Press release

Sensorion announces completion of patient enrollment and dosing in Seliforant phase 2a study

First results are expected by the end of the year

Montpellier, November 27, 2018 – Sensorion (FR0012596468 – ALSEN), a clinical-stage biopharmaceutical company specializing in the treatment of inner ear diseases, announced today the completion of subject enrollment and dosing in a Phase 2a study (SENS-111-202) to confirm that Seliforant, unlike Meclizine, does not affect the vigilance and cognitive performance during a vestibular conflict.

Maintaining vigilance and cognitive performance is very important, as current antivertigo drugs like Meclizine are sedative, preventing the patient from functioning during treatment of the vertigo attack. Sedation delays central compensation because the patient cannot start a vestibular rehabilitation therapy to enhance this process, potentially leading to poor recovery.

Preclinical and phase 1 clinical data have confirmed that Seliforant modulates the peripheral vestibular apparatus, reduces symptoms associated with vestibular dysfunction, and is safe and well tolerated. By assessing the effects of Seliforant and Meclizine, the SENS-111-202 study aims to confirm primarily the lack of negative CNS effects such as sedation, memory impairment and cognitive performance in patients receiving Seliforant and secondarily the potential for improvement of symptoms associated with a vestibular conflict (imbalance, impaired cognitive process, dizziness and nausea).

SENS-111-202 is a randomized, double-blind, placebo-controlled and Meclizine-calibrated, crossover trial, in subjects susceptible to motion sickness designed to assess the safety and pharmacodynamic effects of Seliforant in experimentally evoked vestibular imbalance. It is being conducted in the Netherlands. Subjects received the 4 treatment regimen once (Seliforant 100 mg, Seliforant 200 mg, Meclizine 50 mg, and placebo), one week apart, in a random order. Primary and secondary endpoints include objective psychometric measures of vigilance, cognitive performance, imbalance, dizziness and nausea.

"With the completion of dosing and testing in this trial, we are progressing in the evaluation of the Seliforant's safety and activity. We confirm that first results from the study regarding SENS-111-202 are expected by the end of this year" said Nawal Ouzren, Chief Executive Officer of Sensorion

About Seliforant

Seliforant (formerly SENS-111) is the first representative candidate of the histamine type 4 receptor antagonist class to be tested for the symptomatic treatment of vertigo crises. Displaying a neuromodulation effect of the sensorineural inner ear cell function, Seliforant is a small molecule that can be taken orally or via a standard injection, and is currently in a Phase 2 clinical trial, being conducted in the United States, Europe and South Korea.

About Sensorion

Sensorion is a pioneering clinical-stage biopharmaceutical company, which specializes in the development of novel therapies to restore, treat and prevent inner ear diseases such as hearing loss, vertigo and tinnitus. Our clinical-stage

portfolio includes two phase 2 products: Seliforant (SENS-111) under investigation for acute unilateral vestibulopathy and Arazasetron (SENS-401) for sudden sensorineural hearing loss (SSNHL). We have built a unique R&D technology platform to expand our understanding of the physiopathology and etiology of inner ear related diseases enabling us to select the best targets and modalities for drug candidates. We also identify biomarkers to improve diagnosis and treatment of these underserved illnesses.
We are uniquely placed through our 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 need in medicine today.
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