Press Release

Sensorion Initiates Safety Study of Seliforant Versus Meclizine In Evoked Vestibular Imbalance

Safety and pharmacodynamic effects of seliforant compared to meclizine

Montpellier, July 24, 2018 – Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announced the initiation of patient enrollment in a Phase 2a study (SENS-111-202) to confirm the absence of anticholinergic side effects such as sedation and memory loss experienced with meclizine during a evoked vestibular imbalance.

SENS-111-202 is a randomized, double-blind, double-dummy, placebo-controlled, cross-over trial in patients designed to assess the safety and pharmacodynamic effects of seliforant compared to meclizine and placebo in experimentally evoked vestibular imbalance. The trial will be conducted in the Netherlands. Subjects will receive the 4 treatment regimens (seliforant 100 mg and 200 mg, meclizine 50 mg, or placebo condition) once, one week apart, in a random order. Primary and secondary endpoints will include measures of vigilance and attentiveness, sedation, balance, and activity of seliforant based on severity of induced nausea and associated symptoms.

Preclinical and clinical data have confirmed that seliforant modulates the peripheral vestibular apparatus, reduces symptoms associated with vestibular dysfunction, and is safe and well tolerated. By comparing the effects of seliforant to meclizine, a drug with known anticholinergic side effects, and placebo, the SENS-111-202 study aims to confirm the absence of anticholinergic effects such as sedation and memory loss in patients receiving seliforant.

“Globally, about 70,000 patients per year in Europe and USA suffer debilitating crises from AUV, and over 100 million suffer from some form of vertigo” said Nawal Ouzren, Chief Executive Officer of Sensorion. “Currently, there is no effective and safe immediate treatment for these events, which is critical for these patients. Seliforant has the potential to fill this significant medical need, and the aim of the SENS-111-202 trial is to validate seliforant’s safety and activity, and progress towards registration.”

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 neuromodulatory effect of the sensorineural inner ear cell function, seliforant is a small molecule that can be taken orally or via a standard injection.

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About Sensorion

Sensorion is a biotech company pioneering novel treatments of inner ear diseases such as severe vertigo, tinnitus or hearing loss. Two products are currently in the clinical development stage: SENS-111, in phase 2 in acute unilateral vestibulopathy (vestibular neuritis), and SENS-401, which has completed a phase 1 trial. The company was founded by Inserm (the French Institute of Health and Medical Research) and is utilizing its pharmaceutical R&D experience and comprehensive technology platform to develop first-in-class easy-to administer, notably orally active, drugs for treating and preventing hearing loss and the symptoms of bouts of vertigo and tinnitus.

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Label : **SENSORION**
ISIN : **FR0012596468**
Mnemonic : **ALSEN**

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