Press release

Sensorion Provides an Update on NOTOXIS, its Proof of Concept Phase 2a Clinical Trial of SENS-401 in Cisplatin-Induced Ototoxicity (CIO)

- ***Preliminary data demonstrate that SENS-401 has a favorable safety profile when administered continuously for up to 11 weeks in adult patients undergoing cisplatin-based chemotherapy***
- ***Recruitment is progressing well, with over a third of the required study population enrolled***
- ***Sensorion will provide further updates of its Proof of Concept (POC) Phase 2a clinical trial of SENS-401 CIO during the World Congress of Audiology, being held on September 19-22, 2024, in Paris, France***
- ***The POC Phase 2a clinical trial of SENS-401 in the prevention of residual hearing loss after cochlear implantation is advancing as planned. The end of patient recruitment is anticipated early 2024***

Montpellier, December 18, 2023, at 7.30am CET – 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 disorders, today announces preliminary safety results from NOTOXIS, its Phase 2a Proof of Concept (POC) clinical trial of SENS-401 (Arazasetron) in patients suffering from Cisplatin-Induced Ototoxicity.

Cisplatin and other platinum-based compounds are essential chemotherapeutic agents for many cancers. A serious side effect of these therapies is ototoxicity, or permanent and irreversible hearing loss, which frequently occurs in about 60% of adult and pediatric patients treated with this drug. This indication represents a very significant unmet medical need for patients and is a large potential market with an estimated incidence of more than 500,000 patients in the United States, the European Union and Japan.

The Phase 2a NOTOXIS trial is a multicenter, randomized, controlled, open-label study, designed to evaluate the efficacy of SENS-401 to prevent ototoxicity induced by cisplatin in adult patients with a neoplastic disease 4 weeks after the completion of cisplatin-based chemotherapy. The trial assesses several outcome measures, including the rate and severity of ototoxicity, the change from baseline in Pure Tone Audiometry (PTA) (dB) throughout the study and the tolerance.

Eligible participants are randomized on Day 1 to either Arm A or Arm B in ratio 1:1. In Arm A, patients receive 43.5mg of oral SENS-401 one week before the start of the chemotherapy, continues throughout the entire chemotherapy duration, and extends for up to four weeks post-chemotherapy. This study is conducted in comparison to a control group of patients receiving chemotherapy alone, Arm B. The patients entering the study are to receive high doses of cisplatin, exceeding 70mg/m2 per treatment cycle and totalling at least 210 mg/m2 over the course of their chemotherapy regimen.

Following the enrolment of over one-third of the required study population, preliminary safety data for patients exposed to a daily dose of 43.5 mg SENS-401 administered b.i.d. for up to 11 weeks indicate a favorable profile consistent with previously reported data for patients exposed for up to 7 weeks.

Recruitment is progressing at a sustained path, with 11 clinical centers open to date. Sensorion's management team will communicate further updates of the POC Phase 2a clinical study of SENS-401 in Cisplatin-Induced Ototoxicity during the World Congress of Audiology, being held on September 19-22, 2024, in Paris, France.

Géraldine Honnet, Chief Medical Officer of Sensorion, said: "I'm pleased with the progress in Sensorion's POC Phase 2a clinical study of SENS-401 in the prevention of Cisplatin-Induced Ototoxicity. These are encouraging preliminary safety results and build on the data we have seen to date for SENS-401, our first in-class drug candidate that could prevent hearing loss induced by cisplatin. Our constant effort to include new clinical centers within this study and to accelerate the pace of recruitment have paid off. SENS-401 is also

progressing in a second ongoing Phase 2a clinical study in the prevention of residual hearing loss following cochlear implantation. We are anticipating the end of recruitment early 2024. Sensorion remains highly focused on developing innovative therapies that may have the potential to ultimately transform the quality of life for patients suffering from hearing disorders."

Professor Christophe Tournigand, M.D., Ph.D., Head of the Oncology Department at Henri Mondor Hospital in Créteil, France said**:** "Educating patients about the irreversible and permanent hearing loss frequently seen in adult patients undergoing cisplatin-based chemotherapies can be challenging, as it may seem inconsequential in the context of the cancer they are battling. However, this effort is necessary to pursue the development of a therapeutic solution, that may have the potential to effectively prevent cisplatin-induced ototoxicity."

Professor Yann Nguyen M.D., Ph.D., ENT surgeon at the Otolaryngology Department at the Hospital Pitié Salpêtrière, Paris, France, commented: "It has become paramount to acknowledge the severe and irreversible hearing losses that frequently follow cisplatin treatments and to encourage the development of therapeutic solutions to mitigate this severe effect without interfering with cisplatin efficacy."

In a preclinical model of Cisplatin-Induced Ototoxicity (Petremann et al., 2017), SENS-401 demonstrated an ability to significantly reduce hearing loss without impacting chemotherapeutic potential of cisplatin. Additionally, further analysis of the AUDIBLE-S study in March 2022, to assess the effect of SENS-401 in Sudden Sensorineural Hearing Loss (SSNHL) demonstrated a statistically significant and clinically meaningful treatment effect of at least 10 dB vs placebo with the high dose at Day 84 in the per protocol idiopathic SSNHL population (81 patients) treated with corticosteroids (representing c. 70% of the Intent to Treat population). These data informed the NOTOXIS trial design to extend exposition to SENS-401 treatment, in order to cover all the cycles of cisplatin and to focus on the prevention of hearing loss.

SENS-401 is also progressing in a POC Phase 2a clinical trial for the prevention of residual hearing loss following cochlear implantation, developed with its partner Cochlear Ltd, global leader in implantable hearing devices. In June 2023, Sensorion provided preliminary data, showing the presence of SENS-401 in the perilymph of all five adult patients treated with the product. In July 2023, the Company reported further preliminary data demonstrating a clinically significant 21dB improvement in the preservation of residual hearing compared to the control group 6 weeks after cochlear implantation at 500 Hz. Sensorion is anticipating the end of patient recruitment early 2024 and the publication of POC Phase 2a clinical primary endpoint readout in H1 2024.

About SENS-401

SENS-401 (Arazasetron), Sensorion's clinical stage lead 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 is currently developing SENS-401 in a Phase 2a clinical trial for the prevention of residual hearing loss in patients scheduled for cochlear implantation, and in a Phase 2 clinical trial for the prevention of Cisplatin-Induced Ototoxicity.
SENS-401 has been granted Orphan Drug Designation by the EMA in Europe for the treatment of 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) 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 clinical-stage small molecule programs for the treatment and prevention of hearing loss disorders.
Sensorion's 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, in a study of SENS-401 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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