



## **Sensorion takes a key step towards phase 2 with SENS-401 thanks to the positive results obtained in the phase 1 clinical trial**

### *Safety and pharmacokinetic profile of SENS-401 confirmed*

**Montpellier, June 8, 2017 - Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announces the positive results of the phase 1 clinical trial of SENS-401 treatment of inner ear lesions.**

**Pierre Attali, Sensorion's Chief Medical Officer, said:** *"This study validates SENS-401's safety and pharmacokinetic profile and supports our intention of continuing this compound's clinical development in the treatment of inner ear lesions."*

**Nawal Ouzren, CEO of Sensorion, added:** *"The data obtained will help define the optimal strategy for the phase 2 clinical development of SENS-401 to treat severe hearing loss. This highly-debilitating condition, caused by various factors such as acoustic shock or certain drugs, is characterized by major unmet therapeutic needs."*

SENS-401 is an orally available small molecule whose anti-lesion capabilities in cochlear indications have been identified by Sensorion's screening platform and verified on preclinical models.

The phase 1 trial was carried out in the United Kingdom on 36 healthy volunteers with the aim of assessing SENS-401's tolerability at various doses compared to a placebo and defining its pharmacokinetic profile. SENS-401 was administered orally at 29 mg and 43.5 mg doses once or twice a day over a 7-day period. The trial confirmed the very good clinical tolerance of SENS-401 and the pharmacokinetic data enable Sensorion to select the doses to be used in phase 2 testing.

The plasma concentrations obtained correspond to those observed in animal models that showed the effect of SENS-401 on severe noise-induced hearing loss<sup>1</sup> or Cisplatin-induced hearing loss<sup>2</sup>, Cisplatin being a frequently-used chemotherapy drug.

These results strengthen the Company's growing clinical pipeline and confirm the ability of Sensorion's technological platform to identify novel candidates and predict appropriate doses for clinical testing.

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<sup>1</sup> See the [press release of November 17, 2016](#) on the preclinical results obtained with SENS-401 in acute sensorineural hearing loss, presented at Neuroscience 2016

<sup>2</sup> See the [press release of May 2, 2017](#) on the preclinical results obtained with SENS-401 in Cisplatin-induced hearing loss, presented at COSM 2017

## About SENS-401

SENS-401, R-azasetron besylate, is a drug candidate that aims to protect and preserve inner ear tissue when lesions are present that can cause progressive or sequelar hearing impediments. It is one of the two enantiomer forms of SENS-218, azasetron, a racemic molecule belonging to the family of setrons marketed in Asia under the name Serotone. Enantiomers are molecules that have an identical chemical structure but a different configuration in space, i.e. they are mirror images of each other, like a person's left and right hands. The pharmacological and pharmacokinetic tests completed to date have shown a superior drug candidate profile for SENS-401 compared with the other enantiomer or the racemic form. SENS-401 is a small molecule that can be taken orally or via an injection and has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss.

## About Sensorion

Sensorion is a biotech company specializing in the treatment 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 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.

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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