Press release

Sensorion Announces Approval in Australia to initiate Proof of Concept Clinical Trial of SENS-401 for Residual Hearing Preservation During Cochlear Implantation

Australian approval follows recent trial approval by regulatory authorities in France

Montpellier, July 1, 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, today announces that the initiation of a Proof of Concept (POC) clinical trial of SENS-401 (Arazasetron) in patients scheduled for cochlear implantation has been approved by regulatory authorities in Australia.

Approval has been granted to launch a Phase 2a trial with SENS-401 for hearing preservation in patients who, due to having moderately severe to profound hearing impairment, are scheduled for cochlear implantation. The Australian approval follows confirmation on June 7, 2022 that regulatory authorities in France have approved the trial.

The trial will be a multicenter, randomized, controlled, open-label trial to evaluate the presence of SENS-401 in the cochlea (perilymph) after 7 days of twice-daily oral administration in adult participants prior to cochlear implantation. Patients will receive SENS-401 for 49 days. It will also assess a number of secondary outcome measures, including the change of hearing threshold from baseline to the end of the study in the implanted ear at several frequencies and a two-month period of follow-up is required. As previously announced, first patient enrolment is anticipated by mid-2022.

At the beginning of 2021, Sensorion released positive preclinical data demonstrating that the combination of its SENS-401 molecule alongside a cochlear implant helped reduce loss of residual hearing at a frequency located beyond the electrode array. Preservation of 'natural' hearing is particularly important in speech recognition. Preclinical studies were undertaken in collaboration with the global leader in implantable hearing, Cochlear Ltd.

"Approval by Australian authorities to progress with our clinical trial of SENS-401 for residual hearing preservation in patients scheduled for cochlear implantation paves the way for us to begin this important clinical trial," said **Géraldine Honnet, Chief Medical Officer of Sensorion**. "We have seen compelling clinical data in our recently completed Phase 2 study which supports our confidence that prescribing SENS-401 with cochlear implants can bring significant clinical benefits to patients suffering from hearing loss. We look forward to working with Cochlear to enrolling the first patient shortly."

About SENS-401

SENS-401 (Arazasetron) is a drug candidate that aims to protect and preserve inner ear tissue from damage that can cause progressive or sequelar hearing impairment. A small molecule that can be taken orally or via an injection, SENS-401 has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss, and Orphan Drug Designation from the US FDA for the prevention of platinum-induced ototoxicity in pediatric population. It has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA).

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.

Press release

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 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. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.
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Disclaimer

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