Press Release

GenSight Biologics Confirms 2nd Successful GMP Batch of LUMEVOQ® and Eligibility to Draw Down Bridge Financing 2nd Tranche of €4 million

- Following preliminary results reported on November 13, 2023, an independent laboratory confirms vg titer and success of the second GMP batch of LUMEVOQ® drug substance (DS)
- Confirmation triggers eligibility to draw down second tranche of bridge financing signed in August with Sofinnova Partners, Invus and UPMC Enterprises

Paris, France, November 15, 2023, 5:45 pm 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 an independent laboratory confirmed the vg titer from the second drug substance (DS) batch of LUMEVOQ® manufactured under conditions compliant with Good Manufacturing Practice (GMP) standards.

"*The two successful GMP batches confirm the robustness of our manufacturing process and exemplify the fantastic work achieved by our team with our manufacturing partner in the past 12 months*," commented **Bernard Gilly**, Chief Executive Officer and Co-Founder of GenSight Biologics. "*These successes boost our confidence that we can proceed to a successful PPQ campaign[1] in 2024.*"

As a result from the confirmation, the Company became eligible to draw down the second tranche of the bridge financing signed in August 2023 with Sofinnova Partners, Invus and UPMC Enterprises (the "**Bridge Financing**"). The drawdown of the second tranche will also trigger the automatic conversion of the convertible bonds from the €6 million first tranche at a conversion price of 0.7122 euros.

This second tranche, amounting to €4 million, will extend the Company's cash runway to mid-December 2023.

GenSight Biologics needs to seek other sources of debt, other non-dilutive or equity financing in order to supplement its working capital requirements and fund its operating expenses beyond that date and until the resumption of the early access program in France (*Autorisation d'Accès Compassionnel* or AAC) expected in the beginning of the second quarter of 2024. GenSight Biologics estimates that, in addition to the second tranche of the Bridge Financing, it will need approximately €10 million to finance its activities until that date.

Contacts

GenSight Biologics | **LifeSci Advisors**

[1] A validation campaign, or Process Performance Qualification (PPQ) campaign, consists of at least 3 successful GMP (Good Manufacturing Practice, required standards for human use outside of a clinical trial) batches manufactured 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 only as part of a Marketing Authorisation Application with the EMA and a Biologics License Application (BLA) with the FDA.

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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; a marketing authorization application is currently under review by the EMA 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. LUMEVOQ® (GS010; lenadogene nolparvovec), is an investigational compound and has not been registered in any country at this stage.