Sensorion announces positive topline results from Seliforant Phase 2a study

Results confirmed Seliforant does not affect vigilance, cognitive performance during a motion stimulus

Montpellier, December 14, 2018 – Sensorion (FR0012596468 – ALSEN), 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, tinnitus and vertigo, today announced that the SENS-111-202 study has met its tolerability primary endpoint in a statistically significant manner. Sensorion’s investigational compound Seliforant (SENS-111) does not affect vigilance and cognitive performance during a motion stimulus.

The study showed that Seliforant, in contrast to Meclizine, has no negative CNS side effects such as sedation, impairment of memory and cognitive performance. Meclizine belongs to the class of histamine H1 receptor antagonists, which is the first line treatment used in acute vertigo and motion sickness in the United States.

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.

“We are very pleased with the outcome of the SENS-111-202 study and we look forward to presenting these data shortly to the clinical and scientific communities. This significant achievement in the development of Seliforant adds to the evidence that Seliforant has the potential to become a new key drug in the treatment of acute vertigo with a robust safety profile compared to current standard of care. The next milestone is the Phase 2 POC efficacy trial readout in AUV in H2 2019” said Nawal Ouzren, Chief Executive Officer of Sensorion.

SENS-111-202 is a randomized, double blind, placebo-controlled and Meclizine-calibrated crossover trial, designed to assess the safety and pharmacodynamics effects of Seliforant in experimentally evoked vestibular imbalance. It was conducted in the Netherlands and 32 subjects were randomized to receive the 4-treatment regimen once (Seliforant 100 mg, Seliforant 200 mg, Meclizine 50 mg, and placebo), one week apart, in a random order. Primary endpoints included repeated objective psychometric measures of vigilance and cognitive performance.

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 separate Phase 2 clinical trial, being conducted in the United States, Europe, Israel 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
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pathophysiology 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.

In its drive to continue to deliver additional groundbreaking therapeutic solutions for inner ear patients, Sensorion entered into exclusive negotiations, in November 2018, with Pasteur Institute for hearing loss gene therapy programs including among others the Usher Syndrome Type1 and Otoferlin-deficiency. 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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