



Sensorion Presents New Preclinical Results with SENS-401 in Acute Sensorineural Hearing Loss at Neuroscience 2016

- *Significantly improved recovery of severe noise-induced hearing loss*
 - *Excellent inner-ear penetration via oral administration*

Montpellier, November 17, 2016 - Sensorion (FR0012596468 – ALSEN / PEA-PME eligible), a biotech company specializing in the treatment of inner ear diseases, today announces that new preclinical results obtained with SENS-401, the Company's drug candidate being developed for the treatment of acute sensorineural hearing loss, were presented at the Annual Meeting of the Society for Neuroscience (SfN), Neuroscience 2016, in San Diego, CA, on November 16, 2016. The data were presented in an abstract entitled, "[*Significantly improved recovery of severe noise-induced hearing loss by the orally available, clinical drug candidate SENS-401*](#)".

SENS-401 was assessed in a noise-induced hearing loss model that has been established as a benchmark test in evaluating sudden sensorineural hearing loss, an unexplained, rapid loss of hearing. During this proof-of-concept in-vivo study, animals were exposed to a 120 dB noise level for two hours, then randomly treated over 14 consecutive days with either a placebo or increasing doses (5 mg/kg, 10 mg/kg and 20 mg/kg) of SENS-401, administered orally. This acoustic trauma triggered an injury process that affected the inner ear and led to acute hearing loss of more than 60 dB on the first day of the study. Following the 14 days of treatment, the residual hearing loss was still approximately 52 to 59 dB in the placebo group, but just 33 to 49 dB in the group treated with SENS-401.

Pierre Attali, Sensorion's Chief Medical Officer, comments: *"We are delighted to have had the opportunity to present these encouraging pre-clinical data to the scientific community, which is actively seeking innovative solutions for treating acute sensorineural hearing loss. On the basis of these positive results, we intend to continue the clinical development of SENS-401 in this particularly-debilitating pathology for which there is currently no effective treatment."*

The study also assessed the animals' recovery ability compared with the initial hearing loss measured on the first day. By day 14 of the study, the placebo group had recovered an average of 7.1 to 12.9 dB of their hearing, while the group treated with SENS-401 had recovered an average of 20.8 to 29.2 dB, an improvement of approximately 130% in their hearing recovery ability. A dose-dependent effect was observed, with greater recovery at the highest doses of SENS-401 compared with the lowest dose or placebo.

In addition to this protective effect, the study demonstrated that systematically administering SENS-401 led to a concentration of this small molecule in perilymph (extracellular fluid located in the cochlea) and inner ear tissue, parallel to plasma concentrations and proportional to the administered doses, confirming the relationship between doses, concentrations and efficacy of SENS-401.

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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 products 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 undertaken 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.

About Acute Hearing Loss

Sudden sensorineural hearing loss is a brutal affliction involving a hearing loss of more than 30dB, usually unilateral and occurring rapidly over just a few days. It is perceptive deafness following the deterioration or destruction of neurons and certain hair cells in the inner ear. As these cells do not spontaneously regenerate, their lesions lead to irreversible hearing impairments. There is currently no efficient drug available for treating acute hearing loss resulting from lesions of the inner ear.

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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