



Sensorion Announces Approval of Clinical Trial Application in France for SENS-601, Its Investigational Gene Therapy for the Treatment of GJB2-Related Hearing Loss

- **Clinical trial authorization received from the French National Agency for Medicines and Health Products Safety (ANSM) on August 31, 2026, under the Fast Track assessment process, to initiate HearConnex, the Phase I/II clinical trial of SENS-601 in France**
- **HearConnex site start-up activities in France are underway, with dosing of the first patient targeted by early 2027 and clinical data generation expected throughout 2027**
- **Sensorion to host an online event, SENS-601 Program Day, with Prof. Christine Petit and Dr. Sharon Cushing on September 22, 2026**

Montpellier (France) and Cambridge, MA (United States), September 3, 2026, 7:30 am CET – Sensorion (FR0012596468 – ALSEN) (“the Company”) a pioneering clinical-stage biotechnology company focused on developing novel therapies to restore hearing and treat and prevent hearing loss disorders, today announced that it has received authorization from the ANSM to initiate HearConnex, a Phase I/II clinical trial of SENS-601, the Company’s lead gene therapy candidate for GJB2-related hearing loss, in France. Pathogenic variants in the GJB2 gene are among the most common causes of genetic deafness and no treatment addressing the underlying cause is approved today. The HearConnex authorization was obtained at the conclusion of ANSM’s Fast Track assessment procedure, which provides for a significantly reduced review period relative to the standard pathway.

HearConnex is designed as a two-part, open-label study. Part 1 will assess the safety and tolerability of SENS-601, following unilateral intra-cochlear administration across two ascending-dose cohorts. Part 2 will assess the efficacy of SENS-601 in an expansion cohort following bilateral intra-cochlear administration at the selected dose. HearConnex will also assess the safety, tolerability, performance and usability of Sensorion's injection system. Additional information regarding the trial will be communicated during the SENS-601 Program Day.

The Clinical Trial Application (CTA) approval follows extensive work conducted over many years in collaboration with Prof. Christine Petit's team at Institut Pasteur – Institut de l'Audition/Institut reConnect, which has generated robust data demonstrating significant hearing restoration following SENS-601 administration in clinically relevant animal models developed in Prof. Petit's laboratory. These findings have been complemented by a comprehensive preclinical package assessing the toxicology and activity of SENS-601, alongside successful GMP manufacturing of the gene therapy Drug Product for the clinical trial.

Following this authorization, Sensorion is initiating activities at sites in France, with the objective of dosing the first HearConnex patient by early 2027. Clinical data from the trial are expected to be generated throughout 2027.

HearConnex is designed as a multi-regional trial, and its Coordinating Investigator is Dr. Sharon Cushing, Pediatric Otolaryngologist and Director of the Cochlear Implant Program at The Hospital for Sick Children (SickKids) in Toronto, who will also serve as Principal Investigator for the Canadian site, subject to completion of the ongoing review.

The review by Health Canada of the CTA submitted in Canada in June 2026 also remains on track. Sensorion is targeting the submission of a CTA in Australia and submission of an Investigational New Drug (IND) application in the U.S. by year end 2026.

Fred Chereau, Chief Executive Officer of Sensorion, said: *"Securing approval to initiate HearConnex marks a significant milestone for Sensorion and, above all, for the children and families affected by congenital DFNB1A hearing loss, for whom no treatment addressing the underlying biological cause of the disease exists today. It reflects the depth of the science built over many years with our partners at the Institut Pasteur–Institut de l'Audition/Institut reConnect, as well as the overall quality of the dossier assembled by our multidisciplinary teams. We look forward to continuing to work with investigators, regulatory authorities and patient advocacy groups as we open the first clinical site in France and complete our remaining submissions in other jurisdictions."*

Professor Natalie Loundon, M.D., Director of the Center for Research in Pediatric Audiology, Pediatric Otolaryngologist and Head and Neck Surgeon, Necker Enfants Malades, AP-HP, in Paris, France, and Principal Investigator of the HearConnex clinical trial in France, said: *"Children born with GJB2-related hearing loss, and their families, hope for additional therapeutic options that address the underlying cause of the condition. Bringing gene therapy into the clinic for this population requires a highly specialized surgical and audiological environment, and the teams involved have built this experience over the years notably through the course of our Audiogene clinical trial. We are glad to take part in HearConnex from the outset and to contribute to a rigorous evaluation of SENS-601 in this patient population."*

Dr. Sharon Cushing, M.D., Pediatric Otolaryngologist and Director of the Cochlear Implant Program at The Hospital for Sick Children (SickKids) in Toronto, and Coordinating Investigator of the HearConnex clinical trial, said: *"We are entering an important new chapter in the treatment of hearing loss, one that carries both excitement and important scientific questions still to be answered. With the courage and trust of the patients and families who take part in HearConnex, we look forward to learning as the program advances, and to the insights this trial will generate."*

SENS-601 Program Day, September 22, 2026

Sensorion will host a SENS-601 Program Day on September 22, 2026. The event will be held online and will be dedicated to the SENS-601 program, covering the underlying science and patient population as well as, the design and endpoints of the HearConnex trial. Two external speakers will participate: Prof. Christine Petit, Geneticist and Neuroscientist, Professor at Institut Pasteur–Institut de l'Audition/Institut reConnect, Professor Emeritus at the Collège de France and laureate of several international prizes including the Kavli Prize in Neuroscience, and Dr. Sharon Cushing, Pediatric Otolaryngologist and Director of the Cochlear Implant Program at The Hospital for Sick Children (SickKids) in Toronto, Coordinating Investigator for HearConnex. They will be joined by members of Sensorion's management team. Full details, including the program and registration, will be published on the Company's website at www.sensorion.com.

About SENS-601 (GJB2-GT)

SENS-601 (GJB2-GT) is an innovative investigational 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 loss¹. Recent research has also established that *GJB2* mutations are found in early onset forms of severe presbycusis in adults, which appear to be monogenic and potentially treatable by gene therapy. SENS-601 is currently being evaluated in HearConnex in children with congenital DFNB1A hearing loss. With no approved gene therapies currently available for GJB2-related hearing loss, SENS-601 may have the potential to be among the first gene therapy programs addressing GJB2 mutations, if approved. This program is partially funded by the French State as part of the France 2030 investment plan (ConnexGene project, with Bpifrance).

¹ Institut Pasteur, Boucher et al. 2020



About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore hearing, and 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 pipeline also consists of a clinical-stage small molecule program, SENS-401 (Arazasetron), for the treatment and prevention of hearing loss disorders. Sensorion's small molecule progressed in three Phase II proof of concept clinical studies: 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 II study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in 2022.

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