

GenSight Biologics Reports Cash Position and Revenues as of March 31, 2022

- Sustained demand of LUMEVOQ® ATUs in France generating €3.1 million revenues in Q1 2022
- €36.0 million of cash as of March 31, 2022; runway confirmed to early Q1 2023

Paris, France, Thursday April 21, 2022, 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 and revenues as of March 31, 2022.

“The sustained demand for ATUs illustrates the confidence that the medical community has in LUMEVOQ and in the treatment benefits it brings to LHON patients. Additionally, the safety and efficacy data we have generated in our clinical trials remain impressive, and we continue to demonstrate the sustainability of these results even after long-term follow-up with patients,” commented **Bernard Gilly**, Co-founder and Chief Executive Officer of GenSight Biologics. *“The team at GenSight is working tirelessly to ensure that LUMEVOQ is reliably and consistently produced at the scale needed for the upcoming commercial launch. These measures are part of our commitment to providing LHON patients with access to our innovative treatment as soon as possible.”*

Cash position as of March 31, 2022

GenSight Biologics' cash and cash equivalents totaled €36.0 million as of March 31, 2022, compared to €44.3 million as of December 31, 2021.

The operating cash burn in the first quarter of 2022 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.

“Addressing our manufacturing challenges is our absolute priority in 2022, and this is where we will focus our efforts and resources in the coming months,” commented **Thomas Gidoïn**, Chief Financial Officer of GenSight Biologics. *“With a current cash runway to early Q1 2023, we are assessing several financing options, non or as little dilutive as possible, to ensure a successful European commercial launch of LUMEVOQ in 2023.”*

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

Additional patients were granted early access to treatment with LUMEVOQ® in the first quarter of 2022 under a Temporary Authorization for Use (ATU) approved by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM). LUMEVOQ® treatments will now only resume in early 2023 once PPQ batches become available.

In the first quarter of 2022, the Company recorded revenues from the sale of LUMEVOQ® under an ATU in France amounting to €3.1 million compared to €3.9 million in the same period in 2021. 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 in 2021 of the variable consideration in accordance with IFRS15, have reduced the net price that the Company is using for revenue recognition purposes^{1,2}. As a result, the recorded revenues were higher in Q1 2021 although the number of patients treated was the same over the same period in 2022.

Number of outstanding shares

As of March 31, 2022, GenSight Biologics' number of outstanding shares was 46,335,591 ordinary shares.

GenSight will hold its Annual General Meeting of Shareholders on May 25, 2022, at the Company's headquarters offices in Paris. The meeting will also be broadcast live on GenSight Biologics' website.

GenSight Biologics will report its interim financial statements and cash position as of June 30, 2022, on July 28, 2022.

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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.



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.