NEWS RELEASE

SensorionAnnounces First Patient Enrolled in Phase 2a Proof of Concept Clinical Trial of SENS-401 in Cisplatin-Induced Ototoxicity

1/3/2023

MONTPELLIER, France--(BUSINESS WIRE)-- Regulatory News:

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 first patient has been enrolled in its Phase 2a Proof of Concept 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 occurs in up to 50-60% of adult patients and 90% of pediatric patients who survive cancer. This indication represents a very significant unmet 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 exploratory Phase 2a, multicenter, randomized, controlled, open-label study, NOTOXIS, aims at evaluating the efficacy of SENS-401 to prevent ototoxicity induced by cisplatin in adult patients with a neoplastic disease.

“The need to find a solution for Cisplatin-Induced Ototoxicity is paramount,” said Géraldine Honnet, Chief Medical Officer of Sensorion. “While Cisplatin is a highly effective treatment for many cancers, it is associated with hearing loss in so many adult and pediatric patients. The preclinical and clinical data gathered during SENS-401 development support Sensorion’s confidence in its potential to preserve hearing for patients receiving cisplatin without impacting chemotherapeutic potential and we are therefore very excited to be commencing this trial.”

In a preclinical model of Cisplatin-Induced Ototoxicity (Petremann et al., 2017), SENS-401 demonstrated an ability to significantly reduce hearing loss. Additionally, further analysis of the AUDIBLE-S study earlier in 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 have 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.

The NOTOXIS amended clinical trial application (CTA) was approved in October 2022 in France and in December 2022 in Israel.

Eligible participants will be randomized on Day 1 to either Arm A or Arm B in ratio 1:1 (the aim is to enroll maximum 58 participants in total: 29 participants per arm). Arm A participants will be treated with Cisplatin-based chemotherapy without receiving SENS-401. This control arm will provide natural history data. Arm B participants will receive 43.5 mg of oral SENS-401 1 week prior to the initiation of the cisplatin treatment, during the whole duration of the chemotherapy treatment and 4 weeks after receiving the last cycle of cisplatin. The primary objective of the study will be to assess SENS-401 efficacy measuring the change from baseline of the average of the Pure Tone Audiometry (PTA) 4 weeks after the completion of cisplatin treatment.

The trial will also assess a number of secondary outcome measures, including the rate and severity of ototoxicity, the change in PTA (dB) throughout the study and tolerance.

Sensorion anticipates the publication of interim data in H1 2023.

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. Its portfolio combines both small molecule and inner ear gene therapies programs.

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, 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.

Sensorion pursues its 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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Source: Sensorion