

Sensorion Receives Positive Recommendation from Data Monitoring Committee of SENS-501's Audiogene Phase 1/2 Clinical Trial

- **Committee recommends continuation of Audiogene after reviewing first cohort safety data**
- **Completion of Audiogene's second cohort enrollment on track for H1 2025**

Montpellier, February 21, 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) recommended 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.

Nawal Ouzren, Chief Executive Officer of Sensorion commented: "On behalf of the Sensorion team, I wish to thank the DMC members for their review of Audiogene's safety data generated to date and I am pleased with the Committee's recommendation to proceed with the trial without modifications."

The recommendation made by the DMC confirms the favourable safety profile of SENS-501 at the first dose level in children aged 6 to 31 months at the time of administration while the intra-cochlear administration was well tolerated. The Committee recommended that Audiogene proceeds as planned with the assessment of the second dose which is the escalation part of the trial. Sensorion announced the completion of recruitment of the first cohort of three patients (toddlers and infants aged 6 to 31 months) on December 27, 2024. Recruitment of the second cohort (three patients) is due to be completed by the end of the first half of 2025.

The Audiogene trial is designed to evaluate the safety, tolerability and efficacy of intra-cochlear injection of SENS-501 for the treatment of OTOF gene-mediated hearing loss in paediatric patients aged between 6 and 31 months at the time of gene therapy treatment. By targeting the first years of life, when brain plasticity is at its peak, the chances of these young children with pre-linguistic hearing loss of acquiring normal speech and language are maximised. The trial is comprised of two cohorts of two doses followed by an expansion cohort at the selected dose.

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).

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

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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, 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.

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