Press release

Sensorion receives European authorization to initiate Phase II clinical trial of SENS-111 to treat acute vertigo

- *Protocol valid via the Voluntary Harmonization Procedure*
- *Optimization of the trial's management and enrollment pace*

Montpellier, March 9, 2017 - Sensorion (FR0012596468 – ALSEN), a biotechnology company specializing in the treatment of inner ear diseases, today announces that the HMA (Heads of Medicines Agencies, a European network of the Heads of the National Competent Authorities) has authorized it to conduct a Phase II trial of SENS-111, the Company's oral novel small-molecule drug candidate for treating acute severe vertigo, via the Voluntary Harmonization Procedure (VHP).

The VHP enables Sensorion to conduct its Phase II clinical trial in all European Union countries. This new procedure considerably simplifies the trial's organization because a single country's authority coordinates requests and interactions with national drug agencies and centralized Sensorion's responses and issued a joint opinion.

Importantly, the VHP, allows the trial to be conducted with a single clinical protocol for all European countries. This study was authorized in the United States by the FDA as announced in September 2016.

Laurent Nguyen, CEO of Sensorion, says: "*We are delighted to benefit from the VHP, which is more efficient and allows us to meet the rigorous requirements of each country where we have trial sites, while also facilitating enforcement of our own exacting standards. Thanks to the VHP authorization and our active IND (Investigational New Drug) in the United States, we will be able to undertake this trial simultaneously in many of the world's leading centers of excellence for the treatment of acute severe vertigo, thus enabling us to benefit from an optimal patient enrollment pace.*"

The aim of this multi-center, randomized, double-blind, placebo-controlled study is to assess the safety and efficacy of SENS-111 in 207 patients suffering from acute unilateral vestibulopathy. The primary endpoint is the intensity of the vertigo expressed by the patient and measured using a visual analog scale. Sensorion has already established collaborations with a number of specialized centers in the United States, Europe and South Korea and patient enrollment is scheduled to begin during the first quarter of 2017.

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About SENS-111

SENS-111 is the first histamine type 4 receptor antagonist 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 and 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. Sensorion has set up a phase II clinical trial to assess this drug candidate in 207 patients with acute unilateral vestibulopathy, with enrolment due to begin during the first quarter of 2017.

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 candidates for treating and preventing hearing loss and the symptoms of bouts of vertigo and tinnitus. The first two programs are, respectively, in phase I (SENS-401) and phase II (SENS-111) clinical testing. Based in Montpellier, Southern France, Sensorion has received financial support from Bpifrance, through the InnoBio fund, and Inserm Transfert Initiative.

Sensorion has been listed on the Euronext Alternext Paris exchange since April 2015.

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