

**Manufacturing Update**.

GenSight has continued to work closely with its Manufacturing Partner in the United-States to improve documentation, training and supervision of operating teams ahead of a new manufacturing campaign.

Given the decision to withdraw its EMA application, there is no immediate need for a validation (PPQ) campaign until a new Marketing Authorisation Application (MAA) is submitted. Consequently, the Company decided to manufacture 3 GMP batches as planned, using the commercial process but outside the context of a validation campaign[1], to generate more batch data for a future MAA filing and provide more experience with the manufacturing process to operating teams, while fulfilling the immediate requirement of supplying product for a possible new clinical trial and for the resumption of an early access program for patients in Q1 2024.

GenSight expects to start the manufacturing of these 3 GMP batches early August, with results through September and October 2023. The product would be fully released for human use in Q1 2024.

**Regulatory Update**

As planned, GenSight requested a Scientific Advice meeting with the EMA to discuss a new regulatory pathway for LUMEVOQ® in Europe, including the potential need for generating additional clinical data. This meeting is confirmed to take place end of September, with minutes expected end of October.

**Financial Calendar Update**

Given the particular context in July, the Company decided to postpone the approval by the Board of directors and subsequent reporting of its Interim Financial Statements as of June 30, 2023, initially planned on July 26, to September 15, 2023.

As a result, a quarterly update of the Company's cash position will be provided on August 3, 2023.

The rest of the previously announced financial calendar remains unchanged.

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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, 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.

[1] A validation campaign, or Process Performance Qualification (PPQ) campaign, consists of manufacturing at least 3 successful GMP (Good Manufacturing Practices, required standards for human use) batches 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 as part of a Marketing Authorisation Application both with the EMA and FDA.