Press release

Sensorion provides an update on plans and progress in the development of SENS-401 for the prevention of hearing loss

- ***Clinical trial to treat patients suffering from Cisplatin Induced Ototoxicity (CIO) with SENS-401 expected to start in H2 2021***
- ***Natural history study in CIO expected to start in H1 2021 to generate data on disease evolution***
- ***Phase 2 topline results from SENS-401 study in SSNHL delayed further due to COVID-19 and now expected in Q4 2021***

Montpellier, January 5, 2021 - 7:30 AM 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 loss disorders, announces it plans to initiate a proof-of-concept clinical trial of SENS-401 to treat CIO in H2 2021. The Company also expects to start a natural history clinical study in CIO in adult cancer patients in H1 2021.

"*SENS-401 has demonstrated highly encouraging efficacy in preclinical models and we are excited to progress this small molecule towards clinical trials to address this significant unmet medical need in cancer patients undergoing cisplatin treatment. Hearing loss caused by this chemotherapeutic treatment leads to permanent inner ear problems in 50-60% of cases, significantly impacting patients' quality of life*[1]*. We look forward to further investigating the potential of SENS-401 to prevent this life-altering condition*" says **Géraldine Honnet, Chief Medical Officer of Sensorion.**

An estimated 500,000 people will suffer from CIO in G7 countries by 2025 causing hearing loss, tinnitus and dizziness[2]. A critical requirement of any potential treatment for CIO is that it should not interfere with the efficacy of cisplatin, a potential differentiating feature of SENS-401. The natural history study will generate data on the course of hearing loss from CIO and contribute to the recruitment for the clinical study. Further details on the trial design will be communicated in H2 2021.

SENS-401 is a 5-HT3 receptor antagonist and calcineurin inhibitor which has been shown to siginificantly reduce hearing loss from CIO in preclinical models[3]. The use of SENS-401 has led to the survival of substantially more outer hair cells compared to placebo. Outer hair cells are the most vulnerable sensory cells in the inner ear which help amplify sound signals to increase hearing sensitivity. SENS-401 is also in Phase 2 development for the treatment of Sudden Sensorineural Hearing Loss (SSNHL).

Due to the impact of COVID-19, including the reinitiation of strict lockdown measures in some of the countries involved, Sensorion now expects a further delay in the availability of topline results from the Phase 2 study of SENS-401 in SSNHL. Topline data are now anticipated in Q4 2021 rather than mid-2021 as had been previously estimated. Sensorion continues to review this study and consider opportunities which could aid in its successful completion despite the challenges provided by COVID-19 and its knock-on effects.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL). 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. The Company is also working on the identification of biomarkers to improve

[1] B-ENT, 2017, 13, 85-92, Early detection of platinum-induced ototoxicity in adults E. D'heygere, R. Kuhweide, H. Pottel, L. Mus, T. Vauterin, and Bob Lerut.
[2] Company estimates based on publicly available data in the US, Japan, Germany, France, UK, Italy and Spain
[3] Oral Administration of Clinical Stage Drug Candidate SENS-401 Effectively Reduces Cisplatin-induced Hearing Loss in Rats. Petremann M, Tran Van Ba C, Broussy A, Romanet C, Dyhrfjeld-Johnsen J.Otol Neurotol. 2017 Oct;38(9):1355-1361.

diagnosis of these underserved illnesses. In the second half of 2019, Sensorion initiated two preclinical gene therapy programs aimed at correcting hereditary monogenic forms of deafness including Usher Type 1 and deafness caused by a mutation of the gene encoding for Otoferlin. The Company is potentially uniquely placed, through its platforms and pipeline of potential therapeutics, to make a lasting positive impact on hundreds of thousands of people with inner ear related disorders, a significant global unmet medical need.
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