Press Release

GenSight Biologics Reports Interim Financial Results for the First Half of 2021 and Provides Operational Update

- Operating loss significantly reduced by lower R&D expenses and revenues generated from LUMEVOQ® ATUs in France
- Ramp up of Sales & Marketing in preparation of the expected commercial launch of LUMEVOQ® in Europe in H1 2022
- Successful refinancing in Q1 2021 secures mid-2023 runway
- Multiple regulatory and clinical milestones expected in Q4 2021

Paris, France, July 29, 2021, 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 2021 and provided recent operational updates. The full interim financial report is available on the Company's website in the Investors section. The 2021 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 28, 2021.

"LUMEVOQ has demonstrated robust and consistent data in three independent Phase III trials, showing impressive evidence of clinical benefit and a strong safety profile. Based on this data package, we are now moving forward with the regulatory, manufacturing, and commercial steps necessary for obtaining marketing authorization in Europe and North America," commented **Bernard Gilly**, co-founder and Chief Executive Officer of GenSight Biologics. *"We are building our organization to ensure a smooth and speedy commercial launch in Europe, and we look forward to bringing LUMEVOQ to more patients with Leber Hereditary Optic Neuropathy and helping to change their lives for the better."*

2021 Half-Year Financial Results

In million euros	H1 2020	H1 2021
Revenues	0.7	5.6
Other income	2.6	1.3
Operating income	**3.3**	**6.9**
Research and development expenses	(12.0)	(8.0)
Sales and marketing expenses	(0.9)	(2.3)
General and administrative expenses	(4.0)	(3.3)
Operating profit (loss)	**(13.6)**	**(6.7)**
Net income (loss)*	**(14.7)**	**(8.3)**
EPS (in € per share)*	(0.45)	(0.19)
Net cash flows from operating activities	(6.7)	(10.2)
Net cash flows from investment activities	(0.1)	0.2
Net cash flows from financing activities	4.4	26.4

Net cash flows	**(2.4)**	**16.4**
Cash and cash equivalents at closing	**16.8**	**54.3**

** Financial statements as of June 30, 2020 have been modified in accordance with the reexamination of the Financing contract with Kreos. See Note 9.1 of the 2021 Interim Financial Report.*

"We continued to reduce our R&D expenses by a third in this first half of 2021, while successfully scaling up our organization and preparing for LUMEVOQ's commercial launch in Europe," commented **Thomas Gidoin**, Chief Financial Officer of GenSight Biologics. *"With a successful oversubscribed 30 million euros private placement in March, we have now secured a financing runway to mid-2023."*

The Company's **operating income** significantly increased by 109.9% to €6.9 million from €3.3 million over the period. This increase was essentially driven by 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) sharply progressing to €5.6 million in the first half of 2021 compared to €0.7 million a year earlier. The Company also generated research tax credit (*Crédit d'Impôt Recherche* or CIR), amounting to €1.3 million in the first half of 2021 compared to €2.3 million in the first half of 2020. The decrease in CIR was due to a significant reduction in R&D expenses over the period.

Research and development expenses decreased by 32.8% to €8.0 million in the first half of 2021 from €12.0 million over the same period in 2020. This decrease was primarily due to all Phase III clinical trials of LUMEVOQ® – RESCUE, REVERSE and REFLECT – now being completed and patients entering long term follow-up. In addition, Chemistry, Manufacturing and Controls (CMC) development activities for LUMEVOQ® decreased over the period, as the Company filed a Marketing Authorisation Application with the European Medicines Agency (EMA) in September 2020.

Sales and marketing expenses increased to €2.3 million in the first half of 2021 from €0.9 million over the same period in 2020 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 amounted to €3.3 million and €4.0 million in the first halves of 2021 and 2020, respectively. The variation was mainly related to share-based compensation, both non-cash expenses in accordance with IFRS2 and the related accrued social contribution based on share price.

The Company's **operating loss** was significantly reduced by 50.6% in the first half of 2021 amounting to €(6.7) million compared to €(13.6) million in 2020, 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 the first half of 2021 amounted to €(1.6) million compared to €(1.1) million in 2020. The variation is primarily driven by non-cash calculated expenses related to the bond financing with Kreos, impacted by the share price increase over the period.

The Company's **net loss** for the first half of 2021 was cut by 43.5% to €(8.3) million compared to €(14.7) million in the first half of 2020. The loss per share (based on the weighted average number of shares outstanding over the period) amounted to €(0.19) and €(0.45) for the first halves of 2021 and 2020, respectively.

Net cash flows from operating activities in the first halves of 2021 and 2020 were €(10.2) million and €(6.7) million, respectively. The positive effect of the sharp 50.6% reduction in operating loss on net cash flows was more than offset by a significant negative net change in working capital over the period. This was derived from not having received the 2020 Research Tax Credit (CIR) reimbursement when the 2019

CIR had been already received in the prior year, a decrease in trade payables and €2.1 million of trade receivables from the sales of LUMEVOQ® at the end of June 2021.

Net cash flows from investment activities amounted to €0.2 million in the first half of 2021 compared to €(0.1) million in 2020, mainly driven by the activity of the Company's liquidity contract.

Net cash flows from financing activities amounted to €26.4 million in the first half of 2021, reflecting the net proceeds from the private placement in March for €28.1 million.

Cash and cash equivalents as of June 30, 2021 amounted to €54.3 million.

GenSight Biologics will report on October 19, 2021 its cash position as of September 30, 2021.

LUMEVOQ® Commercial Launch in Europe Still Expected in H1 2022

Following a delay in manufacturing validation batches of LUMEVOQ® as a consequence of the US Defense Production Act (DPA), as announced on May 14, 2021, ThermoFisher Scientific (TFS), the contract manufacturer of LUMEVOQ®, has now confirmed it has resumed manufacturing of the validation batches at its Cambridge, US, manufacturing facility. The Company therefore confirms expecting to respond to the Agency D120 questions by January 2022 as per EMA agreed timelines.

The EU marketing authorization is therefore expected in H1 2022.

As announced on May 19, 2021, GenSight has already hired three country leads in France, Germany and the UK, who have now initiated discussions about LUMEVOQ® with payers, target specialists, potential centers of excellence and patient advocacy groups. The recruitment process for country leads in Italy and Spain has also been initiated and is expected to be completed by the end of 2021. The country leads will be joined by patient access leads and local marketing managers who will support early engagement with local healthcare stakeholders.

In the meantime, LUMEVOQ® was granted a Cohort Temporary Authorization for Use ("*ATU de Cohorte*" or ATUc) in France by the ANSM, allowing the product to continue to be prescribed and reimbursed in France, generating revenues to the Company.

Compassionate use in Italy was also granted with some patients already treated in H1 2021. A compassionate use program in Germany is under review by Competent Authorities. Patients have also been treated in the United States under an Expanded Access Program granted by the US Food and Drug Administration (FDA). For all these compassionate use programs outside France, LUMEVOQ® is provided free of charge to requesting physicians.

LUMEVOQ® Regulatory Pathway in the US: REFLECT Phase III read-out in June 2021; US pre-BLA Meeting with the FDA Expected in Q4 2021; BLA Submission Now Expected Q2 2022

In the United States, following the release in June of the topline results from the REFLECT Phase III trial, GenSight is planning a pre-Biologics License Application (BLA) meeting with the FDA) for Q4 2021. This pre-BLA meeting will be used to discuss with the Agency the full set of evidence of the benefit of LUMEVOQ® in the treatment of *ND4*-LHON, covering analyses from REFLECT, RESCUE and REVERSE, including a comparison against natural history that had been pre-specified in the amended statistical analysis plan.

Pending a positive outcome of the pre-BLA meeting with the FDA, GenSight plans to submit the LUMEVOQ® BLA in Q2 2022.

As patients from the REFLECT trial continue to be monitored, GenSight expects to communicate the 2-year follow-up data in Q4 2021.

The Company also expects to report the 4-year follow-up data from the RESTORE trial in Q4 2021.

LUMEVOQ® Upcoming Regulatory and Commercial Milestones and Timelines

	Timeline	Milestone	Comment
2021	Q4 2021	Pre-BLA meeting with US FDA	Awaiting meeting confirmation from the FDA
	Q4 2021	REFLECT 2-year data	
	Q4 2021	RESTORE 4-year follow-up data	
	Q4 2021	Hiring country leads in Spain and Italy	
2022	January 2022	Respond EMA 120D questions and provide validation batches data	
	H1 2022	EMA CHMP recommendation and European Commission approval (Marketing Autorization)	
	Q2 2022	Launch in France, Germany and the UK	
	Q2 2022	BLA submission to the FDA	Pending positive outcome of pre-BLA meeting in Q4 2021

PIONEER Phase I/II Clinical Trial of GS030 in Retinitis Pigmentosa (RP)

GenSight Biologics reported in May in *Nature Medicine* a first case report of partial recovery of visual function in a blind patient with late stage retinitis pigmentosa (RP) in the first treated subject in the PIONEER Phase I/II clinical trial of GS030.

PIONEER, combining gene therapy and optogenetics for the treatment of RP, has now fully completed recruitment of the 3rd cohort. The Data Safety Monitoring Board (DSMB) is expected to make a recommendation on the optimal dose to use in the extension cohort in the coming weeks. GenSight Biologics expects to complete recruitment of the extension cohort by the end of 2021.

In the meantime, the Company expects to report more preliminary results later in the second half of the year.

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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 subjects 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 subjects a sustainable functional visual recovery.