Press release

Sensorion receives positive opinion for Orphan Drug Designation for OTOF-GT for the treatment of otoferlin gene-mediated hearing loss from the European Medicine Agency

Montpellier, September 12, 2022 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, announces that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has adopted a positive opinion on Sensorion's application for Orphan Drug Designation (ODD) for its lead therapy gene candidate, OTOF-GT, a gene therapy intended for the treatment of otoferlin gene mediated hearing loss. OTOF-GT meeting the criteria for ODD, the European Commission will issue a decision within 30 days of receipt of the COMP positive opinion.

Sensorion's OTOF-GT gene therapy development program aims to restore hearing in people living with otoferlin deficiency. Patients with mutations in OTOF suffer from severe to profound sensorineural prelingual non syndromic hearing loss. Otoferlin deficiency could be responsible for up to 8% of all cases of congenital hearing loss, around 20,000 people are affected in the US and Europe.

"This important regulatory feedback is great news as the ODD will support us in advancing our OTOF-GT development program to bring this innovative therapy to the patients who need it most," said **Valérie Salentey, Regulatory Affairs and Quality Assurance Director of Sensorion**. "We have continued to progress with preclinical and clinical development plans for OTOF-GT and are on track to file a Clinical Trial Application (CTA) for the program in H1 2023. This is a key part of our growing gene therapy franchise for the restoration of auditory function in a number of indications through our collaboration with Institut Pasteur."

ODD is designed to encourage the development of medicines intended for the treatment of life-threatening or chronically debilitating diseases that are rare (defined as affecting fewer than five in 10,000 people in the EU).

The designation provides companies with certain advantages and incentives, including protocol assistance, fee reductions, differentiated evaluation procedures for Health Technology Assessments (HTAs) in certain countries and 10 years' market exclusivity.

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 modalities for drug candidates. Its portfolio combines both small molecule programs and a preclinical portfolio of inner ear gene therapies.
Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) progressing in a planned Phase 2 Proof of Concept clinical study of SENS-401 in Cisplatin-Induced Ototoxicity (CIO) and, with partner Cochlear Limited, a study of SENS-401 in patients scheduled for cochlear implantation.
Sensorion has entered into a broad strategic collaboration with Institut Pasteur focused on the genetics of hearing. It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness, including OTOF-GT, targeting deafness caused by a mutation of the gene encoding for otoferlin, and hearing loss related to mutation in *GJB2* gene to potentially address important hearing loss segments in adults and children (GJB2-GT). The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.
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