*Press release*

# Sensorion Reports Full-Year 2023 Financial Results and Business Update

- ***Milestone achieved for SENS-501 gene therapy program with Clinical Trial Application approval in Europe (France as first country)***
  - ***Communication on first patient expected in H2 2024***
- ***GJB2 gene therapy program advancing towards Clinical Trial Applications filing expected in Q2 2025***
- ***Primary endpoint met in Phase 2a clinical trial of SENS-401 in the preservation of residual hearing following cochlear implantation***
  - ***Presence of SENS-401 detected in 100% of patients sampled at levels compatible with potential therapeutic efficacy***
  - ***Final data readout expected in Q3 2024***
- ***Continued progress for SENS-401 in Phase 2a clinical trial in the prevention of Cisplatin-Induced Ototoxicity***
  - ***Preliminary safety and efficacy data readout expected at the World Congress of Audiology in September 2024***
- ***Completion of two financing rounds, raising €35 million in August 2023 and €50.5 million in February 2024, enabling the company to extend its cash runway through the end of Q2 2025***

**Montpellier, March 14, 2024, 7.30am CET – Sensorion (FR0012596468 – ALSEN)** a pioneering clinical-stage biotechnology company which specializes in the development of novel therapies to restore, treat and prevent hearing loss disorders, today reports full-year 2023 financial results and business update.

**Nawal Ouzren, Chief Executive Officer of Sensorion**, said: "*Over the past months, Sensorion has successfully achieved all the major milestones on its roadmap. Our pioneering gene therapy, SENS-501, is entering clinical development, and our small molecule, SENS-401, has met primary endpoint in its most advanced indication: residual hearing preservation after cochlear implantation, in a Phase 2a study. At the same time, we have succeeded in securing financing for our operations until mid-2025 with the support of international and long-term investors. Sensorion is well equipped to meet its operational objectives for 2024, to continue bringing innovative therapeutic solutions to patients in the field of hearing, and to create value for its shareholders*."

## Pipeline Highlights and Upcoming Milestones

In 2023, Sensorion continued to develop innovative therapies to restore hearing, to treat and prevent hearing loss, and potentially transform quality of life for patients suffering from hearing loss disorders.

### 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 exclusive option to obtain an exclusive license to develop and commercialize drug candidates in gene therapy for the restoration of hearing. The company has made significant progress in its gene therapy pipeline with the submission and approval of clinical trial application for SENS-501 in Europe, and the candidate selection for GJB2-GT. The company has expanded its technical development capabilities over the period along with pilot-scale non-GMP (Good Manufacturing Practices) manufacturing capacity.

- **SENS-501: Milestone achieved with Audiogene Clinical Trial Application approval in Europe. First patient communication anticipated in H2 2024**

Sensorion's SENS-501 (OTOF-GT) dual AAV vector gene therapy development product 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.

In the first half of 2023, Sensorion achieved a major development milestone by completing the preclinical package, and successfully producing the GMP dual AAV SENS-501 clinical batches at 200L scale. The production will enable the Company to cover the needs for the envisioned Phase 1/2 gene therapy clinical trial.

Following the positive feedback from Scientific Advice meetings with regulatory agencies EMA (European Medicines Agency), ANSM (French National Agency for Medicines and Health Products Safety) and the UK's MHRA (Medicines and Healthcare product Regulatory Agency), Sensorion has submitted a Clinical Trial Application (CTA) to initiate a Phase 1/2 clinical trial of SENS-501 to the UK's MHRA on July 10, 2023, and in Europe on July 19, 2023. In parallel, Sensorion submitted a Medical Device Application for the injection system.

On January 19, 2024, Sensorion announced the approval to initiate the Phase 1/2 clinical trial of SENS-501, Audiogene, in Europe (France as first country). The CTA approval follows extensive preclinical studies assessing the safety and efficacy of SENS-501 and successful GMP 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. Audiogene will also assess the clinical safety, performance, and usability of the administration device system under development in partnership with EVEON. The design of the study will consist of two cohorts at two different doses followed by an expansion cohort at the selected dose. While the safety will be the primary endpoint for the dose escalation cohorts, the auditory brainstem response (ABR) will be the primary efficacy endpoint of the dose expansion cohort.

Sensorion will communicate on the first patient in the course of H2 2024 and expects the recruitment completion of the first two cohorts of patients in H1 2025.

- **GJB2-GT: Moving forward towards Clinical Trial Applications submission in Q2 2025**

Sensorion's GJB2 gene therapy program, initiated in 2021 and developed in collaboration with the 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.

On April 6, 2023, Sensorion announced the candidate selection for GJB2-GT during its gene therapy focused R&D Day. The candidate designed with a specific adeno-associated virus (AAV) capsid safely targets key cells in the ear that normally express GJB2.
Sensorion has acquired bioreactors and has completed the non-GMP process development of the GJB2 candidate up to 50L scale. Process and analytical methods will be transferred to the CDMO selected by the Company for the GMP production of the clinical batch. Sensorion is advancing the candidate into IND/CTA

[1] Rodríguez-Ballesteros M, Reynoso R, Olarte M, Villamar M, Morera C, Santarelli R, Arslan E, Medá C, Curet C, Völter C, Sainz-Quevedo M, Castorina P, Ambrosetti U, Berrettini S, Frei K, Tedín S, Smith J, Cruz Tapia M, Cavallé L, Gelvez N, Primignani P, Gómez-Rosas E, Martín M, Moreno-Pelayo MA, Tamayo M, Moreno-Barral J, Moreno F, del Castillo I. 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.

enabling activities for future clinical development and anticipates the submission of the Clinical Trial Applications in Q2 2025.

**SENS-401: Sensorion's small molecule for the prevention of hearing loss**

SENS-401(Arazasetron) is an orally available small molecule that aims to protect and preserve inner ear tissue from damage responsible for 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.
Sensorion is developing SENS-401 in two Proof of Concept (POC) Phase 2a clinical trials. The first one is designed to assess SENS-401 for residual hearing preservation during cochlear implantation in partnership with Cochlear Limited (Cochlear), the global leader in implantable hearing solutions, and the second one is a trial assessing SENS-401 in Cisplatin-Induced Ototoxicity prevention (CIO) in adult patients undergoing a cisplatin-based chemotherapy.

- **SENS-401 to prevent residual hearing loss after cochlear implantation. Milestone achieved with primary endpoint met. Final data readout planned in Q3 2024**

Sensorion is developing SENS-401 in a multicentric, randomized, controlled open-label Phase 2a clinical 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 continue to receive SENS-401 for a further 42 days after implantation.

In June 2023, Sensorion released preliminary data from its Phase 2a study, showing that SENS-401 was detected in the perilymph of all five adult patients treated with the product. Levels of SENS-401 were considered consistent with potential therapeutic effects after seven days of repeated oral treatment.

In July 2023, the Company reported further analysis during its KOL webinar suggesting that SENS-401 treated patients demonstrated a clinically significant 21 dB improvement in the preservation of their residual hearing compared to the control group six weeks after cochlear implantation at 500 Hz. Indeed, in the SENS-401-treated group (N=5), the loss of residual hearing was only 12 dB, contrasting with a larger loss of 33 dB observed in the control group of four participants not treated with SENS-401. These findings reinforce the hypothesis that SENS-401, by crossing the labyrinthine barrier to reach the cochlear compartment, has a positive effect on the preservation of residual hearing.

On February 1, 2024, Sensorion announced the completion of patient inclusion in the Phase 2a POC clinical trial, with 28 patients recruited in the study in total. Following this announcement, Sensorion communicated on March 11, 2024, that a total of 28 patients have been randomized and 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. The study is now completed, the follow-up of the last patients is still ongoing and the secondary endpoints including results on the preservation of the residual hearing will be available and analyzed later this year. The Company plans to publish the complete readout of the study in Q3 2024.

- **SENS-401 to prevent Cisplatin Induced Ototoxicity (CIO) progressing as planned with efficacy and safety preliminary data expected in September 2024**

Cisplatin and other platinum compounds are essential chemotherapeutic agents for many malignancies. Unfortunately, platinum-based therapies cause ototoxicity and hearing loss, which are permanent, irreversible and particularly harmful in about 60% of adult and pediatric patients treated. 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.

SENS-401 is progressing in NOTOXIS, a multicenter, randomized, controlled, open-label Phase 2a clinical study, designed to evaluate the efficacy of SENS-401 to prevent CIO in adult patients with a neoplastic disease four weeks after the completion of cisplatin-based chemotherapy. The trial assesses several outcome

measures, including the rate and severity of ototoxicity, the change from baseline in Pure Tone Audiometry (PTA) (dB) throughout the study and the tolerance.

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 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.

In December 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 consistent with previously reported data for patients exposed for up to 7 weeks.

Recruitment is progressing at a sustained path, with eleven clinical centers open as of December 18, 2023. Sensorion's management team will communicate preliminary efficacy and safety data of the POC Phase 2a clinical study of SENS-401 in CIO during the World Congress of Audiology, held on September 19-22, 2024, in Paris, France.

## Strengthening the Board of Directors and senior leadership

On March 31, 2023, Sensorion appointed Khalil Barrage as interim Chairman of the Board. Mr. Barrage has served on the Board of Sensorion for over three years, supporting with several capital raises and providing leadership on the Company's evolution towards becoming a gene therapy-focused company. He has been a managing director at Invus Group, a major investor in Sensorion, for nearly 20 years, heading its Public Equity group and serves on the Boards of Elevate Bio, Valerio Therapeutics, Orthobond and Protagenic Therapeutics.

On August 3, 2023, following the completion of the private placement, Redmile Group (represented by Natalie Berner) became a board member in replacement of Bpifrance Investissement, whose permanent representative was Jean-François Morin.

On December 12, Sensorion announced the appointment of CMC (Chemistry, Manufacturing and Control) expert Bernd Schmidt as Chief Technical Officer. He brings over 20 years of industry experience in the pharmaceutical sector, covering a broad range of innovative medicines at different stages in development and post launch.

On January 25, 2024, Sensorion announced the nomination of Dr. Federico Mingozzi as Non-Executive Director to the Board of Directors. Mr. Mingozzi brings over 25 years of experience in gene therapy, immunology, as well as biochemistry and molecular biology in academia and industry.

## 2024 Outlook

As of December 31, 2023, the Company had €37.0 million in cash and cash equivalents. Based on this cash position, the net proceeds from the €50.5 million financing announced on February 9, 2024, and its forecasted expenses, the company expects it will be able to finance its operations up until the end of Q2 2025.

In 2024, Sensorion plans on pursuing developments across its portfolio of innovative programs with the aim of treating, restoring and preventing hearing disorders and improving the quality of life of patients suffering from hearing disorders. The Company plans to communicate about the first patient enrolled in Audiogene, its Phase 2a clinical trial of its gene therapy product, SENS-501, in H2 2024. The Company is on track to submit Clinical Trial Applications for its second gene therapy, GJB2-GT, in H1 2025, with ongoing IND/CTA-enabling preclinical activities. In parallel, SENS-401, Sensorion's orally available small molecule, is progressing in two Phase 2a clinical trials. Final data readout is expected in Q3 2024 for its trial of SENS-401 in the prevention of residual hearing loss following cochlear implantation, and preliminary safety and efficacy are expected in September 2024 during the World Congress of Audiology for its second ongoing clinical trial of SENS-401, in the prevention of Cisplatin-Induced Ototoxicity.

**Expected next clinical milestones:**

- Q3 2024 – SENS-401 in combination with cochlear implantation: Final data readout
- H2 2024, World Congress of Audiology – SENS-401 in Cisplatin-Induced Ototoxicity: Preliminary safety and efficacy data
- H2 2024 – SENS-501: First patient communication
- H1 2025 – SENS-501: Enrollment of the first two cohorts of Phase 1/2 Audiogene trial completed
- Q2 2025 – GJB2-GT: Clinical Trial Applications Submission

## Full Year 2023 financial highlights

- **Cash Position**

Cash & Cash Equivalents amounted to €37.0 million as at December 31, 2023, compared to €26.2 million at December 31, 2022.

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

R&D expenses decreased by 0.7 % from €22.9 million in 2022 to €22.8 million in 2023.

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

G&A expenses were €5.3 million for 2023, compared to €5.2 million for 2022.

- **Net Loss**

Net loss was -€22.1 million for 2023, compared to -€23.2 million for 2022.

- **Financial guidance**

Based on cash and cash equivalents of €37.0 million at 31 December 2023, and the net proceeds of a €50.5 million offering of new shares announced on February 9, 2024, amounting to c. €47 million, the Company has sufficient net working capital to meet its cash requirements beyond the next twelve months, i.e. until the end of Q2 2025.

## Financial results

The annual accounts as at December 31, 2023, were prepared according to IFRS standards and approved by the Board of Directors on March 13, 2024.

The simplified income statement as of December 31, 2023, is as follows:

| *In thousands of Euros – IFRS standards* | **31.12.2023** | **31.12.2022** |
|---|---|---|
| **Operating income** | **5,698** | **5,006** |
| Research & Development expenses | -22,756 | -22,925 |
| General & Administrative expenses | -5,252 | -5,217 |
| **Total operating expenses** | **-28,008** | **-28,142** |
| **Operating loss** | **-22,310** | **-23,137** |
| Financial result | 544 | -72 |
| Corporate Income Tax | -297 | 0 |
| **Net loss** | **-22,063** | **-23,209** |

The simplified balance sheet at December 31, 2023, is as follows:

| *In thousands of Euros – IFRS standards* | **31.12.2023** | **31.12.2022** |
|---|---|---|
| **Non-current Assets** | **3,236** | **3,176** |
| Other Current Assets | 6,293 | 9,565 |
| Cash & cash equivalent | 36,974 | 26,204 |
| **Total Assets** | **46,503** | **38,945** |
| **Equity** | **33,276** | **21,885** |
| Non-current Liabilities | 2,950 | 3,467 |
| Current Liabilities | 10,278 | 13,593 |
| **Total Liabilities** | **46,503** | **38,945** |

**2023 certified accounts**

On March 13, 2024, the Board of Directors approved the Company's full year results as of December 31, 2023. The Full Year Financial Report can be found on Sensorion's website (https://www.sensorion.com/en/home/) in the investor section under financial information. The full year accounts of 2023 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. 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) targets deafness caused by mutations of the gene encoding for otoferlin and is currently developed in a Phase 1/2 clinical study, 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 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

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

**Press Relations**
Ulysse Communication
Pierre-Louis Germain / +33 (0)6 64 79 97 51
plgermain@ulysse-communication.com
Bruno Arabian / +33(0)6 87 88 47 26
barabian@ulysse-communication.com

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

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