Press Release

GenSight Biologics Provides Update on Manufacturing Timeline Needed for LUMEVOQ® Regulatory Filing

Paris, France, November 4, 2021, 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 announced that three validation batches have been produced as required for LUMEVOQ®'s Marketing Authorisation Application in Europe. The batches have performed as expected, with consistency between runs. However, a technical issue in a final step of the downstream process will require the Company to repeat these validation batches. Root cause investigations have assessed the technical issue as related to operational conditions and not at all to the intrinsic design of the manufacturing process.

"*This unexpected situation leads to a delay in bringing our promising therapy to patients*," commented **Bernard Gilly**, Co-Founder and Chief Executive Officer of GenSight Biologics. "*But we are buoyed by the finding that the root cause is not related to the manufacturing process itself. With corrective actions now in place, we are determined to resume full-speed in December. We are confident that our successes to date – productive collaboration with the EMA, demonstration of therapeutic benefit, evidence of outstanding safety, and achievement of ATU status – will culminate in regulatory approval.*"

GenSight Biologics and its manufacturing partner have agreed to resume production by December 2021. The new timeline will allow the Company to generate the manufacturing data required for the D120 responses for the European Medicines Agency (EMA) review. Responses in the other areas of the dossier (non-clinical, clinical and pharmacovigilance) are on track based on the original schedule of the D120 clock stop, which was to resume in January 2022.

As a result of the new manufacturing timeline, the Company has requested a 9-month extension to the current D120 clock stop from the Committee for Advanced Therapies (CAT) of the EMA. The request will be discussed in the committee's meeting scheduled November 3-5, 2021. The Company will provide an update as soon as the feedback from the Agency is known.

GenSight's management team will host two webcasts on **Thursday, November 4, 2021.**

- In French at **9:00 am CET**
- In English at **8:00 a.m. EST (1:00 pm CET)**

The webcasts will be available as recordings using the same links below.

Thursday November 4, 2021, 9:00 CET (French)
Webcast Link: https://bit.ly/3nU0fh8

Thursday November 4, 2021, 8:00 EST (13:00 CET) (English)
Webcast Link: https://bit.ly/3GRhI7R

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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.