Press Release

GenSight Biologics Reports Interim Financial Results for the First Half of 2019 and Provides Operational Update

Paris, France, July 24, 2019, 5.45 pm 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, reported its interim financial results for the first half of 2019, and provided recent operational updates. The full interim financial report is available on the Company's website in the Investors section. The 2019 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 23, 2019.

2019 Half-Year Financial Results

In million euros	H1 2018	H1 2019
Operating income	2.0	2.5
Research and development expenses	(9.6)	(16.1)
Sales and marketing expenses	(0.8)	(0.4)
General and administrative expenses	(3.0)	(3.1)
Operating profit (loss)	(11.3)	(17.2)
Net income (loss)	(11.7)	(17.3)
EPS (in € per share)	(0.48)	(0.63)
Net cash flows from operating activities	(13.1)	(19.5)
Net cash flows from investment activities	(0.4)	0.1
Net cash flows from financing activities	(0.3)	7.4
Net cash flows	**(13.7)**	**(12.0)**
Cash and cash equivalents at closing	**41.7**	**14.3**

The Company's **operating income** increased from €2.0 million to €2.5 million over the period. This income was essentially in the form of research tax credit (Crédit Impôt Recherche).

Research and development expenses increased by 68.6% from €9.6 million in the first half of 2018 to €16.1 million over the same period in 2019. This increase is primarily due to ramping up the Chemistry, Manufacturing and Controls (CMC) activities for GS010 in preparation for filing a marketing approval application in Europe, as well as completing recruitment of the REFLECT Phase III trial.

General and administrative expenses remained stable over the period, amounting to €3.0 million and €3.1 million in the first halves of 2018 and 2019, respectively.

The Company's **net loss** for the first half of 2018 amounted to €(11.7) million compared to €(17.3) million in the first half of 2019. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to €(0.48) and €(0.63) for the first halves of 2018 and 2019, respectively.

Net cash flows from operating activities in the first halves of 2018 and 2019 were €(13.1) million and €(19.5) million, respectively, primarily driven by the increase in research and development expenses over the period.

Net cash flows from financing activities amounted to €7.4 million in the first half of 2019, primarily as a result of the net proceeds of the Company's capital increase with Sofinnova Partners in February 2019.

Cash and cash equivalents as of June 30, 2019 amounted to €14.3 million.

"Following Sofinnova's equity investment in February, we are fully financed until the first quarter of 2020," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"We are now allocating most of our resources behind GS010 to move forward our lead product through the regulatory approval pathway in Europe, while continuing to conduct the PIONEER trial with GS030."*

GenSight Biologics will report its cash position as of September 30, 2019 on October 22, 2019.

Clinical Development of GS010

The recruitment of the REFLECT Phase III clinical trial evaluating the efficacy and safety of bilateral injections of GS010 in subjects with LHON due to the ND4 mutation was successfully completed early July, more than 2 months ahead of schedule. Topline results at 52 weeks are expected in the third quarter of 2020.

Results at 96 weeks of the RESCUE Phase III clinical trial evaluating the efficacy and safety of a single intravitreal injection of GS010 in subjects with LHON due to the ND4 mutation with an onset of vision loss up to 6 months are expected in September 2019.

Regulatory Pathway of GS010

Preparatory activities to ensure manufacturing readiness to commercialize under Good Manufacturing Practices (GMP) continue to move forward to support filing a marketing authorization application (MAA) with the European Medicines Agency (EMA). Working with its manufacturing partner, GenSight has assessed the need for continuing manufacturing activities to confirm process control before the planned commercial batches and ensure the most robust dossier for the MAA in Europe. The Company therefore decided to reschedule its pre-submission meeting with the EMA from this Summer to early 2020 and expects to submit application for marketing approval in Europe in the third quarter of 2020.

The End of Phase II meeting with the U.S. Food and Drug Administration (FDA) planned in the Fall remains unchanged and is targeted for September 2019.

"Proving manufacturing readiness is essential for securing the confidence of the regulatory authorities, particularly for novel gene therapies like GS010, and we believe that additional engineering runs will maximize the case for approval," commented **Bernard Gilly**, co-founder and Chief Executive Officer of GenSight Biologics. *"We are of course actively working with our partner in the US to minimize the consequent delay so that patients may have GS010 available as soon as possible."*

GS010 becomes LUMEVOQ™

The brand name for GS010 will be LUMEVOQ™ (lenadogene nolparvovec). The name was approved by the EMA for use in the MAA, and the trademark has been filed in the EU, where it has been approved,

and in the US, where approval is pending. Upon regulatory approval, GenSight intends to commercialize GS010 under this trademark.

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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, 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.