Press Release

Sensorion Reports 2024 First Half Results and Highlights Recent Updates

- ***First patient treated in SENS-501 Audiogene clinical study; well on-track for first cohort recruitment completion by year-end 2024***
- ***Final data to be presented from the Phase 2a study of SENS-401 in the preservation of residual hearing after Cochlear Implantation at the World Congress of Audiology (WCA) on September 20, 2024***
- ***On-track for preliminary efficacy and safety data presentation of SENS-401 Phase 2a in Cisplatin-Induced Ototoxicity at the World Congress of Audiology (WCA) on September 20, 2024***
- ***Cash on-hand of c.€87m to support planned operations into end of 2025***

Montpellier, September 18, 2024, 7.30 am CET – 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, today reports its half-year results as of June 30, 2024, as well as its outlook for the remainder of 2024.

Nawal Ouzren, Chief Executive Officer of Sensorion, said: "*Over the first half of 2024, Sensorion has made steady positive progress, reaching several key milestones in its development plan. Most notably, with SENS-501, our most advanced gene therapy program, we have made significant regulatory and clinical advances. After receiving a green light from European regulators in January 2024, I am thrilled to announce that the first patient has been recruited to the study and injected. We look forward to updating you on the progress with this program in the coming months.*

We have also continued to advance our Phase 2a clinical programs for SENS-401. Firstly, we unveiled new positive efficacy data for SENS-401 in the prevention of residual hearing loss after cochlear implantation, with full data to be presented at the World Congress of Audiology, later this month. Secondly, we have continued to recruit adult patients to the NOTOXIS study in Cisplatin-Induced Ototoxicity.

On the financial front, the steady execution of our clinical development roadmap has attracted new investment into Sensorion, with new recognised specialist international healthcare investors taking part in the two private placements completed last February and April, for a total amount of over €65 million. With these additional resources, we are well-funded to the end of 2025. Overall, I am delighted with the advances we are making, and I look forward to sharing future updates over the course of 2024, which will be rich in terms of clinical data on our lead programs."

Pipeline Highlights and Upcoming Milestones

During the first half of 2024, Sensorion continued to develop innovative therapies to restore hearing, treat and prevent hearing loss, to potentially transform the patients' quality of hearing.

Gene Therapies for Hereditary Monogenic Hearing Loss

Sensorion continues to advance its gene therapy programs, developed as part of its collaboration with the Institut Pasteur, initiated in 2019 and extended for an additional 5-year period in January 2024. The framework agreement for a research partnership grants Sensorion an option to obtain an exclusive license to develop and commercialize gene therapy drug candidates for the restoration of hearing. The company has notably made progress in its lead gene therapy program, SENS-501, with a first patient recruited and injected.

- **SENS-501 (OTOF-GT): several milestones achieved with Clinical Trial Application (CTA) approval in Europe and First Patient Included (FPI) and injected. FPI initial safety data communication planned at the WCA on September 20, 2024**

Sensorion's SENS-501 (OTOF-GT) dual AAV vector gene therapy development candidate aims at restoring hearing in patients with mutations in *OTOF* gene who suffer from severe to profound sensorineural prelingual non syndromic hearing loss. The otoferlin is a protein expressed in the inner hair cells (IHC) present in the cochlea and is critical for the transmission of the signal to the auditory nerve. Otoferlin related hearing loss is responsible for up to 8% of all cases of congenital hearing loss, with around 20,000 people affected in the US and Europe[1]. Sensorion's lead gene therapy program, SENS-501, has been developed as part of its collaboration focused on the genetics of hearing with the Institut Pasteur which was initiated in 2019 and extended for an additional 5-year period in January 2024.

On January 19, 2024, Sensorion announced the approval to initiate the Phase 1/2 clinical trial of SENS-501, Audiogene, in Europe with France as first country. The CTA approval follows extensive preclinical studies assessing the safety and efficacy of SENS-501 and successful manufacturing of the gene therapy Drug Product for the clinical trial. Audiogene aims to evaluate the safety, tolerability, and efficacy of intra-cochlear injection of SENS-501 for the treatment of OTOF gene-mediated hearing impairment in paediatric patients aged 6 to 31 months at the time of gene therapy treatment. Targeting the first years of life, the time period when the auditory system plasticity is optimal, will maximize the chances of these young children with pre-lingual hearing loss to acquire normal speech and language. The design of the study consists of two cohorts of two doses followed by an expansion cohort at the selected dose. While the safety will be the primary endpoint for the dose escalation cohort, the auditory brainstem response (ABR) will be the primary efficacy endpoint of the dose expansion cohort. Audiogene will also assess the clinical safety, performance, and usability of the administration device system developed by Sensorion.

On September 11, 2024, Sensorion received the European Medicines Agency decision agreeing on a Pediatric Investigation Plan (PIP) for SENS-501. A PIP is a development plan aimed at ensuring that the necessary data are obtained to support the marketing authorization of a medicine in the pediatric population in the European Union. All applications for marketing authorization for new medicines require the results of studies as described in an agreed PIP.

Sensorion will communicate initial safety data about the first patient at the WCA, on September 20, 2024, and is on track for the recruitment of the first cohort by end of 2024. The recruitment completion of the two first cohorts of patients is expected in H1 2025.

OTOCONEX, the Company's Natural History Study to document the natural course of disease progression in otoferlin deficiency patients and in children with hearing loss related to *GJB2* mutations, is running across Europe and plays an important role in identifying patients as early as possible.

- **GJB2-GT: progressing CTA/IND-enabling studies towards Clinical Trial Applications Submission in H2 2025**

Sensorion's *GJB2* gene therapy program, developed in collaboration with the Institut Pasteur, has the potential to address three forms of hearing loss 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 populations.

[1] Rodríguez-Ballesteros M, *et al.*,A multicenter study on the prevalence and spectrum of mutations in the otoferlin gene (OTOF) in subjects with nonsyndromic hearing impairment and auditory neuropathy. Hum Mutat. 2008 Jun;29(6):823-31. doi: 10.1002/humu.20708. PMID: 18381613.

On April 6, 2023, Sensorion announced the candidate selection for GJB2-GT during its R&D Day focusing on gene therapy. The candidate is designed with a specific adeno-associated virus (AAV) capsid and includes specific regulatory sequences to safely target key cells in the ear that normally express *GJB2* and avoids ototoxicity.

Sensorion has developed the non-GMP process development of the GJB2 candidate up to 50L scale. Process and analytical methods are under transfer to the CDMO for the GMP production of the clinical batch. Sensorion is advancing the candidate into CTA/IND-enabling activities for anticipated submission in H2 2025.

The Company plans on providing updates on preclinical activities related to GJB2-GT including additional Proof-of-Concept data at the European Society of Cell & Gene Therapy (ESGCT), taking place on October 22-25, 2025, Rome, Italy.

SENS-401

Sensorion is developing SENS-401 (Arazasetron) in three indications and two Proof of Concept Phase 2a clinical trials are ongoing, including a study designed to assess SENS-401 for residual hearing preservation during cochlear implantation in partnership with Cochlear Limited; the final results of which will be reported on September 20, 2024, during the World Congress of Audiology. The second study is a proof-of-concept trial in Cisplatin-Induced Ototoxicity (CIO).

SENS-401 is an orally available small molecule that aims to protect and preserve inner ear tissue from damage responsible of hearing impairment. SENS-401 has been granted Orphan Drug Designation by the EMA in Europe for the treatment of sudden sensorineural hearing loss (SSNHL), and by the FDA in the U.S. for the prevention of platinum-induced ototoxicity in pediatric population.

- **Milestones achieved for SENS-401 in the prevention of residual hearing loss after cochlear implantation with primary endpoint achieved and positive secondary efficacy endpoints data. Full final data readout to be presented at the WCA, on September 20, 2024**

Sensorion has advanced its small molecule SENS-401 in a multicentric, randomized, controlled open-label Phase 2a trial aimed at evaluating the presence of SENS-401 in the cochlea (perilymph) after 7 days of twice-daily oral administration in adult patients prior to cochlear implantation due to moderately severe to profound hearing impairment. Patients start treatment with SENS-401 7 days before implantation and continue to receive SENS-401 for a further 42 days.

On February 1, 2024, Sensorion announced the completion of patient inclusion in the Phase 2a POC clinical trial. Following this announcement, Sensorion communicated in March 2024, that a total of 25 patients have been implanted with a cochlear implant: 16 in the treated arm and 9 in the control non-treated arm. The presence of SENS-401 in the perilymph at a level compatible with potential therapeutic efficacy has been confirmed in 100% of the patients sampled, 7 days after the start of the treatment, confirming that the primary endpoint was met.

On July 13, 2024, Professor Stephen O'Leary, M.D., Ph.D., the study principal investigator, presented new medical data and analysis of results from the SENS-401 Phase 2a clinical trial at the 17th International Conference on Cochlear Implants and Other Implantable Technologies (CI2024) in Vancouver, Canada. The study design included a number of secondary endpoints, notably the change of hearing threshold from baseline to the end of the treatment period in the implanted ear at several frequencies. Study entry criteria required patients to have a pure tone audiometry (PTA) threshold of 80 dB or better (i.e., ≤80 dB) at 500 Hz, defined as indicating a minimal level of residual hearing. The descriptive results show that the administration of SENS-401 reduced hearing loss following cochlear implantation. Six weeks post cochlear implantation (corresponding to end of SENS-401 treatment), the data indicate that the mean hearing loss induced by the surgery at 500 Hz is 19 dB for patients treated

with SENS-401 (N=16) compared to 32 dB for control group of SENS-401 untreated patients (N=8). Similar clinically meaningful difference is observed for the mean of the three following frequencies (250, 500 and 750 Hz) with 16 dB in the SENS-401 treated group compared to 31 dB in the control group. These good descriptive results remained clinically meaningful over time and up to the last study visit fourteen weeks after cochlear implantation and confirm the key role of SENS-401 in preserving residual hearing.

The Company plans on communicating the results of the final analysis at the WCA, held in Paris, France, on September 19-22, 2024.

- **SENS-401 in Cisplatin-Induced Ototoxicity progresses with patient recruitment progressing at a steady pace and positive Data Safety Monitoring Board (DSMB) recommendation to pursue the study**

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.

The NOTOXIS Proof-of-Concept (POC) Phase 2a trial is a multicenter, randomized, controlled, open-label study designed to assess the efficacy of SENS-401 in preventing cisplatin-induced ototoxicity in adult patients with neoplastic disease, four weeks after completion of cisplatin-based chemotherapy. The trial assesses several endpoints, including the rate and severity of ototoxicity, changes in pure tone audiometry (PTA) (dB) throughout the study compared to before cisplatin treatment, and tolerability.

Eligible participants are randomized on Day 1 to either Arm A or Arm B in ratio 1:1. In Arm A, patients receive 43.5mg of oral SENS-401 one week before the start of the chemotherapy, continues throughout the entire chemotherapy duration, and extends for up to four weeks post-chemotherapy. This study is conducted in comparison to a control group of patients receiving chemotherapy alone, Arm B. The patients entering the study are to receive high doses of cisplatin, exceeding 70mg/m2 per treatment cycle and totaling at least 210 mg/m2 over the course of their chemotherapy regimen.

On December 18, 2023, Sensorion announced that over one-third of the required study population had been recruited and that preliminary safety data for patients exposed to a daily dose of 43.5 mg SENS-401 administered b.i.d. for up to 11 weeks indicated a favorable profile.

On July 23, 2024, Sensorion announced that the independent Data Safety Monitoring Board (DSMB) had undertaken a review of the safety data for the patients participating in the NOTOXIS POC Phase 2a clinical trial. The DSMB recommended the continuation of the study and confirmed the absence of any concern as to the safety of SENS-401 when administered in adult patients receiving a daily dose of 43.5 mg, administered twice daily, over a period of up to 23 weeks. The patient enrolment continues to progress at a steady pace, in 13 clinical centers open to date. Sensorion will report preliminary safety and efficacy data of the Phase 2a POC clinical trial of SENS-401 CIO at the WCA, to be held on September 19-22, 2024, in Paris, France.

Expected future milestones and estimated timelines:

- September 2024 – SENS-401 in combination with cochlear implantation: Final data readout
- September 2024 – SENS-401 in Cisplatin-Induced Ototoxicity: Preliminary safety and efficacy data
- September 2024 – SENS-501: FPI initial safety data
- October 2024 (ESGCT) – *GJB2*-GT: Update on additional Proof-of-Concept efficacy and safety data

- H2 2024 – SENS-501: Enrollment completion of the first cohort in Audiogene
- H1 2025 – SENS-501: Enrollment completion of the second cohort in Audiogene
- H1 2025 – SENS-401 in Cisplatin-Induced Ototoxicity: Patient recruitment completion
- H2 2025 – *GJB2*-GT: Clinical Trial Applications filing

First-half 2024 financial highlights

- **Cash Position**

Cash & Cash Equivalents amounted to 87.3 million as of June 30, 2024, compared to €37.0 million as of December 31, 2023.

- **Research And Development (R&D) Expenses**

R&D expenses increased by 19% from €12.3 million as of June 30, 2023, to €14.7m as of June 30, 2024, primarily due to an increase in gene therapy programs with the start of GJB2-GT manufacturing.

- **General And Administrative (G&A) Expenses**

G&A expenses were €3.8 million for half-year 2024, compared to €2.6 million for the same period in 2023.

- **Net Loss**

Net loss was -€13,9 million for half-year 2024, compared to €12.3 million for half-year 2023.

- **Financial guidance**

Based on its forecasted expenses and a cash position of €87.3 million as of June 30, 2024, the Company expects to be able to fund its operations until end of 2025.

Financial structure

The half-year accounts on June 30, 2024, drawn up according to IFRS standards, were approved by the Board of Directors on September 17, 2024.

The simplified income statement as of June 30, 2024, is as follows:

In thousands of Euros – IFRS standards	**30.06.2024**	**30.06.2023**
Operating income	**3,332**	**2,647**
Research & Development expenses	14,660	12,271
General & Administrative expenses	3,791	2,572
Total operating expenses	**18,451**	**14,844**
Operating loss	**-15,119**	**-12,196**
Financial result	1,323	130
Pre-tax current income	**-13,796**	**-12,066**
Corporate Income Tax	-98	-222
Net loss	**-13,895**	**-12,288**

The simplified balance sheet as of June 30, 2024, is as follows:

In thousands of Euros – IFRS standards	**30.06.2024**	**31.12.2023**
Non-current Assets	**3,536**	**3,236**
Other Current Assets	10,649	6,293
Cash & cash equivalent	87,344	36,974
Total Assets	**101,529**	**46,503**
Equity	**83,462**	**33,276**
Non-current Liabilities	3,897	2,950
Current Liabilities	14,110	10,278
Total Liabilities	**101,529**	**46,503**

First-Half 2024 certified accounts

On September 17, 2024, the Board of Directors approved the Company's first half-year results as of June 30, 2024. The Company's statutory auditors have completed their limited review and are in the process of issuing an unqualified report, which shall be available in the coming days.

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.

It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness, developed in the framework of its broad strategic collaboration focused on the genetics of hearing with the Institut Pasteur. SENS-501 (OTOF-GT) currently being developed in a Phase 1/2 clinical trial, targets deafness caused by mutations of the gene encoding for otoferlin and GJB2-GT targets hearing loss related to mutations in GJB2 gene to potentially address important hearing loss segments in adults and children. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.

Sensorion's portfolio also comprises clinical-stage small molecule programs for the treatment and prevention of hearing loss disorders. Sensorion's 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, in a study of SENS-401 in patients scheduled for cochlear implantation. A Phase 2 study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in January 2022.

www.sensorion.com

Contacts

Press Release

Investor Relations
Noémie Djokovic, Investor Relations and Communication Associate
ir.contact@sensorion-pharma.com

Press Relations
Ulysse Communication
Bruno Arabian / 00 33(0)6 87 88 47 26
barabian@ulysse-communication.com
Nicolas Entz / 00 33 (0)6 33 67 31 54
nentz@ulysse-communication.com

Label: **SENSORION**
ISIN: **FR0012596468**
Mnemonic: **ALSEN**

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