Press Release

GenSight Biologics Provides Business and Financial Update

- A Scientific Advice confirms UK MHRA could accept a marketing authorisation application for LUMEVOQ® with the most recent clinical data from existing trials (not necessarily including RECOVER data)
- GenSight plans to file an application for a marketing authorisation in the UK in H2 2024, aiming for a possible decision by H2 2025
- Decision to mix the two successful Drug Substance batches into one single Drug Product batch to optimise the number of available vials for patients; product now expected to be fully released in Q3 2024 (vs early Q2 2024 previously)
- Extended cash runway to mid-February 2024; ongoing discussions to bridge AAC resumption in France in Q3 2024; estimated need amounting to €14 million

Paris, France, Wednesday December 27, 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 provides an update on its regulatory strategy in the United Kingdom, the possible resumption of early access ("*Autorisation d'Accès Compassionnel*" or AAC) in France and its financial situation.

"*We are grateful to the MHRA experts for their thoughtful in-depth consideration of the massive amount of clinical and experimental data generated over the past many years*," commented **Pr. José-Alain Sahel**, Co-founder of GenSight, Distinguished professor and Chairman of Ophthalmology at the University of Pittsburgh School of Medicine (US), Founding Director of the *Institut de la Vision*, Paris (France). "*It is reheartening to feel hopeful that patients affected with this blinding disease will possibly access the life-changing medicine developed by the teams at the Paris Vision Institute and the GenSight teams over close to twenty years and especially the past decade*."

Regulatory Update

A Scientific Advice meeting with the UK *Medicines and Healthcare products Regulatory Agency* (MHRA) took place in November 2023 to discuss the conditions for accepting a marketing authorisation application in the United Kingdom.

Based on the clinical data presented, MHRA experts issued a letter dated December 19, 2023, which states that "*the package proposed by the Company appears comprehensive*" and could support a marketing authorisation application in the UK not necessarily including data from the upcoming RECOVER trial.

This application is expected to be filed during the second half of 2024 and could be eligible for a rolling review. This initial application would not include data from the RECOVER trial that would later complete the dossier.

GenSight very positively welcomes this first step towards a possible commercialisation in the United Kingdom in 2025.

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 mandatory retainers for archives and samples for quality controls and in order to maximise the number of available vials for patients, the Company decided to mix the two manufactured DS into one single Drug Product (DP) batch. Through this operation, the total number of vials will increase while the number of vials used for retainers and controls will remain the same, hence increasing the number of potential vials available for patients. This helps to ensure that the Company will be able to supply LUMEVOQ® for patients treated under AAC in France until more batches are manufactured. Pending the completion of this mixing operation, the new DP batch is now expected to be fully released by Q3 2024, vs early Q2 2024 initially.

Financial Update

Since the €4.7 million offering announced in November, GenSight continued to work on cash preservation measures, notably additional savings and other means to optimise short-term cash management, extending the cash runway from mid-January to mid-February 2024. These new measures also include several ongoing discussions with some business partners and creditors.

As a result of AAC in France now being expected to resume in Q3 2024, and including aforementioned cash preservation measures, the Company estimates it will require approximately €14 million to finance its activities until July 2024 (vs €10 million with AAC resumption previously expected early Q2 2024), after which revenues from AAC in France are expected to significantly contribute to extend the cash runway until 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.

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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.