Press Release

GenSight Biologics Provides Update on LUMEVOQ® Manufacturing Timeline

- Restart of PPQ campaign targeted for Q4 2022
- Scott Jeffers joins as new Chief Technical Officer overseeing manufacturing and supply chain operations

Paris, France, April 7, 2022, 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 announced a delay in the completion of the validation (PPQ) batches for LUMEVOQ®, the Company's gene therapy for the treatment of Leber Hereditary Optic Neuropathy (LHON). The delay is necessary to implement operational adjustments that will prevent the recurrence of issues with the latest PPQ campaign. The Company targets the restart of the campaign in Q4 2022.

The latest campaign, which was initiated after the Company addressed an equipment issue that caused the 2021 campaign to fail, generated drug substance whose viral genome titer fell below the acceptance threshold. Resulting investigations led by external experts have traced the outcome to operational difficulties in specific stages of the downstream process. To prevent the repeat of these issues, the Company is working with its manufacturing partner to implement targeted corrections around enhanced process control and more rigorous supervision inside the manufacturing suites. In addition, the Company has decided to manufacture smaller engineering lots to confirm the robustness of the corrective actions.

"*We understand the difficult position in which this may place LHON patients, so we are moving quickly but thoughtfully to act on the clear set of targeted corrections identified by our experts,*" explained **Bernard Gilly**, Chief Executive Officer and Co-Founder of GenSight Biologics. "*We are more determined than ever to get things right. By performing additional checks through the engineering runs, we will restart the PPQ campaign with extra confidence that the manufacturing process will be performed reliably and at the highest standard of execution."*

"In the meantime, our teams will be working with KOLs, treatment centers and local authorities to ensure that patients who are identified during this adjustment phase do receive treatment in due course," added Bernard Gilly. The supply of LUMEVOQ® vials available for compassionate use has been used up, so treatments can only resume in early 2023 when test results confirm the quality of the product from the new PPQ campaign. *"We are steadfastly committed to providing LHON patients access to our innovative therapy as soon as possible.*"

Leading the effort to secure a more robust PPQ campaign will be the Company's new Chief Technical Officer, **Scott Jeffers**, who will assume the responsibilities of the former Vice President of Pharmaceutical Operations. Scott joins GenSight with extensive experience exercising senior executive responsibilities over CMC operations in various pharmaceutical companies as well as contract manufacturing companies.

"*I am excited to lead GenSight's drive to enhance the executability of its established manufacturing process*," commented Scott Jeffers. "*Manufacturing AAV vectors is, in general, a relatively well-known process, but there are specificities for LUMEVOQ that need to be taken into account. The additional time we have built into the corrections will secure the impact and success of our action plan.*"

Scott will be supported by **Jay Stout**, a leading expert and consultant on biologics, cell and gene therapy manufacturing and supply chain. Both based in the USA, they will be able to collaborate intensively with the Company's manufacturing partner at the site where LUMEVOQ® manufacturing operations are conducted.

GenSight has initiated discussion of the new manufacturing timeline with the European Medicines Agency, while finalizing all Day 120 responses not related to the manufacturing of the PPQ batches. The Company will provide an update as soon as the Agency has given its feedback.

GenSight's management team will host a live webcast today, **Thursday, April 7, 2022,** to discuss the manufacturing plan**.** The webcast will be in English, and a simultaneous French translation will also be available.

Thursday April 7, 2022
8:00 EDT / 2:00 pm CEST

Live webcast in **English**: https://bit.ly/3ugqMcZ
Simultaneous **French** translation: https://bit.ly/3jdSuk2

The webcast will be available as recordings using the same links used to access the live webcast.

GenSight Biologics will report its 2021 Financial Results on April 8, 2022.

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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), has been submitted for marketing approval in Europe 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.

About LUMEVOQ® (GS010; lenadogene nolparvovec)

LUMEVOQ® (GS010; lenadogene nolparvovec) targets Leber Hereditary Optic Neuropathy (LHON) by leveraging a mitochondrial targeting sequence (MTS) proprietary technology platform, arising from research conducted at the Institut de la Vision in Paris, which, when associated with the gene of interest, allows the platform to specifically address defects inside the mitochondria using an AAV vector (Adeno-Associated Virus). The gene of interest is transferred into the cell to be expressed and produces the functional protein, which will then be shuttled to the mitochondria through specific nucleotidic sequences in order to restore the missing or deficient mitochondrial function. “LUMEVOQ” was accepted as the invented name for GS010 (lenadogene nolparvovec) by the European Medicines Agency (EMA) in October 2018.