Press release

Sensorion Reports Full-Year 2022 Financial Results and Business Update

- ***CTA filing for OTOF-GT planned for Q2 2023***
- ***Presented new preclinical data supporting continued progress of OTOF-GT, and potential for safe and efficient clinical translation of gene therapy for otoferlin delivered by a dual AAV vector at the 45th Association for Research in Otolaryngology (ARO)***
- ***Promising results obtained in Proof-of-Concept studies supporting the identification of a GJB2-GT therapeutic candidate***
- ***Preliminary results from Phase 2a trials of SENS-401 for hearing loss prevention due to Cisplatin-Induced Ototoxicity and cochlear implantation in Q2 2023***
- ***Cash position of €26.2 million at year end provides extended cash runway until end of 2023***
- ***Strengthened company leadership with the appointments of David Lawrence as Chief Financial Officer and Dr Aniz Girach as an Independent Board Director***
- ***Sensorion will hold an R&D Day, focused on its gene therapy programs, on April 6, 8am (2pm CEST). The event will be held at the Hearing Institute (Institut de l'Audition), an Institut Pasteur center in Paris, France. A live webcast and a replay of the presentation will be made available.***

Montpellier, March 16, 2023 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company which specializes in gene therapies in the inner ear, announces today its full-year 2022 financial results and provides a business update.

Nawal Ouzren, Chief Executive Officer commented: "During the year, Sensorion has put the foundations in place for a pioneering franchise in gene therapy for hearing loss disorders which we believe will support clinical development plans later this year and beyond. We're incredibly excited about the potential of our gene therapy franchise and programs, which builds on our ongoing collaboration with Institut Pasteur, to provide solutions for people with genetic hearing loss disorders.

"Our lead gene therapy candidate OTOF-GT has promising preclinical data and we are on track to submit a Clinical Trial Application in Q2 2023. We are also making encouraging progress with the identification of our GJB2-GT therapeutic candidate.

"We are now on the threshold of advancing our gene therapy programs into clinical development and have a unique opportunity to help redefine the treatment landscape for people with hearing loss disorders. We also anticipate reporting preliminary data from our Phase 2a SENS-401 studies in mid-2023. Our focus is now on execution and capital discipline to deliver on our key catalysts."

Pipeline Highlights and Upcoming Milestones

Gene Therapies for Hereditary Monogenic Hearing Loss

- **OTOF-GT: continued progress with positive regulatory support**

OTOF-GT is Sensorion's lead gene therapy program for the treatment of children born with hearing loss caused by otoferlin deficiency.

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

conference, held in February 2022. Otoferlin *de novo* expression in inner hair cells (IHCs) in a DFNB9 mouse model (OTOF-KO) demonstrates long-term expression and hearing restoration for at least one year post injection. Sensorion has also developed, in non-human primates, an optimal surgical procedure close to the one used for cochlear implantation and demonstrated an effective transduction rate of the targeted IHCs.

Sensorion announced in January 2023 that it is designing and developing the injection system to administer gene therapy into the cochlea. This injection system used in the Non-Human Primate (NHP) GLP (Good Laboratory Practices) toxicology study is compliant with the defined specifications, notably those related to performance. Verification and validations steps are ongoing to allow the injection system's use in clinics. Sensorion is collaborating with Eveon, a company specialized in designing and manufacturing custom medical devices for the preparation and delivery of drugs to optimise this approach.

Sensorion achieved a development milestone in mid-2022, by successfully producing dual AAV OTOF-GT batches at 200L clinical scale to conduct the GLP (Good Laboratory Practice) toxicology study in NHPs. The in-life part of the study has been completed and analyses are ongoing.

Sensorion has also achieved significant regulatory milestones in H2 2022 which support the medical plausibility and the development plan of OTOF-GT. On September 12, 2022, the Company announced that the European Medicine Agency (EMA) had adopted a positive opinion on Sensorion's application for Orphan Drug Designation (ODD) for OTOF-GT, which was approved 30 days later by the European Commission. On November 7, 2022, the Company announced that the US Food and Drug Administration (FDA) granted, Rare Pediatric Disease Designation (RPDD) and on November 30, 2022, Orphan Drug Designation to Sensorion's lead gene therapy candidate, OTOF-GT. Sensorion has received scientific advice from regulatory agencies on preclinical, CMC and clinical development plans for OTOF-GT in Q3 2021 and in Q2 2022. The company submitted a follow-up scientific advice to the EMA in H1 2023 and expects feedback in the following weeks.

The European Medicines Agency's advisors welcomed the ongoing Natural History Study, Audioferline (NCT04202185), a component of the AUDINNOVE project coordinated by Hôpital Necker-Enfants Malades (Necker Hospital) in partnership with Sensorion (Project ANR-18-RHUS-0007). Sensorion is expanding the study across Europe to document the natural course of disease progression in otoferlin deficiency patients and to select the most relevant and clinically meaningful endpoints. The company is on track to file a Clinical Trial Application for OTOF-GT in Q2 2023.

- **GJB2-GT program progressing with promising pre-clinical results**

On February 15, 2021, Sensorion announced its largest gene therapy program to date, a collaboration with Institut Pasteur, targeting the *GJB2* gene in pediatric and adult deafness. Research by Institut Pasteur demonstrated that anomalies in *GJB2* gene, known to be the most common cause of congenital deafness, are also a broad contributor to severe age-related hearing loss in adults. Although the types of *GJB2* mutation in children and adults may differ, gene therapy could potentially provide solutions for both.

Sensorion's GJB2 gene therapy programs have 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.

Proof-of-Concept (POC) studies have confirmed the potential of Sensorion's promising product candidate to improve congenital and progressive hearing loss forms related to *GJB2* mutations in a mouse model recapitulating both human conditions. Sensorion plans to confirm the candidate selection based on the POC results in H1 2023.

SENS-401, our small molecule for the prevention of hearing loss

- **SENS-401 to prevent Cisplatin Induced Ototoxicity (CIO) study ongoing**

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 up 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 POC clinical trial application in CIO to evaluate the potential of SENS-401 treatment. The NOTOXIS clinical trial application (CTA) has been approved earlier in 2022. Following extensive analysis of the AUDIBLE-S study data beginning of 2022, Sensorion has adapted the design of this trial to focus on the prevention of hearing loss. The amended Phase 2a POC Clinical Trial of SENS-401 in Cisplatin-Induced Ototoxicity was approved in France on October 24, 2022.

The exploratory Phase 2a, multicenter, randomized, controlled, open-label study, NOTOXIS, aims at evaluating the efficacy of SENS-401 to prevent ototoxicity induced by cisplatin in adult patients with a neoplastic disease. The trial also assesses a number of outcome measures, including the rate and severity of ototoxicity, the change in Pure Tone Audiometry (PTA) (dB) throughout the study and the tolerance.

The first patient was enrolled in December 2022 and Sensorion anticipates preliminary results in Q2 2023.

- **SENS-401 to prevent residual hearing loss after cochlear implantation study ongoing**

At the beginning of 2021, Sensorion released positive preclinical data demonstrating that the combination of its SENS-401 molecule and a cochlear implantation helped reduce loss of residual hearing at a frequency located beyond the electrode array. Preservation of 'natural' hearing is particularly important in speech recognition.

Following this initial success, Sensorion and its partner Cochlear Limited (Cochlear) announced on September 8, 2021, the initiation of a POC clinical trial of SENS-401 (Arazasetron) in patients scheduled for cochlear implantation. Regulatory authorities in Australia and France have respectively approved the initiation of the trial on July 1, 2022, and on October 24, 2022.

The Phase 2a trial is a multicentric, randomized, controlled, open-label trial aimed at evaluating the presence of SENS-401 in the cochlea (perilymph) after 7 days of twice-daily oral administration in adult participants prior to cochlear implantation due to moderately severe to profound hearing impairment. 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.

The first patient was enrolled in September 2022 and the Company expects to release preliminary data in mid-2023.

Expansion of technology platform

In 2022, to further strengthen its technology base, Sensorion has expanded its CMC (Chemistry, Manufacturing and Control) gene therapy platform. The Company has acquired bioreactors (2L, 10L and 50L scale) to develop the AAV process in suspension and automates to increase the throughput analysis for process and product characterization.

This great achievement strengthens Sensorion's autonomy in process and analytical development and eases technology transfer to CDMOs.

Corporate Highlights:

Strengthening the Board of Directors and senior leadership

On January 4, 2022, Sensorion appointed Dr. Aniz Girach as Independent Board Member. He brings over 22 years' experience in the industry. He is currently serving as Chief Medical Officer at ProQR Therapeutics NV, where he is leading the development of genetic therapies for inherited retinal diseases.

On March 1st, 2023, after the period end, Sensorion appointed David Lawrence as Chief Financial Officer. Mr Lawrence has over 30 years' experience of leadership roles in life sciences, ranging from large biopharma companies such as GSK to start-ups and earlier stage companies. He brings extensive industry experience

including strategy, business development and M&A, and currently sits on the Boards of Enterobiotix Limited and is an advisor to ACM Biolabs Pty.

2023 Outlook

As of December 31, 2022, the Company had €26.2 million in cash. Based on its cash position and its forecasted expenses, the Company believes it will be able to fund its operations up to the end of 2023.

Sensorion is on track to file a Clinical Trial Application for OTOF-GT in Q2 2023 and to select a gene therapy candidate to treat hearing loss related to mutations in *GJB2* gene in collaboration with the Hearing Institute (Institut de l'Audition), a center of the Institut Pasteur. The company expects the publication of its ongoing clinical trials' interim results of SENS-401 in association with cochlear implants to prevent residual hearing loss, with partner Cochlear, and to prevent Cisplatin-Induced Ototoxicity in 1H 2023.

Expected future milestones and estimated timelines:

- April 6, 2023 – Sensorion to host a Gene Therapy R&D day
- Q2 2023 – SENS-401 in combination with cochlear implants: Interim results
- Q2 2023 – SENS-401 CIO: Interim results
- Q2 2023 – OTOF-GT: Submission of the Clinical Trial Application (CTA)
- Q2 2023 – GJB2-GT: Candidate selection

2022 financial results

The annual accounts at December 31st, 2022, drawn up according to IFRS standards and approved by the Board of Directors on March 15th, 2023[1].

The simplified income statement as of 31 December 2022 is as follows:

In Euros – IFRS standards	**31.12.2022**	**31.12.2021**
Operating income	**5.005.515**	**4.348.647**
Research & Development expenses	-22.924.960	-14.623.652
General & Administrative expenses	-5.217.203	-4.749.593
Total operating expenses	**-28.142.143**	**-19.373.245**
Operating loss	**-23.136.648**	**-15,024,597**
Financial result	-72.442	-112.192
Net loss	**-23.209.090**	**-15.136.789**

[1] The audit procedures on individual and consolidated financial statements have been carried out. The audit reports will be issued after completion of the procedures required for the publication of the annual financial report.

For the year ended 31st December 2022, Sensorion reported **operating income** of €5.0 million, which included €3.9 million in research tax credit (including €3.7m in France and €0.2m in Australia) and €1.0 million in grants from the Audinnove[2] (RHU), and Patriot[3] (PSPC) collaborations.

Operating expenses increased by 45% from €19.4 million in 2021 to €28.1 million for fiscal year 2022. In 2022, our R&D expenses and General & Administrative expenses account approximately for 81% and 19% respectively of our operating expenses, against 75% and 25% respectively in 2021.

- **R&D expenses** increased by 57% from €14.6 million in 2021 to €22.9m in 2022. The increase was primarily due to increased efforts in OTOF-GT CTA-enabling studies including increased costs in preclinical and in manufacturing.

- **G&A expenses** are up 10% from €4.8m in 2021 to €5.2 million in 2022, due mostly to an increase in headcount in order to support the growth of R&D activities.

Operating loss at 31 December 2022 was -€23.1 million compared with -€15.0 million at 31 December 2021.

The net financial loss decreased by €0.04 million compared to 2021, mainly due to an increase in financial income.

Net loss was -€23.2 million at 31 December 2022 compared with -€15.1 million at 31 December 2021.

As of 31 December 2022, the company employed 46 people.

Financial structure

The simplified balance sheet at December 31st, 2022 is as follows:

In Euros – IFRS standards	**31.12.2022**	**31.12.2021**
Non-current Assets	**3.175.915**	**2.142.885**
Other Current Assets	9.565.307	6.946.055
Cash & cash equivalent	26.203.905	50.001.110
Total Assets	**38.945.127**	**59.090.050**
Equity	**21.885.121**	**44.055.803**
Non-current Liabilities	3.467.116	4.504.691
Current Liabilities	13.592.890	10.529.556
Total Liabilities	**38.145.127**	**59.090.550**

Non-current assets increased by €1.0 million mainly due to investments in equipment for manufacturing.

Other current assets increased by €2.6 million mainly due to the increase of research tax credit expected for 2022 which amounts €3.9 million and a decrease in prepaid expenses.

[2] Audinnove is a project coordinated by Hôpital Necker-Enfants maladies to develop new diagnostic and therapeutic approaches for congenital deafness (Project ANR-18-RHUS-0007). The consortium includes AP-HP, the Pasteur Institute, the Hearing Foundation and Sensorion

[3] The "PATRIOT" consortium (PSPC14 – n°2019), of which Sensorion is the leader, also involves the Institut de recherche biomédicale des Armées en anglais?, the Institut Pasteur and the company Electronique du Mazet. This project aims to protect and preserve inner ear tissue from damage that could lead to deafness.

Cash and cash equivalents amounted to €26.2 million at 31 December 2022 compared to €50.0 million at December 31st, 2021.

Total equity amounted to €21.9 million as of December 31st, 2022 compared to €44.1 million at December 31st, 2021; this decrease of -€22.2 million is mainly related to the net loss of -€23.2 million for the period.

Current liabilities increased by €3.1 million mainly explained by an increase in R&D expenses.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of gene therapies to restore 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. OTOF-GT 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 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.
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