Press release

Sensorion to Initiate a Phase 2 Clinical Trial with SENS-111, its Drug Candidate for Acute Severe Vertigo

- *Planned enrolment of 207 patients with acute unilateral vestibulopathy*
- *Participation of 25 specialized centers in the US, Europe and South Korea*

Montpellier, November 29, 2016 - Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announces the set-up of a phase 2 clinical trial with SENS-111, its drug candidate for acute severe vertigo.

The aim of this international multi-center randomized double-blind placebo-controlled study is to assess the efficacy and safety of SENS-111 in 207 patients suffering from acute unilateral vestibulopathy. The patients will be randomly divided into 3 groups and orally treated over four consecutive days with either the placebo or one of the two doses of SENS-111 being tested (100 mg and 200 mg), and will be monitored each day during the treatment and up to 28 days thereafter.

The primary endpoint will be the intensity of the vertigo expressed by the patient and measured using a visual analog scale. Secondary criteria will notably include the impact of SENS-111 on the patient's quality of life and the medium-term recovery of their vestibular function.

Given the incidence of this disease (between 3.5 and 15.5 patients out of every 100,000 people), Sensorion has already selected 25 specialized centers with substantial expertise in caring for patients with vestibular pathologies in the United States, Europe and South Korea in order to support the pace of enrolment. Sensorion has also commissioned a CRO (Contract Research Organization) to oversee the implementation and coordination of this trial in all the participating centers.

The trial is scheduled to last around 18 to 24 months, with the enrolment of patients suffering from acute unilateral vestibulopathy due to begin during the first quarter of 2017. This slight delay compared with the initial schedule is due to the manufacturing of the new formulation of the product in orodispersible (mouth-dissolving) tablet form, which is particularly suited to these patients who also suffer from nausea and vomiting, and to the ongoing interactions with the regulatory authorities of all the various countries concerned (see the FDA approval obtained to initiate clinical studies in the United States announced on September 1, 2016).

Laurent Nguyen, CEO of Sensorion, says: "*We are delighted to be able to launch a phase 2 clinical study of this size with SENS-111 that is a major first in acute severe vertigo. Our preclinical results and the activity signals observed in healthy volunteers during the phase 1b trial are enabling us to make rapid progress with this small orally-active molecule that aims to treat this highly-debilitating pathology for which physicians lack effective and well-tolerated drugs.*"

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About acute unilateral vestibulopathy

Acute unilateral vestibulopathy is a sudden dysfunction of the vestibular system that generates very pronounced symptoms that appear in just minutes, including intense rotary vertigo, nausea and vomiting, but no tinnitus or hearing loss. The severity of these symptoms is highly debilitating, with sufferers having to go to ER or be hospitalized and patients often being bedbound for a day or two. This pathology equally affects both genders, and its most common age of onset is between 30 and 60, with a peak at between 40 and 50 years old. The incidence of this disease is between 3.5 and 15.5 cases per 100,000 people per annum. Its origin is not as yet fully understood, although the underlying causes may be a viral infection or a vascular origin.

Treatment involves a two-part process. Firstly, the patient's attack is relieved by isolating them and administering anti-vertigo agents among few drugs available, antiemetics and even sedatives. They then undergo vestibular rehabilitation in order to facilitate central vestibular compensation during the recovery period. In general, the severity of the symptoms decrease in a few days, following which there is a positive progression over the next one to six weeks via central compensation and/or thanks to the partial or total recovery of the vestibular function, although some patients may continue to have long-term persistent symptoms such as loss of balance, vertigo or continuous and involuntary eye movements (oscillopsia).

About SENS-111

SENS-111 is the first representative of the histamine type 4 receptor antagonist class tested in inner-ear pathologies. This drug candidate displays a neuromodulation effect of the sensorineural inner ear cell function and is being developed for the symptomatic treatment of vertigo crises or tinnitus. SENS-111 is a small molecule that can be taken orally or via a standard injection, and has been successfully assessed in humans in phase 1b.

About Sensorion

Sensorion specializes in the treatment of pathologies of the inner ear such as acute vertigo, tinnitus and hearing loss. 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, drug candidate programs for treating hearing loss and the symptoms of vertigo and tinnitus, for preventing and treating complications associated with progressive lesions in the inner ear, and for preventing the toxicity of chemotherapy in the inner ear. Based in Montpellier, southern France, Sensorion received financial support from Bpifrance, through the InnoBio fund, and Inserm Transfert Initiative.

Sensorion is listed on Alternext Paris since April 2015. www.sensorion-pharma.com

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