Press release

Sensorion announces results from SENS-111 Phase 2b trial in acute unilateral vestibulopathy

- *Safe and well tolerated in 105 AUV patient study; primary efficacy endpoint not met*
- *No further activities related to SENS-111 will be pursued*
- *Sensorion will now focus on advancing its hearing loss disorders pipeline*

Montpellier, December 2, 2019 – Sensorion (FR0012596468 – ALSEN / PEA-PME eligible), a pioneering clinical-stage biotech company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, reported today results from a Phase 2 proof-of-concept trial of SENS-111 for the treatment of acute unilateral vestibulopathy (AUV).

SENS-111 was safe and well tolerated. However, it did not meet the primary endpoint of vertigo intensity, measured by the area under the curve of the vertigo intensity visual analogue scale (VI-VAS) in standing position over the four treatment days, with eight post baseline assessments.

"*We are disappointed that the clinical endpoint was not met. As already announced before today's readout, we had not planned to further develop the compound. Sensorion is building a leadership position in hearing loss therapies with a promising pipeline of innovative therapeutic solutions to restore, treat and prevent within in the field of inner ear disorders and we are supported by leading academic and industry collaborations. We will now focus on further building our pipeline by concentrating investment in the ongoing development of SENS-401, currently in Phase 2 for Sudden Sensorineural Hearing Loss (SSNHL) and in two preclinical gene therapy programs, which are being developed in collaboration with Institut Pasteur."* **said Nawal Ouzren, CEO of Sensorion**. *"I would like to thank the patients, the investigators and Sensorion employees for their engagement throughout the development of the SENS-111 program.*"

About the trial

The SENS-111 phase 2b proof-of-concept trial was a randomized, double-blind, placebo-controlled study, which had three parallel arms and evaluated the efficacy and safety of SENS-111 histamine H4 receptor antagonist. A total of 105 patients were included in the study, conducted in Europe, Israel, South Korea and the United States, with a 1:1:1 randomization ratio, stratified by duration of vertigo before treatment (≤24 hours, >24 hours). Each patient participated in the study for four weeks, with four days of double-blind treatment and a follow up with no investigational product until 28 days after inclusion.

About SENS- 111

SENS-111 (Seliforant) is an orally available small molecule histamine type 4 receptor antagonist, displaying an inhibitory effect on vestibular neuron activity.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one phase 2 product: SENS-401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL).
Sensorion has built a unique R&D technology platform to expand its understanding of the pathophysiology and etiology of inner ear related diseases enabling it to select the best targets and modalities for drug candidates. The Company has also identified biomarkers to improve diagnosis and treatment of these underserved illnesses.
Sensorion has launched in the second half of 2019 two preclinical gene therapy programs aiming at correcting hereditary monogenic forms of deafness including Usher Type 1 and deafness caused by a mutation of the gene encoding for Otoferlin.
The Company is uniquely placed through its 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 medical need.
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Press release

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Label: **SENSORION**
ISIN: **FR0012596468**
Ticker symbol: **ALSEN**

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