

Sensorion Announces the End of Patient Inclusion in NOTOXIS Phase 2a Clinical Trial of SENS-401 for the Prevention of Cisplatin-Induced Ototoxicity

Montpellier, March 7, 2025, 7.30 am CET - 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 enrollment of the last patient in its NOTOXIS Proof of Concept (POC) Phase 2a clinical trial of SENS-401 for the prevention of Cisplatin-Induced Ototoxicity (CIO).

The NOTOXIS trial (ClinicalTrials.gov ID: NCT05628233) evaluates the efficacy of SENS-401 in preventing CIO in adult patients with neoplastic disease, four weeks after completion of cisplatin-based chemotherapy. Eighty patients have been screened for a total of forty-seven patients randomized (twenty-four in the SENS-401 group and twenty-four in the control group) in this multicenter, randomized, controlled, open-label Phase 2a trial.

Subjects randomized to the SENS-401 received 43.5 mg of the agent orally, twice daily, for up to 23 weeks including 1 week prior to the initiation of the cisplatin treatment, during the whole duration of the chemotherapy treatment (estimated to last up to 18 weeks) and 4 weeks after stopping chemotherapy. The subjects on the control arm not only served as a comparator but also as a method of assessing time and dose of onset of ototoxicity after cisplatin administration. The primary endpoint of the trial, measured 4-weeks after the last cisplatin dose, is change of pure tone audiometry (PTA) (dB) throughout the study compared with the measurement before cisplatin treatment. Secondary endpoints include safety, change from baseline in speech discrimination (noise versus quiet), and in the tinnitus handicap inventory (THI) scale.

Preliminary results (16 patients) presented at the World Congress of Audiology, in Paris, in September 2024, suggested SENS-401's potential to achieve an otoprotective effect at cisplatin doses of >300 mg/m². In addition, the Company reported a favorable safety profile from this preliminary analysis of the trial. Sensorion is on track to report topline results of the Phase 2a NOTOXIS study end of H2 2025.

Géraldine Honnet, M.D., Chief Medical Officer of Sensorion, said: "Today's announcement marks a key development milestone for SENS-401, our small molecule therapeutic candidate that has potential to mitigate the irreversible and permanent hearing loss frequently seen in adults following cisplatin-based chemotherapies without interfering with cisplatin efficacy. I would like to thank the patients and physicians involved in the trial for their trust and commitment. The preliminary results are encouraging, and I look forward to assessing the full data of all patients treated in NOTOXIS and communicating the topline results of this trial by end of 2025."

Cisplatin and other platinum-based compounds are essential chemotherapeutic agents in the treatment of many cancers. A serious side effect of these therapies is ototoxicity, permanent and irreversible hearing loss, which occurs in 40 to 60%¹ of adult and pediatric patients treated. This indication represents a significant unmet medical need for patients and constitutes a potential large global market.

About SENS-401

SENS-401 (Arazasetron), Sensorion's clinical stage drug candidate, is an orally available small molecule that aims to protect and preserve inner ear tissue from damage responsible of progressive or sequelae hearing impairment. Sensorion currently develops SENS-401 in a Phase 2 clinical trial for the prevention of Cisplatin-Induced Ototoxicity and has completed a Phase 2a study to prevent residual hearing loss in patients scheduled for cochlear implantation. SENS-401 has been granted Orphan Drug Designation by the EMA in Europe for the treatment of

¹ JCO Oncology practice, ASCO, volume 19, Issue 5/ CIO: a concise review of the burden, prevention and interception strategies, May 2024 Chattaraj.

Press Release



sudden sensorineural hearing loss, and by the FDA in the U.S. for the prevention of platinum-induced ototoxicity in pediatric population.

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 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 progresses in a Phase 2 proof of concept clinical study of SENS-401 in Cisplatin-Induced Ototoxicity (CIO) for the preservation of residual hearing, and. Sensorion, with partner Cochlear Limited, has completed in 2024 a Phase 2a study of SENS-401 for the residual hearing preservation in patients scheduled for cochlear implantation. A Phase 2 study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in January 2022.

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