Press Release

GenSight Biologics Reports Full Year 2020 Financial Results and provides an Outlook on 2021

- Operating loss significantly improved by reducing R&D expenses and generating revenues from LUMEVOQ® ATU in France
- Ramp up of Sales & Marketing in preparation of the expected commercial launch of LUMEVOQ® in Europe early 2022
- Successful refinancing in 2020 secures end of 2022 Q1 runway

Paris, France, March 10, 2021, 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 full year 2020 financial results and provided an outlook on 2021. Audit procedures on the Company's 2020 consolidated financial statements were completed by the Company's statutory auditors. Issuance of the audit report is now pending.

"Following the filing of the Marketing Authorisation Application of LUMEVOQ with the European Medicines Agency, our team remains focused on taking GenSight to its next chapter of growth and to turn the Company into a commercial organization. The European sales and marketing infrastructure is being established to be ready for commercial launch as early as the beginning of 2022. At the same time, we continue to prepare for the filing of the LUMEVOQ Biologics License Application with the U.S. Food and Drug Administration during the second half of 2021, anticipating data from the REFLECT US pivotal clinical trial in Q2 2021," commented **Bernard Gilly**, Co-founder and Chief Executive Officer of GenSight Biologics.

2020 Financial Results

In million euros	2019	2020
Operating income	4.9	7.4
Research and development expenses	(28.7)	(22.4)
Sales and marketing expenses	(0.8)	(2.0)
General and administrative expenses	(5.7)	(8.0)
Operating profit (loss)	(30.3)	(24.9)
Financial profit (loss)[1]	(0.6)	(9.1)
Net profit (loss)[1]	(30.9)	(34.0)
EPS (in € per share)[1]	(1.09)	(0.97)
Net cash flows from operating activities	(28.1)	(15.0)
Net cash flows from investing activities	(0.1)	(0.4)
Net cash flows from financing activities	21.2	33.9
Net cash flows	**(7.0)**	**18.4**

[1] Financial statements as of December 31, 2019 have been modified as a result of reassessing the Bond Financing agreement with Kreos in accordance with IFRS9. An additional financial expense of €158,000 was recorded over the period. Further detail will be provided in sections 7 and 18 of the 2020 Universal Registration Document.

Cash and cash equivalents at closing	**19.2**	**37.9**

"By reducing our operating cash burn by 46%, while successfully preparing for LUMEVOQ's commercial launch in Europe, and securing 34 million euros of financing in 2020, we are heading into 2021 on solid financial grounds," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"We are currently financed until the end of the first quarter of 2022 and will continue to be opportunistic and seek optimal conditions to finance the commercial launch of LUMEVOQ through 2022."*

The Company's **operating income** significantly increased by 51.5% to €7.4 million in 2020 from €4.9 million in 2019. This increase was primarily driven by revenues generated by LUMEVOQ® (GS010) through the named patient Temporary Authorization for Use ("*ATU nominative*") granted by the French National Drug Safety Agency (*Agence Nationale de Sécurité du Médicament* or ANSM) at a price of €700,000 per patient for a bilateral injection. These revenues amounted to €4.4 million[2] in 2020 compared to €0.7 million in 2019. The Company also generated research tax credit (*Crédit Impôt Recherche or CIR*), amounting to €2.8 million in 2020 compared to €4.2 million in 2019. The decrease in CIR was due to a reduction in R&D expenses in 2020 over 2019.

Research and development expenses were reduced 22.0% year-on-year to €22.4 million in 2020 compared to €28.7 million in 2019. This significant decrease was primarily driven by both RESCUE and REVERSE Phase III trials being completed, as well as the recruitment of the REFLECT Phase III trial ended, both in 2019. Although, we continued to invest in Chemistry, Manufacturing and Controls (CMC) activities to support the marketing authorisation application of LUMEVOQ® in Europe.

Sales and marketing expenses increased to €2.0 million in 2020 from €0.8 million in 2019 to reflect the ramp up of key strategic marketing and market access activities in preparation for the expected commercial launch of LUMEVOQ® in Europe in 2022.

General and administrative expenses increased to €8.0 million in 2020 compared to €5.7 million in 2019. This increase was mainly driven by non-cash share-based compensation expenses, in accordance with IFRS2, as well as the related accrued social contribution increasing over the period alongside the share price.

The Company's **operating loss** was reduced by 17.7% in 2020 amounting to €24.9 million compared to €30.3 million in 2019, both driven by the increase in revenues generated by ATUs of LUMEVOQ® in France and the reduction in research and development expenses over the period.

The **financial loss** in 2020 amounted to €9.1 million compared to €0.6 million in 2019. The amount in 2020 was essentially composed of the change in derivative financial instrument fair value of the convertible option and share warrants attached to the bond financing with Kreos between December 31, 2019 and 2020, which should be recognized in profit or loss in accordance with IFRS9. The related €7.4 million non-cash financial expense in 2020 was mainly driven by the share price increase over the period.

The Company's **net loss** in 2020 amounted to €34.0 million compared to €30.9 million in 2019. The average weighted number of shares increased to 35.1m in 2020 from 28.4m in 2019 leading the loss per share to decrease by 11.0% to €(0.97) in 2020 from €(1.09) in 2019. Excluding both share-based compensation (IFRS2) and financial Kreos-related (IFRS9) non-cash expenses, the **adjusted net loss** improved to €22.5 million in 2020 from €29.4 in 2019.

[2] While the Company reported gross revenues of €5.6 million on January 19, 2021, it since 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 will be provided in sections 7 and 18 of the 2020 Universal Registration Document.

Net cash flows from operating activities significantly improved over the period at €(15.0) million in 2020 compared to €(28.1) million a year earlier, primarily as a result of revenues generated by ATUs of LUMEVOQ® in France, the reduction in research and development expenses over the period, as well as a positive change in working capital in 2020.

Net cash flows from investment activities amounted to €(0.4) million in 2020 compared to €(0.1) million in 2019, mainly driven by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €33.9 million in 2020, reflecting the net proceeds from the private placement in October for €23.1 million, the state-guaranteed loan (*Prêt Garanti par l'État* or PGE) obtained for a total of €6.8 million, as well as the Tranche B of the bond financing from Kreos, for an amount of €3.9 million, compared to €21.2 million in 2019, reflecting the net proceeds from the private placement in February for €7.9 million, as well as Tranche A of the bond financing from Kreos and the private placement in December for €5.7 million and €8.3 million, respectively.

Cash and cash equivalents totaled €37.9 million as of December 31, 2020, compared to €18.1 million as of September 30, 2020. The amounts of expected future cash flows related to the reimbursement of our financial debts were €2.1 million at less than one year and €17.7 million at more than one year.

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 now 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 expected to read out at 78 weeks in the second quarter of 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 in the second quarter of 2021 and more preliminary results later in the second half of the year.

GenSight Biologics will host an earnings call today, March 10, 2021, at 9.30am CET in French, and at 2.00pm CET (8.00am ET) in English, to further discuss these results and upcoming news flow.

Webcast & Conference call in French (9.30am CET)
Dial-in numbers:
France: +33 (0)1 7037 7166
Password: GenSight
Webcast link: https://bit.ly/2Oeu6mA

Webcast & Conference call in English (2.00pm CET / 8.00am ET)
Dial-in numbers:
United States: +1 212 999 6659
France: +33 (0)1 7037 7166
United Kingdom: +44 (0)33 0551 0200
Password: GenSight
Webcast link: https://bit.ly/3enhDHO

A replay of the calls and webcasts will be available by using the above links.

GenSight Biologics will report its cash position as of March 31, 2021 on April 20, 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.