Press Release

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

Paris, France, January 18, 2022, 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 reported its cash position as of December 31, 2021, and provided an operational update.

"Our work in 2021 driving the marketing approval process of LUMEVOQ and advancing the clinical development of GS030 has put us in a good position as we enter 2022," commented **Bernard Gilly**, Co-founder and Chief Executive Officer of GenSight Biologics. *"The trials for both therapies continue to generate positive data, and we keep on establishing solid organizational foundations for the commercial launch of LUMEVOQ in Europe. We are confident that GenSight will be ready for the next phase of its evolution as a leader in gene therapies."*

Cash position as of December 31, 2021

GenSight Biologics' cash and cash equivalents totaled €44.3 million as of December 31, 2021, compared to €49.1 million as of September 30, 2021.

The operating cash burn in the last quarter of 2021 mainly reflected the final pharmaceutical development steps for LUMEVOQ® supporting the Marketing Authorisation Application currently being reviewed by the European Medicines Agency (EMA). These were mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) and notably the production of validation batches. In addition, the Company continued to conduct the REFLECT and RESTORE (long-term follow-up of REVERSE and RESCUE patients) Phase III clinical trials 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.

"With a current runway to Q1 2023, we are focusing our resources in 2022 on strengthening the commercial organization for LUMEVOQ while advancing GS030 as a pioneering optogenetics treatment," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"We will continue to be opportunistic and seek optimal conditions to finance the commercial launch of LUMEVOQ early 2023."*

Temporary Authorization for Use (ATU) of LUMEVOQ® in France

More patients were granted early access to treatment with LUMEVOQ® in the last quarter of 2021 under a Temporary Authorization for Use (ATU) approved by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM). Some of these ATUs were requested and approved in Q4 2021, with patients scheduled for treatment in early 2022 at the CHNO of the *Quinze-Vingts* in Paris. Related revenues will therefore be recognized accordingly in Q1 2022.

In 2021, the Company recorded revenues from the sale of LUMEVOQ® under an ATU in France amounting to €5.3 million compared to €4.4 million in 2020, despite the COVID situation. The retroactive application as of July 1st, 2021, of mandatory discounts fixed by the new Decree on Early Access to Treatment in

France, as well as the periodic revision of the variable consideration in accordance with IFRS15, have more than offset revenues generated in the last quarter of 2021. [1] [2]

GenSight Biologics is committed to providing the drug, limited to available stock. Bilateral injections are priced at €700,000 per patient (excluding mandatory discounts and variable consideration in accordance with IFRS15) and are expected to generate revenues in France prior to regulatory approval and official reimbursement.

Update on LUMEVOQ® EMA Regulatory Procedure in Europe

Following a technical issue in the manufacturing of the validation batches of LUMEVOQ®, the EMA granted a 3-month extension to the Day 120 clock stop during the review of the LUMEVOQ® Marketing Authorisation Application (MAA), as announced on November 15, 2021. The procedure will resume in April 2022 when the Company files its D120 responses, which will include batch data for three new validation batches.

The production of these replacement batches restarted as planned in December 2021 at the Company's manufacturing partner in the US.

GenSight Biologics will provide the stability data for the new batches at the next (Day 180) clock stop.

Update on LUMEVOQ® FDA Regulatory Pathway in the United States

As planned, GenSight Biologics provided the U.S. Food and Drug Administration (FDA) with an update on the clinical data generated to date with LUMEVOQ®, including the indirect comparison to Natural History and the REFLECT data, in the context of a Type-C meeting held in December 2021.

The Agency provided feedback in January 2022 recommending that the Company conduct an additional placebo-controlled trial to bolster the demonstration of LUMEVOQ® efficacy in view of the unexpected bilateral effect observed in unilaterally treated patients in the RESCUE, REVERSE and REFLECT trials.

The Company is engaging with the FDA on the design of such a trial and aims to initiate it as soon as possible in 2022.

Number of outstanding shares

As of December 31, 2021, GenSight Biologics' number of outstanding shares was 46,300,591 ordinary shares.

GenSight Biologics will report its 2021 Financial Results on March 10, 2022.

[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.

[2] The Article 78 of the French Social Security Budget for 2021 (*"Loi de Financement de la Sécurité Sociale"*, or LFSS) came into force as of July 1st, 2021, following application of the Decree 2021-869 in France. The purpose was to reform and simplify the various existing protocols for early access to treatment. Temporary Authorizations for Use (*"Autorisations Temporaires d'Utilisation"*, or ATUs) are now replaced by Authorizations for Early Access (*"Autorisations d'Accès Précoce"*). One of the main changes impacting the Company's financial statements is the implementation of mandatory discounts set by law according to a progressive scale based on revenues.

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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.