



## **Sensorion successfully completes the first part of the clinical trial on SENS-111, which aims to treat severe bouts of vertigo**

*The trial's Steering Committee has validated better-than-anticipated results for SENS-111, a drug for the symptomatic treatment of severe bouts of vertigo*

**Montpellier, April 23, 2015 (FR0012596468 – ALSEN / PEA-PME eligible) – Sensorion, a biotech specialising in the treatment of inner ear diseases, today announces the successful completion of the first part of the clinical trial on its SENS-111 drug candidate and the continuation of the second part.**

SENS-111, which aims to treat severe bouts of vertigo, is one of a comprehensive portfolio of drug candidates chosen by Sensorion to cover all severe inner ear pathologies.

### **A two-part phase 1b clinical trial**

A phase 1b clinical trial is currently taking place to supplement the existing pharmacokinetic and clinical tolerance data on the SENS-111 product and to provide information regarding use of the caloric test, a pharmacodynamics test used in clinical practice by ENT specialists on patients suffering from dizziness.

This study, for which the recruitment of healthy volunteers began in January 2015, comprises two parts:

- Part 1: a study of single oral doses of SENS-111 or a placebo, with increasing doses;
- Part 2: a study of repeated oral doses of SENS-111 or a placebo over 4 to 7 days, with increasing doses and the carrying out of the caloric test.

### **Better-than-anticipated results for SENS-111, a drug for the symptomatic treatment of severe vertigo**

In part 1 of this study, involving 4 cohorts of 8 subjects, the doses foreseen by the protocol were achieved with no significant adverse effects observed. The plasma concentrations obtained with SENS-111 were significantly higher than those identified as efficient by Sensorion via its screening platform. The study's steering committee has therefore decided to end the recruitment of further subjects for this part of the study.

Regarding part 2 of the study, no significant adverse effects have been observed on the first 2 cohorts of 12 subjects involved in the study in accordance with the study's schedule. Recruitment for this part of the study is continuing, and the pharmacokinetic and pharmacodynamic data – notably the results of the caloric tests – will be available during the final quarter of 2015.

These results mean that the development of SENS-111 for the symptomatic treatment of severe vertigo can continue on schedule. The phase 2 clinical trial on SENS-111 should thus be able to begin in 2016 in patients from the general population or presenting an orphan disease of the inner ear.

**Pierre Attali, Sensorion's Chief Medical Officer, says:** *"These first phase 1b clinical results for SENS-111 are very positive and highly promising regarding the symptomatic treatment of severe bouts of vertigo. The absence of any significant adverse effects confirms the known clinical tolerance profile of this drug that had already been tested on humans. SENS-111, selected by our screening technological platform, can be administered orally, which represents a highly-competitive advantage for treating inner-ear disorders compared with our peers who are testing products using invasive intratympanic injections."*

## 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 neurosensorial inner ear cell function and is being developed for the symptomatic treatment of bouts of vertigo or tinnitus. SENS-111 is a small molecule that can be taken orally or via a standard injection, and is currently tested in human in phase 1b.

## About Sensorion

Spun off from Inserm (the French institute of health and medical research) in 2009, Sensorion is a biotech that specialises in the treatment of pathologies of the inner ear such as acute vertigo, tinnitus and hearing loss. Backed by its pharmaceutical R&D experience and a comprehensive technology platform, Sensorion is developing three drug candidate programmes for treating the symptoms of vertigo or tinnitus, for preventing 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, within the university and hospital hub, Sensorion has a portfolio of 7 patent families, employs 15 staff and receives financial support from Bpifrance, through the InnoBio fund, and Inserm Transfert Initiative.

For more information: [www.sensorion-pharma.com](http://www.sensorion-pharma.com)

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