

Sensorion's SENS-401 Reduces Hearing Loss in Preclinical Study When Oral Administration Initiated Up to Four Days after Acoustic Trauma

Key finding is that SENS-401 was effective even when time between acoustic trauma and treatment initiation reached up to four days

Montpellier, April 23, 2018 (7h30 CEST)– Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, will present new data today in an oral presentation at the 53rd American Neurotology Society (ANS) Annual Spring Meeting at the Combined Otolaryngology Spring Meetings (COSM), held in National Harbor, Maryland, April 20th to 22nd, 2018.

The results are from a study in a preclinical model of sudden sensorineural hearing loss (SSNHL), which was designed by Sensorion's team to determine how long after acoustic trauma SENS-401 could be effectively administered. The title and details of the oral presentation are as follows:

The Clinical Stage Otoprotectant SENS-401 Effectively Reduces Hearing Loss in Rats When Administered up to 96 hours after Severe Acoustic Trauma Mathieu Petremann et al.

Nawal Ouzren, Sensorion's Chief Executive Officer, comments: "The acceptance of our data for an oral presentation at such a prestigious scientific event as COSM underscores the high regard of the scientific community in the research and development at Sensorion. This new preclinical study not only suggests that our drug-candidate for SSHNL, SENS-401, can be effective for SSNHL but that it is effective even if used several days after acoustic trauma. This bodes well for the ongoing clinical development of SENS-401 and reinforces our view that this approach can address the high unmet clinical need in these patients."

One of the challenges faced in treatment of patients with sudden sensorineural hearing loss (SSNHL) is the delays between the time of onset and diagnosis and the start of treatment. In this study, Sensorion addressed this challenge by evaluating whether SENS-401, a drug candidate can effectively treat acoustic trauma-induced SSNHL even after delayed administration in a rat model. SENS-401 has received Orphan Drug Designation for the treatment of SSNHL in Europe, and for platinum-induced ototoxicity in pediatric populations in the United States.

In the study, beginning from 24 to 96 hours after severe acoustic trauma, rats orally received either 13.2 mg/kg SENS-401 or placebo control twice daily for 28 days. Hearing outcomes and otoprotection were evaluated via auditory brainstem response (ABR) and distortion product otoacoustic emission (DPOAE) testing as well as cochleograms. SENS-401 treatment significantly improved recovery of hearing loss in rats when initiated up to 96 hours after severe acoustic trauma (p=0.006) as well as enhancing the survival of sensory outer hair cells (p=0.027).

Pierre Attali, Sensorion's Chief Medical Officer, comments: "These findings provide support for the potential of SENS-401 as an effective therapeutic agent even when



Press release The Inner Ear Diseases company administered several days after onset of SSNHL. This is important, given that many patients do not seek immediate medical care."

Sudden sensorineural hearing loss (SSNHL) is a rare condition which has no cure. One of the greatest clinical problems in SSNHL is the delay in diagnosis since patients may assume that their hearing loss is temporary. However, the window of opportunity for SSNHL treatment is limited and delayed diagnosis increases the probability of permanent hearing loss. Our SENS-401 data for treatment of SSNHL show promise for this indication and Sensorion looks forward to further development of this drug candidate.

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. A small molecule that can be taken orally or via an injection, SENS-401 has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss, and Orphan Drug Designation from the US FDA for the prevention of platinum-induced ototoxicity in pediatric population.

About Sensorion

Sensorion is a biotech company pioneering novel treatments 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 unilateral vestibulopathy (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 Growth Paris exchange since April 2015.

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