Press release

Sensorion Announces Positive Data Safety Monitoring Board Review of Phase 2 trial for SENS-401 in Sudden Sensorineural Hearing Loss

Montpellier, 23 December, 2019 – Sensorion (FR0012596468 – ALSEN) 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, today announces that an independent Data Safety Monitoring Board (DSMB) has undertaken a review of the safety data for the patients who were included into the phase 2 clinical trial for SENS-401 in the treatment of Sudden Sensorineural Hearing Loss (SSNHL).

The DSMB has confirmed the absence of any concern as to the safety of SENS-401 and has recommended continuing the trial as scheduled. Around 260 patients are expected to be enrolled in the trial and results are expected at the end of H1 2020.

The DSMB review is part of the regular monitoring of multi-center and randomized phase 2 clinical trials.

About SENS-401 Phase 2 trial

The AUDIBLE-S Phase 2 is a multi-center, randomized, double-blind, placebo-controlled study of SENS-401 in subjects with severe or profound sudden sensorineural hearing loss (SSNHL). Included patients will receive twice a day for 4 weeks one of the following: a 43,5mg dose of SENS-401, a 29mg dose of SENS-401 or a placebo. The primary endpoint is change in pure tone audiometry PTA (dB) in the affected ear from baseline to the end of treatment visit (day 28).

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 within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (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 has also identified biomarkers to improve diagnosis and treatment of these underserved illnesses. Sensorion has launched in the second half of 2019 two preclinical gene therapy programs aiming 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 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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