Press release

Sensorion Achieves Key Regulatory Milestones for SENS-601 for GJB2-related Hearing Loss and Selects Program as Lead Gene Therapy Candidate

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- **Clinical trial applications for SENS-601 (GJB2-GT) filed in Canada and France with Fast Track procedure granted by the French agency (ANSM)**
- **IND submission in the U.S. and submission in Australia targeted by year-end 2026**
- **SENS-601 originated utilizing gene therapy platform co-developed with the Institut Pasteur, addresses GJB2-related hearing loss, the most common cause of genetic deafness**
- **SENS-501 (OTOF-GT) discontinued and company resources focused on SENS-601; cash runway extended to the end of 2027**

MONTPELLIER, France & CAMBRIDGE, Mass.--(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 announced the selection of SENS-601 which addresses GJB2-related hearing loss as its lead program. A Clinical trial application has been filed in Canada and France to evaluate the safety, tolerability and efficacy of intra-cochlear administration of SENS-601, for the treatment of GJB2 gene-mediated hearing loss in paediatric patients. In conjunction with this milestone, Sensorion has decided to discontinue the clinical development activity for SENS-501 for OTOF-related hearing loss after conducting a strategic review of its therapeutic candidate pipeline and is consequently ending recruitment in the Audiogene trial.

Sensorion has recently submitted Clinical Trial Applications for SENS-601 (Hearconnex) in Canada, and in France, with Fast Track procedure granted by the French Agency (ANSM). The trial is intended to evaluate the safety, tolerability and efficacy of intra-cochlear administration of SENS-601, for the treatment of GJB2 gene-mediated hearing loss in pediatric patients. Hearconnex will also assess the clinical safety, performance and ease-of-use of

the delivery system developed by Sensorion. The submissions follow productive pre-submission alignment discussions with the regulatory authorities, and the Company has high confidence in the completeness and scientific quality of the dossier. The Fast Track procedure granted in France provides a significantly reduced assessment period compared to the standard pathway.

The IND submission with the FDA in the U.S. and the submission in Australia are on track by year-end 2026.

Fred Chereau, Chief Executive Officer of Sensorion, said: “On behalf of Sensorion, I wish to express our sincere gratitude to the patients and their families for their courage and trust, and to the investigators for their exceptional dedication in the Audiogene trial. In my early weeks at Sensorion, working closely with the Board, management team, and our scientific partners, I am confident that dedicating our gene therapy development resources to SENS-601 is the right strategic decision. GJB2-related hearing loss is the most common cause of genetic deafness, affecting a large patient population. The scientific, clinical, and operational foundation built through SENS-501 gives us a meaningful head start in advancing SENS-601 toward the clinic. With the regulatory progress announced today, built on years of dedicated work by our teams and the strength of our partnership with the Institut Pasteur – Institut reConnect/Institut de l’Audition, we are entering a genuinely exciting phase for the program and the Company, as SENS-601 is positioned to be among the leading gene therapies to enter clinical development for this debilitating hearing loss disorder. I am fully committed to executing on this opportunity and delivering on the promise of gene therapy for patients and families."

Christine Petit, Professor at Institut Pasteur – Institut reConnect/Institut de l’Audition, and Professor Emeritus at the Collège de France, laureate of the Kavli Prize in Neurosciences, said: “GJB2 mutations are the most common cause of genetic hearing loss, and the work we have conducted with Sensorion over many years has built a strong foundation for what I believe will be a pivotal program. We have generated extremely robust, comprehensive data demonstrating significant hearing restoration after SENS-601 administration, in clinically relevant animal models developed in our laboratories. I look forward to continuing this collaboration and to the prospect of providing patients with a meaningful therapeutic option. The scientific and clinical advances of Audiogene are directly guiding and increasing our confidence in SENS-601, confirming the very promising results my team first obtained in mice back in 2019. The rigor with which the multidisciplinary teams from the Institut Pasteur-Institut reConnect/Institut de l’Audition, Necker Enfants-Malades Hospital (AP-HP), the Fondation Pour l’Audition and Sensorion have conducted this program is a credit to everyone involved.”

OTOF-related hearing loss is an ultra-rare condition, and the recent availability of a gene therapy demonstrating meaningful clinical efficacy in this indication has notably changed the development environment for SENS-501. In this context, the Board and management concluded that concentrating Sensorion’s resources on SENS-601, where the unmet need is an order of magnitude larger and no approved therapy is currently available, is the right strategic

decision for the Company and its stakeholders. Sensorion extends gratitude to the clinical teams, investigators, and patients of the Audiogene trial for their contribution to advancing gene therapy for hearing loss. The scientific and operational platform built through this work, developed in close collaboration with Prof. Christine Petit's team (Institut reConnect, Institut de l'Audition, Institut Pasteur, Inserm, CNRS), are directly transferrable to SENS-601 and provide a unique and foundational head start for the program. In accordance with applicable regulatory requirements, Sensorion remains fully committed to ensuring the long-term follow-up of all patients enrolled in the Audiogene trial.

The cash runway is extended until the end of 2027, supporting the execution of the clinical advancement of SENS-601 and the generation of first in human data.

About SENS-601 (GJB2-GT)

SENS-601 (GJB2-GT) is an innovative AAV-based gene therapy program developed in collaboration with Prof. Christine Petit's team (Institut reConnect, Institut de l'Audition, Institut Pasteur, Inserm, CNRS) 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, SENS-601 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 among the first gene therapy addressing GJB2 mutations. This program is partially funded by the French State as part of the France 2030 investment plan (ConnexGene project, with Bpifrance).

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. 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, Institut Pasteur), who also unravelled the pathophysiology of the corresponding deafness (DFNB9).

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. SENS-601 (GJB2-GT) is the Company’s lead gene therapy program, targeting hearing loss related to mutations in the GJB2 gene to address important hearing loss segments in adults and children developed in the framework of its broad strategic collaboration focused on the genetics of hearing with the Institut Pasteur.

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

Press Relations
Maarc Communication
Bruno Arabian / 00 33(0)6 87 88 47 26
bruno.arabian@maarc.fr

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