Press Release

GenSight Biologics Announces Extension of Day 120 Clock Stop of LUMEVOQ® EMA Regulatory Filing; MAA Review to Resume in April 2022

Paris, France, November 15, 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 it has reached an agreement with the Committee for Advanced Therapies (CAT) of the European Medicines Agency (EMA) to extend by 3 months the Day 120 clock stop during the review of the LUMEVOQ® Marketing Authorisation Application (MAA). The procedure will resume in April 2022 when the Company files its D120 responses, which will include batch data for three new validation batches. GenSight Biologics will provide the stability data for the new batches at the next (Day 180) clock stop.

"*This is an excellent, pragmatic solution to the unexpected issue we encountered with the validation batches,*" commented **Bernard Gilly**, Co-Founder and Chief Executive Officer of GenSight Biologics. "*We are thankful for the continuing support and flexibility of the European authorities as we work to bring the regulatory review of LUMEVOQ to a speedy and successful conclusion.*"

GenSight Biologics had requested an extension of 9 months to allow the Company time to submit all required batch and stability data after the three validation batches for LUMEVOQ® suffered from the same unanticipated technical issue in the final tangential flow filtration (TFF) step. The issue, which subsequent investigations traced to the use of a ready-to-process version of the TFF filter used in previous manufacturing runs for improved manufacturing efficiency, caused a significant reduction in the amount of viral vectors in all three validation batches. The batches otherwise performed as expected, with consistency between runs, confirming the soundness of the manufacturing process itself.

The Company and its manufacturing partner have agreed to revert to the original version of the filter, which had not caused a similar issue in any of the previous runs. Manufacturing will restart in December 2021.

While the manufacturing of the new validation batches proceeds, GenSight Biologics will be able to use existing stock to satisfy compassionate use requests covered by the Temporary Authorization for Use (ATU) program in France. The Company now expects the review of the Committee for Medicinal Products for Human Use (CHMP) to be completed by the end of 2022 and anticipates the commercial launch of LUMEVOQ® in the first half of 2023.

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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.