Press Release

GenSight Biologics Reports its Cash Position as of December 31, 2019 and Provides Operational Update

Paris, France, January 21, 2020, 7.30 am CET – 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 December 31, 2019, and provided operational updates.

"The Temporary Authorization for Use (ATUs) recently implemented in France demonstrates physicians' confidence in the efficacy and safety of LUMEVOQ™ in LHON patients," commented **Bernard Gilly**, co-founder and Chief Executive Officer of GenSight Biologics. *"Results from REVERSE and RESCUE, showing a clinically significant and durable bilateral improvement of vision, demonstrating clear superiority to natural history, together with mechanistic explanations of bilateral visual improvement, form a solid basis for our marketing authorization application in Europe planned in the 3rd quarter this year."*

Cash position and financing runway

GenSight Biologics' cash and cash equivalents totaled €19.2 million as of December 31, 2019, compared to €5.1 million as of September 30, 2019.

The cash burn in the last quarter of 2019 principally reflects the final steps of pharmaceutical development for LUMEVOQ™ (GS010) 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). These expenses were more than offset by the €4.3 million reimbursement of the 2018 Research Tax Credit, as well as the net proceeds from the bond issuance and reserved capital increase completed in December 2019 amounting to €14.2 million.

"The successful financing operation completed at the end of 2019 with limited dilution extends our financing runway until the end of 2020," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"The additional tranches from the bond issuance, together with potential revenues from the Temporary Authorization for Use of LUMEVOQ™ in France, could further extend this runway to 2021."*

In accordance with the section "Working capital statement" of the press release dated December 20, 2019, the Company considers having sufficient net working capital to meet its obligations until the end of November 2020. As of the date of this press release, the lack of financial resources to fund all of the Company's activities in 2020 remains estimated at €1.3 million, notably relating to the active preparation for the launch of its LUMEVOQ™ product in Europe in 2021, if approved by regulatory authorities. In order to meet these obligations as of December 2020, and subject to the realization of a Qualifying Financing[1] of €10 million, the Company will be able to receive a second tranche of €4.0 million from the bond issuance with Kreos Capital. The Company will also explore other financing options through debt or equity in order to complete its working capital needs and to finance its operating expenses. In this respect, a third optional tranche of €2 million could be made available to the Company by Kreos Capital at a later date.

[1] **Qualifying Financing** means a financing of the Company in the form of equity (or Non-Dilutive Payment or subordinated convertible bonds, or a combination of the above) from existing shareholders and/or new top tier investors reasonably satisfactory to Kreos, with a minimal amount of gross proceeds of €10 million, being specified that such amount may be reduced, up to a maximal amount of €2 million, by the proceeds susceptible to be received by the Company under *Autorisations Temporaires d'Utilisation payantes*. In this definition, **Non-Dilutive Payment** means an upfront or milestone related payment under a licensing agreement.

Temporary Authorization for Use (ATU) of LUMEVOQ™

The French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM), granted in December 2019 a first named patient Temporary Authorization for Use ("*ATU nominative*") for LUMEVOQ™ (GS010) to the CHNO of the Quinze-Vingts. Dr Catherine Vignal, who as the prescribing physician originated the request, will be able to use LUMEVOQ™ to treat a patient recently affected by Leber Hereditary Optic Neuropathy (LHON).

In France, the use of pharmaceutical products not yet approved with a Marketing Authorization (AMM) and not recruiting for a clinical trial requires an ATU from the ANSM as a first step.

Named patient ATUs are granted by the ANSM under the following conditions:

- The product is meant to treat, prevent or diagnose a severe or rare disease,
- No other appropriate treatment is available in France,
- The product's efficacy and safety are presumed within the context of scientific knowledge, and that treatment cannot be delayed,
- The ATU is issued when the drug has the potential to benefit the patient and at the request and under the responsibility of the prescribing physician.

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.

Regulatory Pathway of LUMEVOQ™

In accordance with what had been previously communicated by the Company, an End of Phase II meeting with the U.S. Food and Drug Administration (FDA) was held on December 19, 2019 to present the full 96-week results from the REVERSE and RESCUE studies, as well as the results from the non-clinical study in monkeys aimed at explaining the mechanism of bilateral visual improvement observed in clinical studies. A next meeting is expected in the 2nd quarter of 2020 to discuss manufacturing and quality aspects with the agency, pending the results from the Phase III REFLECT trial, expected in the 1st quarter of 2021 and necessary for the submission of an application for marketing authorization in the United States.

GenSight Biologics is planning a pre-submission meeting with the European Medicines Agency (EMA) in early 2020 and expects to submit an application for marketing authorization (MAA) in Europe in the 3rd quarter of 2020.

Number of outstanding shares

As of December 31, 2019, GenSight Biologics' number of outstanding shares was 32,827,362 ordinary shares.

GenSight Biologics will report its cash position as of March 31, 2020 on April 21, 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), 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 each eye by intravitreal injection to offer patients a sustainable functional visual recovery.