Press release

Sensorion provides update on SENS-401 SSNHL Phase 2 AUDIBLE-S trial enrollment

Montpellier, March 13, 2020 – 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, announced today an update on timelines for the ongoing Phase 2 study of SENS-401 to treat Sudden Sensorineural Hearing Loss (SSNHL). Patient recruitment rates from this trial now indicate the data will be available by mid-year 2021, which is later than previously announced.

"The AUDIBLE-S trial is progressing but we are obviously disappointed that the recruitment rate is at a slower pace than our original expectations", says **Nawal Ouzren, CEO of Sensorion.**
"An important factor also impacting recruitment in our trial is the reprioritization of emergency room resources due to the current COVID-19 situation. As the epidemic situation is rapidly changing, our revised estimate is for a top-line data readout by mid-year 2021. We will continue to monitor the situation and will provide updates should there be significant changes to this timeline".

"We are doing our utmost to ensure we can provide the clinical data set as quickly as possible, so that we can define the next steps with SENS-401 within the field of SSNHL and use our scientific know-how and expertise to develop much needed treatments for people suffering from hearing loss disorders", says **Géraldine Honnet, CMO of Sensorion.**

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, a 29mg dose 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 is also working on the identification of biomarkers to improve diagnosis 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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