Press Release

GenSight Biologics Reports Full Year 2022 Consolidated Financial Results

- Efforts to reduce cash burn in 2023 while securing LUMEVOQ® manufacturing and preparing for commercial launch in Europe in H1 2024
- PPQ campaign to start early May 2023 with results expected in Q3 2023
- Cash runway confirmed to June 2023
- Advanced discussions on refinancing bridge with certain shareholders ongoing, targeted closing in coming weeks

Paris, France, March 24, 2023, 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 full year 2022 consolidated financial results, as approved by the Board of Directors on March 23, 2023. Audit procedures on the Company's 2022 consolidated financial statements were completed by the Company's statutory auditors. Final certification will take place after the completion of procedures required before the Universal Registration Document is filed with the French market authority (*Autorité des Marchés Financiers*).

"We are now focusing our efforts and resources on securing the upcoming LUMEVOQ validation campaign with our manufacturing partner in the US, while discussing a financing bridge with certain existing shareholders to extend the cash runway beyond the results of this campaign expected in Q3 2023," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"The combination of this financing bridge targeted to close in the coming weeks and the EIB Tranche B expected in Q3 upon the success of the validation campaign would extend our cash runway to the end of 2023."*

Annual Consolidated Financial Statements (IFRS) for the Year Ending December 31, 2022 and December 31, 2021

In million euros	2021	2022
Operating income	7.7	4.9
Research and development expenses	(22.9)	(19.3)
Sales and marketing expenses	(5.5)	(8.0)
General and administrative expenses	(7.4)	(5.4)
Operating profit (loss)	(28.1)	(27.8)
Financial profit (loss)	(0.5)	0.2
Net profit (loss)	(28.6)	(27.6)
EPS (in € per share)	(0.63)	(0.60)
Net cash flows from operating activities	(17.1)	(33.8)
Net cash flows from investing activities	(0.0)	0.2
Net cash flows from financing activities	23.7	0.1
Net cash flows	**6.6**	**(33.5)**
Cash and cash equivalents at closing	**44.3**	**10.6**

The Company's **operating income** reduced by 36.9% to €4.9 million in 2022 from €7.7 million in 2021. This decrease was essentially driven by a single quarter of revenues generated in 2022 by LUMEVOQ® in France through the supply of named patient Temporary Authorizations for Use ("*ATU nominative*"), compared to a full year of revenues generated in 2021, following manufacturing issues at the Company's partner leading to all available vials being used up in March 2022. These revenues amounted to €2.6 million[1] in 2022 compared to €5.3 million a year earlier. The Company expects to resume supply of AAC (*Autorisation d'Accès Compassionnel*, or Early Access Authorisation, former ATU) in France in Q4 2023 as soon as the product becomes available.

The Company also generated research tax credit (*Crédit d'Impôt Recherche* or CIR), amounting to €2.2 million in 2022 compared to €2.4 million in 2021. This evolution stems directly from the end of the clinical development of LUMEVOQ® towards its pre-commercialization phase for which expenses are not eligible to CIR.

Research and development expenses decreased by 15.6% year-on-year amounting to €19.3 million in 2022 compared to €22.9 million in 2021. While Phase III clinical trials of LUMEVOQ® – RESCUE, REVERSE and REFLECT – are now completed and patients entered long term follow-up, the Company maintains its efforts in Chemistry, Manufacturing and Controls (CMC) activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) and notably the production of validation batches as required to complete the Marketing Authorisation Application (MAA) of LUMEVOQ® in Europe.

The PIONEER Phase I/II Clinical trial for GS030 continued throughout 2022 showing a good safety profile and encouraging efficacy signals. The Company is now recruiting an extension cohort at the highest dose.

Sales and marketing expenses sharply increased by 45.3% over the period amounting to €8.0 million in 2022 from €5.5 million in 2021 reflecting the ramp up of key strategic marketing and market access activities in preparation for the expected commercial launch of LUMEVOQ® in Europe in H1 2024. The Company is also building its local presence in the main European countries, France, Germany, the United Kingdom, Italy and Spain by setting up local commercial affiliates.

General and administrative expenses significantly reduced by 27.7% year-on-year amounting to €5.4 million in 2022 compared to €7.4 million in 2021. This decrease was mainly driven by a reversal of share-based payment non-cash expenses, due to the cancellation of performance shares plans whose conditions were not met timely due to the manufacturing issues at the Company's partner in the United States. The entirety of plans granted in 2020 and 2021 to management were voided in 2021 and 2022.

This decrease was partially offset by a significant increase in professional fees, mainly legal fees in the context of financing transactions and strategic opportunities conducted in 2022, as well as communication fees related to corporate communication and investor relations efforts in 2022.

The Company's **operating loss** was stable in 2022 amounting to €27.8 million compared to €28.1 million in 2021. Excluding share-based compensation (IFRS2) non-cash expenses, the adjusted operating loss amounted to €31.2 million in 2022 compared to €23.3 in 2021.

The **financial profit** in 2022 amounted to €0.2 million compared to a loss of €(0.5) million in 2021. The amount in 2022 was essentially composed of a non-cash financial gain related to the change in derivative financial instrument fair value of the Kreos bond financing, fully repaid in December 2022. This financial

[1] €3.1 million initially reported in the Q4 2022 Press Release on January 26, 2023. The initial amount reported did not include the non-cash accretion of the variable consideration under IFRS15. This has no impact on the number of vials sold nor on cash received from the sales.

gain was offset by interest expenses attached to the Kreos bond and the state-guaranteed loan (*Prêt Garanti par l'État* or PGE) based on the effective interest rate.

The Company also recorded foreign exchange gains and losses primarily driven by the purchase of services denominated in U.S. dollars. The net foreign exchange result in 2022 was a gain of €0.6 million.

The Company's **net loss** in 2022 amounted to €27.6 million compared to €28.6 million in 2021. The average weighted number of shares increased to 46.3 million in 2022 from 45.2 million in 2021 leading the loss per share to decrease by 5.9% to €(0.60) in 2022 from €(0.63) in 2021. Excluding both share-based compensation (IFRS2) and financial Kreos-related (IFRS9) non-cash expenses, the adjusted net loss amounted to €32.7 million in 2022 compared to €24.0 in 2021.

Net cash flows from operating activities amounted to €(33.8) million in 2022 compared to €(17.1) million a year earlier, primarily as a result of a single quarter of revenues generated by LUMEVOQ® in France through ATUs in 2022, as well as building the commercial infrastructure and preparing for the launch of LUMEVOQ® in Europe in H1 2024.

The change was also derived from a significant increase in working capital, amounting to €4.8 million in 2022 compared to €(3.9) million in 2021. This significant change was due to increased prepaid expenses, mainly in manufacturing activities, and no trade receivables at closing in 2022.

Net cash flows from investment activities amounted to €0.2 million in 2022 compared to €(16) thousand in 2021, mainly driven by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €0.1 million in 2022, reflecting the net proceeds from the convertible note with Heights Capital in December for €10.8 million offset by the amortized repayment of the state-guaranteed loan (*Prêt Garanti par l'État* or PGE) for €3.6 million and the full repayment of the bond financing from Kreos for €4.2 million, as well as the payment of interest on these debts and related to IFRS16 standard application for €1.9 million, and the repayment of obligation under finance leases for €0.9 million.

In 2021, these financing activities amounted to €23.7 million in 2021, reflecting the net proceeds from the private placement in March for €28.1 million partially offset by the amortized repayment of the state-guaranteed loan (*Prêt Garanti par l'État* or PGE) and the bond financing from Kreos.

Cash and cash equivalents totaled €10.6 million as of December 31, 2022, compared to €44.3 million as of December 31, 2021. The amounts of expected future cash flows related to the reimbursement of our financial debts were €3.4 million at less than one year and €14.5 million at more than one year.

The Company has taken measures aimed at reducing its operating cash burn in 2023, thereby extending its current cash runway through June 2023, while actively discussing options with certain existing shareholders and financial partners with a view to bridge beyond the results of the validation campaign expected in Q3 2023, which in turn would trigger the €12 million Tranche B of the EIB loan and extend the Company's cash runway to the end of 2023.

GenSight Biologics will report its cash position as of March 31, 2023 on April 20, 2023.

Contacts

GenSight Biologics
Corporate Communications Director
Clothilde Caillet
ccaillet@gensight-biologics.com

RooneyPartners
Media Relations
Jeanene Timberlake
jtimberlake@rooneypartners.com
+1 646-770-8858

LifeSci Advisors
Investor Relations
Guillaume van Renterghem
gvanrenterghem@lifesciadvisors.com
+41 (0)76 735 01 31

Orpheon Finance
Retail Investors
James Palmer
j.palmer@orpheonfinance.com
+33 (0)7 60 92 77 74

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), is an investigational compound and has not been registered in any country at this stage; a marketing authorization application is currently under review by the EMA 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.