Press release

Sensorion Reports 2022 First Half Results

- ***Continued progress toward planned development for SENS-401 and gene therapy programs***
- ***Positive progress for two clinical trials for SENS-401: in Cisplatin-Induced Ototoxicity (CIO) and to prevent residual hearing loss following cochlear implantation***
- ***Development milestone achieved for the OTOF-GT program with delivery of batches for the toxicology study; plan to file Clinical Trial Application in 1H 2023***
- ***GJB2-GT advancing after promising results, candidate selection expected in 2H 2022***
- ***Ended Q2 2022 with a cash position of €39m***

Montpellier, September 22, 2022 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, announces its half-year results as of June 30, 2022, alongside its outlook for the remainder of 2022.

Nawal Ouzren, CEO of Sensorion, said*: "*Sensorion has made good progress across our pipeline of small molecule and gene therapy programs in the first half of this year. We are excited about the potential of our pipeline, and we remain highly focused on the development of our most promising candidates to produce life-changing therapies to restore, treat and prevent hearing loss disorders.

"SENS-401 now advances with two planned proof-of-concept clinical programs, in CIO and to prevent residual hearing loss following cochlear implantation. Meanwhile, across our gene therapy portfolio, we have also achieved key milestones for our lead gene therapy candidate OTOF-GT, ahead of the planned submission of our Clinical Trial Application in the first half of 2023*."*

Business highlights

SENS-401

Sensorion is making good progress advancing its small molecule product SENS-401 (Arazasetron) in two clinical trials. The first is a proof-of-concept trial in Cisplatin-Induced Ototoxicity (CIO) and the second assesses SENS-401 for residual hearing preservation during cochlear implantation in partnership with Cochlear Ltd.

- **Progressing on SENS-401 in Cisplatin-Induced Ototoxicity, a major unmet medical need**

Cisplatin and other platinum compounds are essential chemotherapeutic agents for many malignancies. Unfortunately, platinum-based therapies cause ototoxicity, or hearing loss, which is permanent, irreversible and particularly harmful to 50-60% of adult patients and 90% of pediatric patients who survive cancer. This indication represents a very significant unmet need for patients and is an attractive market with more than 500,000 patients forecast in 2025 in the G7 countries.

In late 2021, Sensorion filed a proof-of-concept clinical trial application in CIO to evaluate the potential of SENS-401 treatment. The NOTOXIS clinical trial application (CTA) was approved earlier in 2022. Following further analysis of the AUDIBLE-S study earlier in 2022, Sensorion has adapted the NOTOXIS trial design to focus SENS-401 in the prevention arm only. An amendment to the planned CTA has recently been submitted to regulatory authorities with a decision expected by year end 2022.

- **Continuous progress of SENS-401 to prevent residual hearing loss after cochlear implantation with trial approval granted in France and Australia**

The first patient has now been enrolled in a proof-of-concept (POC) clinical trial of SENS-401 in patients scheduled for cochlear implantation, in partnership with Cochlear Ltd. The trial is being conducted in France and Australia, and regulatory authorities in both countries have approved the trial.

The trial is a multicenter, randomized, controlled, open-label trial to evaluate the presence of SENS-401 in the cochlea (perilymph) after 7 days of twice-daily oral administration in adult participants prior to cochlear implantation. Following implantation, patients will continue to receive SENS-401 for 42 days. The study also assesses a number of secondary endpoints, including the change of hearing threshold from baseline to the end of the study in the implanted ear at several frequencies. These will also be measured after a 2-month follow-up period.

First results from this trial are expected to be provided during 1H 2023.

In line with a disciplined approach to capital allocation, Sensorion continues to explore partnership opportunities with SENS-401 in Sudden Sensorineural Hearing Loss (SSNHL).

Gene Therapy programs

Sensorion continues to advance its gene therapy programs, developed as part of its collaboration with Institut Pasteur. The company has expanded its technical development capabilities over the period along with pilot-scale manufacturing capacity.

- **OTOF-GT**

Sensorion has continued to progress with preclinical and clinical development plans for OTOF-GT, the Company's dual-vector AAV gene therapy program for the treatment of children born with hearing loss caused by otoferlin deficiency.

Sensorion presented preclinical data at The Association for Research in Otolaryngology conference that indicated the potential for safe and efficient clinical translation of gene therapy for otoferlin delivered by a dual AAV vector.

Otof *de novo* expression in inner hair cells (IHCs) in a DFNB9 mouse model (OTOF-KO) demonstrates long-term expression of otoferlin and hearing restoration of at least one year post injection. Sensorion has also developed, in non-human primates, an optimal surgical procedure similar to cochlear implantation and demonstrated an effective transduction rate of the targeted IHCs. This procedure includes the use of an injection device system currently being developed by Sensorion.

During the period, Sensorion has expanded its CMC (Chemistry, Manufacturing and Control) gene therapy platform. The Company has developed a small-scale process and analytical methods for transfer to its CDMO partner, Thermo Fisher.

Sensorion achieved a development milestone mid-2022, by successfully producing dual AAV OTOF-GT batches at 200L clinical scale to conduct the GLP toxicology study in animals.

In September 2022, the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) issued a positive opinion on the company's application for orphan drug designation (ODD) for OTOF-GT. The European Commission is expected to issue a decision within 30 days of receipt of the COMP positive opinion.

An application has been submitted to the FDA for ODD and Rare Pediatric Disease Designation (RPDD). An opinion is expected during 1H 2023. The company plans to file the CTA for its OTOF-GT program in 1H 2023.

- **GJB2-GT candidate selection is progressing**

Sensorion's GJB2 gene therapy program, developed in collaboration with Institut Pasteur, has the potential to address three pathologies related to *GJB2* mutations: early onset of presbycusis in adults, progressive forms of hearing loss in children, and pediatric congenital deafness. Although the types of GJB2 mutations in children and adults may differ, gene therapy offers potential solutions for both.

Sensorion generated preliminary positive data in a GJB2 mouse model to evaluate the most promising product candidate options. The company believes this data will support the selection of a drug candidate by year end 2022.

Expected future milestones

- 2H 2022 – GJB2-GT: candidate selection
- 2H 2022 – SENS-401 CIO: NOTOXIS CTA study amendment approval
- 1H 2023 – SENS-401 in combination with cochlear implantation: first results
- 1H 2023 – OTOF-GT: approval for U.S. ODD and RPDD
- 1H 2023 – OTOF-GT: submission of the Clinical Trial Application (CTA)

First-half 2022 financial highlights

- **Cash position**

As of June 30, 2022, cash and cash equivalents amounted to €39m, compared to €50m at December 31, 2021.

- **Research and developments expenses**

Research and development expenses increased by 85%, from €6.0m for the period ended June 30, 2021 to €11.1m for June 30, 2022. The increase is mainly due to the development of preclinical, manufacturing, and clinical studies as well as an increase in R&D headcount.

- **General and administrative expenses**

G&A expenses increased by 74%, from €1.7m for the period ended June 30, 2021 to €3.0m for June 30, 2022, mainly due to *mali* on treasury shares, an increase in headcount, and higher consulting fees.

- **Financial guidance**

Based on its forecasted expenses, the Company expects the cash position of €39m on June 30, 2022, to be sufficient to fund its operations until the end of Q3 2023.

Financial structure

The simplified income statement as of June 30, 2022 is as follows:

In Euros – IFRS Standards	**30.06.2022**	**30.06.2021**
Operating income	**1,901,426**	**1,603,749**
Research and Development expenses	11,079,156	6,003,596
General and Administrative expenses	3,037,382	1,748,922
Total operating expenses	**14,116,535**	**7,752,518**
Operating profit/loss	**-12,215,108**	**-6,148,769**
Financial profit/loss	-49,383	-94,152
Net profit/loss	**-12,264,491**	**-6,242,921**

As of June 30, 2022, the company employed 45 people.

The simplified balance sheet at June 30, 2022 is as follows:

In Euros – IFRS standards	**30.06.2022**	**31.12.2021**
Non-current Assets	**2,264,149**	**2,142,885**
Other Current Assets	8,024,441	6,946,055
Cash & cash equivalent	39,003,038	50,001,110
Total Assets	**49,291,657**	**59,090,050**
Equity	**32,472,636**	**44,055,803**
Non-current Liabilities	3,889,916	4,504,691
Current Liabilities	12,929,105	10,529,556
Total Liabilities	**49,291,657**	**59,090,550**

First-Half 2022 certified accounts

On September 21, 2022, the Board of Directors approved the Company's first half-year results as of June 30, 2022. The Half-Year Financial Report can be found on Sensorion's website (https://www.sensorion.com/en/home/) in the investor section under financial information. The first-half year accounts of 2022 have been subject to a limited review by the Company's statutory auditors and an unqualified report is being issued.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent hearing loss disorders, a significant global unmet medical need.
Sensorion has built a unique R&D technology platform to expand its understanding of the pathophysiology and etiology of inner ear related diseases, enabling it to select the best targets and mechanisms of action for drug candidates. Its portfolio combines both small molecule programs and a preclinical portfolio of inner ear gene therapies.
Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) progressing in a planned Phase 2 proof of concept clinical study of SENS-401 in Cisplatin-Induced Ototoxicity (CIO) and, with partner Cochlear Limited, a study of SENS-401 in patients scheduled for cochlear implantation.
Sensorion has entered into a broad strategic collaboration with Institut Pasteur focused on the genetics of hearing. It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness including OTOF-GT, targeting deafness caused by a mutation of the gene encoding for otoferlin, and hearing loss related to mutation in *GJB2* gene to

potentially address important hearing loss segments in adults and children (GJB2-GT). The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.
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