Press Release

GenSight Biologics Reports Cash Position as of March 31, 2021 and Provides Operational Update

Paris, France, April 20, 2021, 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 reported its cash position as of March 31, 2021, and provided an operational update.

"We enter the final stretch of LUMEVOQ's registration phase in a very strong financial position," commented **Bernard Gilly**, Chief Executive Officer of GenSight Biologics. "*This allows us to approach the coming commercial launch of LUMEVOQ in Europe with confidence while pushing forward in the US and accelerating our GS030 clinical development."*

Cash position and financing runway

GenSight Biologics' cash and cash equivalents totaled €61.1 million as of March 31, 2021, compared to €37.9 million as of December 31, 2020.

The operating cash burn in the first quarter of 2021 mainly reflects the conduct of the REFLECT Phase III clinical trial of LUMEVOQ® in the treatment of Leber Hereditary Optic Neuropathy, as well as the PIONEER Phase I/II trial of GS030 in the treatment of Retinitis Pigmentosa. The Company also focused on the final pharmaceutical development steps for LUMEVOQ® in preparation for the European marketing authorization expected in Q4 2021. These were mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP).

The operating cash burn was more than offset by the net proceeds from the oversubscribed €30 million private placement in March.

The Company also recorded revenues from the sale of LUMEVOQ® under a Temporary Authorization for Use (ATU) in France amounting to €3.9 million in the first quarter of 2021 compared to €0.7 million in the first quarter of 2020 and a total of €4.4 million in 2020.[1]

"With a successful oversubscribed €30 million private placement in March, in addition to revenues generated by ATUs in France, we have now extended the runway to at least Q2 2023," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"We continue to concentrate on transitioning GenSight Biologics into a commercial company ahead of LUMEVOQ's launch in Europe expected early next year."*

Temporary Authorization for Use (ATU) of LUMEVOQ®

Additional patients were treated with LUMEVOQ® in the first quarter under a Temporary Authorization for Use (ATU) granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM). Additional ATUs have been requested by the CHNO of the Quinze-Vingts in Paris.

[1] The Company elected to account for a variable consideration in accordance with IFRS15 to reflect the uncertainty of the actual net commercial price that will be obtained after negotiation with the French public payer. Any difference with the initial ATU price would then have to be repaid. The variable consideration is assessed by using an expected value method based on a range of probability-weighted net prices and discounted at market rate. Further detail is provided in sections 7 and 18 of the 2020 Universal Registration Document.

GenSight Biologics has committed to providing the drug, limited to available stock. Bilateral injections are priced at €700,000 per patient and are expected to generate revenues prior to regulatory approval and reimbursement in France.

In addition, the Company has submitted to the ANSM an application for a cohort ATU to further facilitate access to LUMEVOQ® for patients in France and in Europe. The application is being reviewed and patients can benefit from nominative ATUs in the meantime.

LUMEVOQ® Marketing Authorisation Application to European Medicines Agency (EMA)

GenSight Biologics submitted the Marketing Authorisation Application (MAA) for LUMEVOQ® to the European Medicines Agency (EMA) in September 2020 as planned, seeking approval for the treatment of patients with vision loss due to Leber Hereditary Optic Neuropathy (LHON) caused by mutation in the *ND4* mitochondrial gene. The dossier was validated, and the review procedure officially started on October 29, 2020.

As expected and in accordance with the EMA Marketing Authorisation Application procedure, GenSight Biologics received a list of questions from the Agency at Day 120 of the review procedure, stopping it for an initial 3-month period, possibly renewable for an additional 3 months following agreement with the Agency, for the Company to reply. None of these questions were unexpected, and the Company is fully committed to provide a timely and detailed response to the EMA. Based on the questions received, GenSight Biologics continues to expect LUMEVOQ® to receive an opinion from the EMA in Q4 2021.

REFLECT Phase III clinical trial of LUMEVOQ®

The REFLECT Phase III clinical trial, designed to assess the efficacy and safety of a bilateral injection of LUMEVOQ® in subjects affected by Leber Hereditary Optic Neuropathy (LHON) due to a mutation in the *ND4* gene, is still expected to read out at 78 weeks in June 2021.

PIONEER Phase I/II clinical trial of GS030

The first-in-human PIONEER Phase I/II clinical trial, designed to assess the safety and tolerability of GS030 leveraging optogenetics by combining a gene therapy and an optronic stimulation device in patients with late-stage retinitis pigmentosa, is expected to complete recruitment of the extension cohort by the end of the year. The Company expects to report early findings shortly in the second quarter of 2021 and more preliminary results later in the second half of the year.

Number of outstanding shares

As of March 31, 2021, GenSight Biologics' number of outstanding shares was 45,977,277 ordinary shares.

GenSight Biologics will report its interim financial statements and cash position as of June 30, 2021 on July 29, 2021.

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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. 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. Developed as a treatment for Leber Hereditary Optic Neuropathy (LHON), GenSight Biologics' lead product candidate, LUMEVOQ® (GS010; lenadogene nolparvovec), is currently in the review phase of its registration process in Europe, and in Phase III to move forward to a BLA filing in the U.S.