

GenSight Biologics Reports Cash Position as of March 31, 2020 and Provides Operational Update

Paris, France, April 21, 2020, 7.30 am CEST – GenSight Biologics (Euronext: SIGHT, ISIN: FR0013183985, PEA-PME eligible), a biopharma company focused on discovering and developing innovative gene therapies for retinal neurodegenerative diseases and central nervous system disorders, today reported its cash position as of March 31, 2020, and provided an operational update.

“Following our pre-submission meeting with the European Medicines Agency (EMA), we are confirming our intention to submit LUMEVOQ® for European approval in September 2020, as planned,” commented **Bernard Gilly**, co-founder and Chief Executive Officer of GenSight Biologics. *“We are eager to collaborate with the EMA’s review team in this last mile to possible approval and commercialization of LUMEVOQ® in Leber Hereditary Optic Neuropathy, the first asset developed from our leading Mitochondrial Targeting Sequence technology platform.”*

Cash position and financing runway

GenSight Biologics’ cash and cash equivalents totaled €12.8 million as of March 31, 2020, compared to €19.2 million as of December 31, 2019.

The cash burn in the first quarter of 2020 principally reflects the conduct of all clinical trials of LUMEVOQ® (GS010) in the treatment of Leber Hereditary Optic Neuropathy, mainly the REFLECT Phase III trial, as well as the PIONEER Phase I/II trial of GS030 in the treatment of Retinitis Pigmentosa. The Company also focused on final steps of pharmaceutical development for LUMEVOQ® in preparation for a marketing authorization filing in Europe. These are mainly preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP).

The Company is financed until the end of 2020 and is investigating other financing options through debt or equity, focusing particularly on several non-dilutive financing initiatives promoted by the French government and Bpifrance in addition to existing commitments from Kreos Capital for up to €6 million. The Company also expects the reimbursement in 2020 of the 2019 Research Tax Credit for an amount of €4.2 million.

“We are now actively working on extending our financing runway to 2021, primarily investigating non-dilutive opportunities,” commented **Thomas Gidoïn**, Chief Financial Officer of GenSight Biologics. *“The additional tranches from the bond issuance with Kreos Capital, together with potential revenues from the Temporary Authorization for Use of LUMEVOQ® in France, could also provide further resources and runway.”*

Temporary Authorization for Use (ATU) of LUMEVOQ®

A patient was treated with LUMEVOQ® under a first Temporary Authorization for Use (ATU) granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) in December 2019. A second patient was treated early 2020, and several additional ATUs have been requested and are being reviewed by the ANSM.

GenSight Biologics has committed to provide the drug for potential additional requests, limited to available stock. These bilateral injections are priced at €700,000 per patient and are expected to generate revenues in 2020. Hospitals focusing their resources on the current COVID-19 situation may delay requesting additional ATUs as well as the treatment of patients in the next few weeks. GenSight Biologics expects any delays to be overcome as soon as patients regain normal access to their treatment site, with no material impact on the related revenues expected in 2020; this will be more precisely assessed as soon as the situation improves.

In addition, the Company is discussing with the ANSM the possibility to broaden individual named patient ATUs to a cohort ATU as soon as feasible to further facilitate access to LUMEVOQ® for patients in Europe.

European Submission of LUMEVOQ® on track for September 2020

GenSight Biologics met with the EMA on March 19, 2020, at the pre-submission meeting for LUMEVOQ®. During this meeting, the EMA confirmed the information needed for the Company's September regulatory submission. The agency also provided updated guidance on various administrative topics, as well as advice on topics to be discussed in the meetings between the Company and the Rapporteurs and Co-rapporteurs planned for June 2020.

Based on this meeting with the EMA, GenSight Biologics confirmed its intention to submit the MAA for LUMEVOQ® in September 2020, as planned.

PIONEER Phase I/II clinical trial of GS030 – DSMB confirmed moving to maximal dose

The independent Data Safety Monitoring Board (DSMB) completed its second planned safety review of the ongoing PIONEER Phase I/II clinical trial of GS030, GenSight's novel product combining gene therapy and optogenetics for the treatment of Retinitis Pigmentosa. The DSMB confirmed the absence of any safety issues for the second cohort of three subjects who received the dose of 1.5e11 vg, and recommended moving forward as planned without any modification in the protocol and recruiting the third cohort of three subjects who are to receive the maximal dose of 5e11 vg.

Number of outstanding shares

As of March 31, 2020, GenSight Biologics' number of outstanding shares was 32,827,362 ordinary shares.

GenSight Biologics will report its interim financial statements and cash position as of June 30, 2020 on July 30, 2020.

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About GenSight Biologics

GenSight Biologics S.A. is a clinical-stage biopharma company focused on discovering and developing 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 in Phase III trials in Leber Hereditary Optic Neuropathy (LHON), a rare mitochondrial disease that leads to irreversible blindness in teens and young adults. Using its gene therapy-based approach, GenSight Biologics' product candidates are designed to be administered in a single treatment to the eye by intravitreal injection to offer patients a sustainable functional visual recovery.