



Sensorion's Oral SENS-401 Prevented Cisplatin-Induced Hearing Loss By More than 50 Percent in Preclinical Study

Data in Peer-Reviewed Otolology & Neurotology Supports SENS-401 Orphan Drug Designation for Prevention of Platinum-Induced Ototoxicity in Pediatric Patients

Montpellier, September 11, 2017 – 5:45 pm (CEST) - Sensorion (FR0012596468 – ALSEN), a biotech company pioneering novel treatments of inner ear diseases, today announced data published in *Journal of Otolology & Neurotology* show that oral clinical-stage SENS-401 significantly prevented cisplatin-induced hearing loss in preclinical models. Cisplatin, a commonly-used chemotherapy to treat cancer, induces severe hearing loss in 50-60% of treated patients. There are no pharmaceutical treatments currently available to address this issue.

The results, published ahead-of-print in peer-reviewed *Otolology & Neurotology*,

(http://journals.lww.com/otology-neurotology/Abstract/publishahead/Oral_Administration_of_Clinical_Stage_Drug.96926.aspx)

demonstrate that all doses showed significant activity (improvement of more than 50%) in the prevention of cisplatin-induced hearing loss versus placebo.

The study¹ describes a series of *in vitro* and *in vivo* preclinical studies conducted by Sensorion to evaluate the protective potential and pharmacokinetics of SENS-401 in cisplatin-induced hearing loss.

In these studies, rats randomly received a daily oral administration of either SENS-401 or placebo immediately followed by a 30-minute intravenous infusion of cisplatin with daily SENS-401 oral treatment continued for a total of 14 consecutive days. Three doses of SENS-401 (6.6, 13.2, 26.4 mg/kg/day) were evaluated:

- All doses showed significant activity versus placebo in the prevention of cisplatin-induced hearing loss (i.e. improvement of more than 50%)
- Consistently, all doses of oral SENS-401 significantly reduced the loss of outer hair cells by up to 10 fold; outer hair cells are the most vulnerable sensory cells in the inner ear and locally amplify sound signals to increase hearing sensitivity
- Active concentrations in plasma were similar to those obtained in the phase 1 clinical trial of SENS-401 (see press release from June 8, 2017).
- SENS-401 did not reduce the cytotoxic effect of cisplatin on human cancer cell lines *in vitro* at concentrations close to 30 fold the expected therapeutic concentrations.

These data were submitted to the FDA and support the Orphan Drug Designation granted to SENS-401 for prevention of platinum-induced ototoxicity in pediatric patients. Cisplatin is the most commonly used chemotherapy in this patient population, even though it can cause severe hearing disability for the rest of their lives.

¹ References: Oral Administration of Clinical Stage Drug Candidate SENS-401 Effectively Reduces Cisplatin-induced Hearing Loss in Rats. Mathieu Petremann, Christophe Tran Van Ba, Audrey Broussy, Charlotte Romanet, and Jonas Dyhrfeld-Johnsen. *Otolology & Neurotology*. © 2017

Pierre Attali, Chief Medical Officer of Sensorion, said, “*These preclinical results further demonstrate the activity of SENS-401 in the prevention and treatment of cisplatin-induced hearing loss. These data also support the activity of this drug candidate shown in models of noise-induced hearing loss. Collectively, the results from these studies confirm the therapeutic potential of SENS-401.*”

Nawal Ouzren, CEO of Sensorion, added, “*The publication of our results in this prestigious peer-reviewed journal is indicative of the quality and importance of our research in areas of unmet need. Following the recent ODD granted by the FDA for SENS-401 prevention of platinum-induced ototoxicity in pediatric populations, we have selected this compound as our drug candidate in this indication. We can now expect this program to head towards a Phase 2 clinical trial to start in 2018. Of course we remain confident in the potential of SENS-401 as a safe and effective treatment also for Sudden Sensorineural Hearing Loss, for which Sensorion has received Orphan Drug Designation in Europe.*”

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. 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.

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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