Press Release

Sensorion Reports Independent Data Monitoring Committee Raises No Safety Concerns and Agrees to Continue SENS-501's Audiogene Phase 1/2 Trial

Montpellier, December 8th, 2025, 7.30 am CET – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company specializing in the development of novel therapies to restore, treat and prevent hearing loss disorders, today announced that the Data Monitoring Committee (DMC) supports the continuation of the Audiogene Phase 1/2 clinical trial of SENS-501, the Company's gene therapy program being developed to treat a specific form of congenital deafness linked to mutations in the OTOF (otoferlin) gene. Based on the DMC's safety observations to date which include good procedural tolerance, the Committee has raised no safety concerns.

The Audiogene trial is designed to evaluate the safety, tolerability and efficacy of intra-cochlear administration of SENS-501 for the treatment of OTOF gene-mediated hearing loss in paediatric patients aged 6 to 31 months at the time of treatment. By intervening during the critical early window of brain plasticity and enrolling infants who have not yet received a cochlear implant, the study aims to isolate the therapeutic effect of SENS-501 as monotherapy. The trial consists of two sequential dose-escalation cohorts, each involving unilateral injection to allow a clear assessment of the kinetics of hearing restoration. Moreover, Audiogene aims to evaluate the usability, the clinical and the technical performances of the injection system in development.

On December 4th, the DMC reviewed the first part of the SENS-501 Audiogene Phase 1/2 clinical trial including cohort 2 which completed enrolment in July 2025. This cohort includes three patients aged between 6 and 31 months who received the dose 2 of SENS-501 (4.5E11 vg/vector/ear). Across both the first and second cohorts, the surgical procedure was well tolerated, and intra-cochlear administration of SENS-501 was uneventful, and no serious adverse events or serious side effects have been reported.

"*The safety findings combined with the early efficacy signals observed so far in infants and toddlers support further clinical investigation of SENS-501*," **said Nawal Ouzren, Chief Executive Officer of Sensorion**. "*Treating otoferlin-mediated congenital deafness before cochlear implantation and during heightened neural plasticity is essential to fully evaluate the potential of gene therapy as a monotherapy. We will continue to generate rigorous and comprehensive data to guide development decisions for this important patient population*."

In children with age and baseline hearing characteristics comparable to those reported in recent publications, Sensorion has observed in the second cohort early directional improvements in two of the three treated patients by Month 3 on pure-tone audiometry. At Month 3, Patient 4 demonstrated a behavioural threshold of approximately 60 dB HL at the best-performing frequency, while Patient 5 demonstrated approximately 70 dB HL at the best-performing frequency. Follow-up is ongoing to assess the durability of these effects and the potential for further clinically meaningful functional gains.

The Company will review the upcoming six-month efficacy data and will communicate during Q1 2026 once the dataset has reached sufficient maturity.

Press Release

About SENS-501

SENS-501 (OTOF-GT) is an innovative gene therapy program developed to treat a specific form of congenital deafness linked to mutations in the OTOF (otoferlin) gene. This gene plays a key role in the transmission of auditory signals between the hair cells of the inner ear and the auditory nerve. When this gene is defective, affected individuals are born with severe to profound hearing loss. The aim of SENS-501 (OTOF-GT) is to restore hearing by introducing a functional copy of the OTOF gene directly into hair cells via viral vector technology (AAV). This therapy aims to restore the normal process of converting sound into electrical signals, enabling patients to regain their hearing ability. Currently in the clinical research phase, this gene therapy program represents significant hope for families affected by this rare form of genetic deafness. SENS-501 (OTOF-GT) embodies a commitment to scientific innovation in the field of hearing, with the potential to dramatically improve the quality of life of patients suffering from genetic deafness. This gene therapy for patients suffering from otoferlin deficiency has been developed in the framework of RHU AUDINNOVE, a consortium composed of Sensorion with the Necker Enfants Malades Hospital, the Institut Pasteur, and the Fondation pour l'Audition. The project is partially financed by the French National Research Agency, through the "investing for the future" program (ref: ANR-18-RHUS-0007). The OTOF gene targeted by the Audiogene trial was discovered in 1999 at the Institut Pasteur, by Prof. Christine Petit's team (Institut reConnect, Institut de l'Audition, Pasteur Institute), who also unraveled the pathophysiology of the corresponding deafness (DFNB9).

About the Audiogene 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 loss in infants and toddlers aged 6 to 31 months at the time of gene therapy treatment. By targeting the first years of life, when brain plasticity is optimal, the chances of these young children with pre-linguistic hearing loss acquiring normal speech and language are maximized. The study comprises two cohorts of two doses followed by an expansion cohort at the selected dose. While safety will be the primary endpoint of the first part of the dose escalation study, auditory brainstem response (ABR) will be the primary efficacy endpoint of the second part of the expansion. Audiogene will also evaluate the clinical safety, performance and ease-of-use of the delivery system developed by Sensorion.

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 programs of a clinical-stage small molecule, SENS-401 (Arazasetron), for the treatment and prevention of hearing loss disorders. Sensorion's small molecule progresses in a Phase 2 proof of concept clinical study of SENS-401 in Cisplatin-Induced Ototoxicity (CIO) for the preservation of residual hearing. Sensorion, with partner Cochlear Limited, has completed in 2024 a Phase 2a study of SENS-401 for the residual hearing preservation 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

Press Release

Contacts

Investor Relations
Sensorion
Nicolas Bogler, Investor Relations and Communication
ir.contact@sensorion-pharma.com

Press Relations
Maarc
Bruno Arabian / 00 33(0)6 87 88 47 26
bruno.arabian@maarc.fr
Nicolas Entz / 00 33 (0)6 33 67 31 54
nicolas.entz@maarc.fr

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

Disclaimer

This press release contains certain forward-looking statements concerning Sensorion and its business. Such forward looking statements are based on assumptions that Sensorion considers to be reasonable. However, there can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the 2024 full year report published on March 14, 2025, and available on our website and to the development of economic conditions, financial markets and the markets in which Sensorion operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Sensorion or not currently considered material by Sensorion. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Sensorion to be materially different from such forward-looking statements. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Sensorion shares in any country. The communication of this press release in certain countries may constitute a violation of local laws and regulations. Any recipient of this press release must inform oneself of any such local restrictions and comply therewith.