

GenSight Biologics Reports Interim Financial Results for the First Half of 2022

- Ramp up of sales & marketing actions and investments to drive commercial launch of LUMEVOQ® in Europe in 2023
- Cash runway confirmed to early Q1 2023
- Advanced discussions on refinancing close to completion

Paris, France, Thursday July 28, 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 interim financial results for the first half of 2022. The full interim financial report is available on the Company's website in the Investors section. The 2022 half-year financial statements were subject to a limited review by the Company's statutory auditors and approved by the Board of Directors on July 27, 2022.

"We continue to focus our efforts and resources in 2022 on addressing our manufacturing challenges while getting ready for the successful commercial launch of LUMEVOQ in 2023," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. "With a current cash runway to early Q1 2023, we have been assessing several financing options, non or as little dilutive as possible, over the past few months, and are now wrapping up discussions aiming at closing a transaction in favorable terms in the Fall."

2022 Half-Year Financial Results (IFRS)

In million euros	H1 2021	H1 2022
Revenues	5.6	3.1
Other income	1.3	1.2
Operating income	6.9	4.3
Research and development expenses	(8.0)	(9.9)
Sales, medical and marketing expenses	(2.3)	(4.0)
General and administrative expenses	(3.3)	(2.3)
Operating profit (loss)	(6.7)	(12.0)
Net income (loss)	(8.3)	(10.7)
EPS (in € per share)	(0.19)	(0.23)
Net cash flows from operating activities	(10.2)	(16.7)
Net cash flows from investment activities	0.2	0.1
Net cash flows from financing activities	26.4	(3.3)
Net cash flows	16.4	(19.9)
Cash and cash equivalents at closing	54.3	24.1

The Company's **operating income** decreased by 38.2% to €4.3 million from €6.9 million over the period. This decrease was essentially driven by a single quarter of revenues generated by LUMEVOQ[®] in France 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) in 2022, following manufacturing issues at the Company's partner leading to available vials being used up in March 2022. These revenues amounted to €3.1 million in the first half of 2022 compared to €5.6 million a year earlier. The Company expects to resume ATUs in early 2023 as soon as the product becomes available again. The Company also generated research tax credit (*Crédit d'Impôt Recherche* or CIR), amounting to €1.2 million in the first half of 2022 compared to €1.3 million in the first half of 2021.

Research and development expenses increased by 23.3% amounting to €9.9 million in the first half of 2022 compared to €8.0 million a year earlier. Phase III clinical trials of LUMEVOQ® – RESCUE, REVERSE and REFLECT – are now completed and patients entered long term follow-up. More importantly, 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. Strong focus is made on this topic required to complete the Marketing Authorisation Application (MAA) in Europe.

Sales, medical and marketing expenses sharply increased by 76.7% to €4.0 million in the first half of 2022 from €2.3 million over the same period 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 end of 2023. The Company is also building its local presence in the main European countries, France, Germany, the United Kingdom, Italy and Spain by setting up commercial affiliates.

General and administrative expenses significantly reduced by 28.6% to €2.3 million in the first half of 2022 compared to €3.3 million over the same period in 2021. This decrease was mainly driven by lower personnel expenses, resulting from the cancellations of the remaining 50% of the 2020 performance share plans and of 50% of the 2021 performance share plan following manufacturing issues at the Company's partner in the United-States.

The Company's **operating loss** increased by 79.1% in the first half of 2022 amounting to €(12.0) million compared to €(6.7) million over the same period in 2021, both driven by the reduction in revenues generated by ATUs of LUMEVOQ® in France, as well as the increase in CMC expenses and the ramp up of sales, medical and marketing expenses over the period to support the Marketing Authorisation and the subsequent commercial launch in Europe. Cash control remains an important priority to the Group.

The financial income in the first half of 2022 amounted to €1.3 million compared to €(1.6) million over the same period in 2021. The variation is primarily driven by a non-cash calculated income related to the bond financing with Kreos, impacted by the share price decrease over the period.

The Company's **net loss** for the first half of 2022 amounted to \in (10.7) million compared to \in (8.3) million in the first half of 2021. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to \in (0.23) and \in (0.19) for the first halves of 2022 and 2021, respectively.

Net cash flows from operating activities in the first halves of 2022 and 2021 were €(16.7) million and €(10.2) million, respectively. The variation in 2022 is mainly driven by the increase in operating expenses to support the Marketing Authorisation and the subsequent commercial launch of LUMEVOQ® in Europe as well as the negative impact of non-cash IFRS items related to share-based payments and the change in fair value of derivatives financial instruments in the Kreos Bond agreement driven by the decrease in the share price over the period.

Net cash flows from investment activities amounted to €0.1 million in the first half of 2022 compared to €0.2 million in 2021, mainly driven by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €(3.3) million in the first half of 2022, reflecting the amortization of our bond agreement with Kreos and our State-guaranteed loan over the period. The



net cash flows from financing activities in the first half of 2021 amounted to €26.4 million and reflected the €28.1 million net proceeds from the private placement in March 2021.

Cash and cash equivalents as of June 30, 2022 amounted to €24.1 million.

GenSight Biologics will report on October 27, 2022 its cash position as of September 30, 2022.

Contacts

GenSight Biologics

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

LifeSci Advisors

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

RooneyPartners

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

Orpheon Finance

Retail Investors
James Palmer
<u>i.palmer@orpheonfinance.com</u>
+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), 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.