*Press release*

# Sensorion Reports Six-Month Update from the Audiogene Phase 1/2 Trial of SENS-501 and Advances GJB2-GT (SENS-601) Toward First-in-Human Clinical Development

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- **Six-month follow-up data from Cohort 2 of the Audiogene trial demonstrated sustained early efficacy signals, consistent with a dose-response relationship across cohorts; Sensorion is considering a third dose level, and will consult with regulatory authorities**

- **Clinical know-how built through Audiogene strengthens Sensorion's gene therapy platform as the Company advances the GJB2 program (SENS-601), which addresses the largest cause of genetic congenital deafness (CTA submission on track in H1 2026 and IND submission targeted by year-end 2026)**

- **Presenting GJB2-GT (SENS-601) preclinical data at the American Society of Gene & Cell Therapy (ASGCT) annual meeting in May 2026**

MONTPELLIER, France--(BUSINESS WIRE)-- Regulatory News:

**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 reported updated six-month efficacy data from Cohort 2 of the Audiogene Phase 1/2 clinical trial evaluating SENS-501, its gene therapy for the treatment of otoferlin-mediated congenital deafness, and provided a timeline update on the advancement of its GJB2-GT (SENS-601) gene therapy program toward clinical development in Europe and in the U.S.

The early directional improvements in pure-tone audiometry reported at Month 3 in two of three patients treated with the higher dose of SENS-501 (Cohort 2) were sustained at the six-month follow-up assessment. These findings build on observations from Cohort 1, where initial signs of auditory pathway activation were reported at a lower dose level, and are consistent with a dose-response relationship across the two cohorts. Across all six patients

treated in the dose-escalation phase, the surgical procedure and intra-cochlear administration of SENS-501 continued to be well tolerated, with no serious adverse events or serious side effects reported.

Based on the dose-response signal observed across the first two cohorts, the Company is considering a third dose level within the Audiogene trial framework and will consult with regulatory authorities as part of this evaluation, while continuing to monitor the evolving regulatory and competitive landscape for gene therapies in the hearing loss space.

“The Audiogene trial continues to generate consistent and informative data in a very young patient population. The sustained hearing signals observed at six months in children born with profound deafness, combined with the favorable safety profile and the reproducibility of the surgical procedure with our injection system across patients and dose levels, reinforce our confidence in the potential of gene therapy for genetic hearing loss” **said Pr. Natalie Loundon, Principal Investigator of the Audiogene trial.** “These results provide hope for families affected by otoferlin-mediated deafness, and the clinical expertise built through Audiogene will directly benefit patients with other monogenic forms of hearing loss who may benefit from similar gene therapy approaches in the future.”

“The data generated through Audiogene validates the key components of our gene therapy platform, from surgical delivery, and safety through dose escalation to the observation of a dose-response relationship,” **commented Amit Munshi, Chairman and Interim Chief Executive Officer of Sensorion.** "This growing body of clinical and procedural experience, together with the relationships we have built with leading clinical centers, regulatory agencies, and our partners, provides further confidence in the advancement of SENS-601, our potential first-in-human gene therapy program targeting GJB2-related hearing loss. Our strengthened financial position following the recent financing, anchored by Sanofi's strategic investment, positions the Company well to execute on this next phase of growth. Ultimately, our goal is to bring meaningful therapeutic options to the families and patients who today have no targeted treatment for genetic hearing loss, and we remain fully committed to this mission."

The 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 unravelled the pathophysiology of the corresponding deafness (DFNB9).

The Company intends to provide regular updates on the GJB2-GT (SENS-601) program as it advances toward the clinic, and will present preclinical safety, biodistribution and efficacy data for SENS-601 in a poster entitled "Safety, biodistribution and efficacy of SENS-601, an AAV-based gene therapy treatment candidate for the autosomal recessive non-syndromic deafness 1A (DFNB1A)" at the American Society of Gene & Cell Therapy (ASGCT) annual

meeting in May 2026 in Boston, USA.

GJB2 mutations represent the most common cause of genetic congenital deafness, responsible for approximately 50% of autosomal recessive non-syndromic hearing loss. Sensorion's SENS-601 program, developed in collaboration with the Institut Pasteur, targets this significant unmet need with an AAV-based gene therapy approach.

CTA-enabling studies are progressing well, and the program remains on track for CTA submission in H1 2026 and IND submission is targeted by year-end 2026. With a dual CTA/IND strategy targeting both European and U.S. regulatory pathways, SENS-601 is positioned to be the first gene therapy to enter clinical development for GJB2-related hearing loss.

**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 unravelled 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 GJB2-GT (SENS-601)**

GJB2-GT (SENS-601) is an innovative AAV-based gene therapy program developed in collaboration with the Institut Pasteur to treat hearing loss linked to mutations in the GJB2 gene, which plays a critical role in maintaining the ionic balance necessary for sound transduction in the inner ear. GJB2 mutations represent the most common cause of genetic congenital deafness, responsible for approximately 50% of autosomal recessive non-syndromic hearing loss. Recent research has also established that GJB2 mutations are found in early onset forms of severe presbycusis in adults, which appear to be monogenic potentially treatable by gene therapy. As such, GJB2-GT has the potential to address three distinct pathologies: paediatric congenital deafness, progressive forms of hearing loss in children, and early onset of presbycusis in adults.

With no approved gene therapy currently available for GJB2-related hearing loss, SENS-601 has the potential to be the first-in-human gene therapy addressing GJB2 mutations. CTA-enabling studies are progressing well and the program is on track for CTA submission during H1 2026.

**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 the 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 progressed in three Phase 2 proof of concept clinical study: firstly, in Cisplatin-Induced Ototoxicity (CIO) for the preservation of residual hearing, completed in Q1 2026. Secondly, with partner Cochlear Limited, a study of SENS-401 for the residual hearing preservation in patients scheduled for cochlear implantation, completed in 2024. Thirdly, a Phase 2 study of SENS-

401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in 2022.

**www.sensorion.com**

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