

Sensorion Presents New SENS-401 Data at ARO 2018 MidWinter Meeting

*Five Poster Presentations Included SENS-401 Efficacy, Dosing and Pharmacokinetic Data
in Inner Ear Disorders*

Montpellier, February 14th, 2018 – Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announces new data presented in multiple poster presentations at the Association for Research in Otolaryngology’s (ARO) 41st Annual MidWinter Meeting in San Diego, California, which took place February 9th to 14th, 2018.

Nawal Ouzren, Sensorion’s Chief Executive Officer, comments: *“The new data presented at the ARO MidWinter Meeting further support the significant potential of our development programs in safely and effectively treating inner ear diseases. We are especially excited about the SENS-401 results presented, which provided critical information on treatment regimen and dose translation to the clinical setting for this promising drug candidate. Given the presence of many leading key opinion leaders, the ARO MidWinter Meeting was the ideal venue to present these positive data.”*

SENS-401 translational research:

- *Twice versus once daily oral dosing of SENS-401 for 28 days reveals exposure duration driven treatment effect against severe acoustic trauma induced hearing loss in rats.*

This study compared the efficacy of twice daily low dose versus once daily high dose oral administration of SENS-401, and results suggested that the daily duration of drug exposure is more important than maximal dose drug exposure for the otoprotective efficacy of SENS-401. Results also showed that a 28-day treatment provides better hearing outcome than a 14-day treatment. There is currently no approved pharmaceutical treatment for hearing loss. SENS-401 is Sensorion’s clinical-stage small molecule drug candidate with orphan drug designation for treatment of Sudden Sensorineural Hearing Loss (SSNHL) and cisplatin-induced ototoxicity (CIO), and has previously demonstrated an ability to reduce hearing loss and enhance survival of outer hair cells of rats exposed to acoustic trauma or cisplatin infusion.

- *Translational development of the clinical stage oral otoprotectant SENS-401 for sensorineural hearing loss.*

Early clinical data for SENS-401 have previously provided compelling scientific rationale for further clinical evaluation. Pre-clinically, oral doses of SENS-401 versus placebo were tested in models of severe noise-induced hearing loss and cisplatin induced ototoxicity. In both models, SENS-401 demonstrated significant improvement of hearing and enhancement of outer hair cell survival vs placebo. Additionally, pharmacokinetic profile and dose dependency were evaluated. A phase 1 clinical trial demonstrated that SENS-401 was well tolerated by patients and determined that the clinical pharmacokinetic profile is consistent with the drug

exposures needed for preclinical efficacy. Clinical trial planning is ongoing and Sensorion intends to initiate a phase 2 study with SENS-401 in this indication during the first half of 2018.

Tinnitus preclinical research:

- *Tinnitus or Hearing Loss? Relationship between GPIAS deficits and ABR thresholds after repeated salicylate administration in rats.*

The gap-prepulse inhibition of acoustic startle (GPIAS) paradigm using salicylate induction is widely used in preclinical settings for the study of tinnitus. The GPIAS behavioral paradigm measures the ability of a silent gap in background noise to inhibit the startle response to a loud noise. Salicylate is often used because it rapidly induces deficits in startle inhibition by gap-detection which are interpreted as tinnitus-related. However, recent work emphasizes that hearing loss can be a confounding variable using the GPIAS paradigm, rendering a straightforward interpretation of gap-detection deficits as a clear measure of tinnitus difficult. This study demonstrated that there is a strong relationship between salicylate-induced hearing loss and gap-detection deficits using the GPIAS paradigm. Results from this study emphasize the need for concurrent control measurements of hearing ability when using the GPIAS paradigm to assess tinnitus, particularly in animal models with bilateral hearing impairment.

Novel drug screening approach:

- *Live cell imaging of neurite length and cell death in cultures of dissociated neurons from Scarpa's ganglion.*

In-vivo models of inner ear disorders are widely used to test candidate drugs. However, in-vitro models may be more efficacious for initial screening of candidate targets and compounds. In this study, live cell imaging was used to quantify neurite length and cell death as measures of neurodegeneration in cultures of primary neurons from Scarpa's ganglion following application of different concentrations of either hydrogen peroxide or cisplatin. Results from this study showed that this method was capable of quantifying differences between concentrations and type of insult, suggesting that this High Content Screening assay is applicable for the screening of targets and compounds in the future.

- *Live cell imaging of cisplatin induced ototoxicity in Organ of Corti explant cultures reveals differences in sensitivity and lesion kinetics between hair cells and supporting cells.*

Ototoxicity is one of the most frequent and disabling side-effects of chemotherapy, especially in pediatric oncology patients, and often leads to hearing loss and tinnitus. In-vivo models of cisplatin-induced hearing loss are currently used to test candidate drugs. However, an in-vitro model would be more efficacious for initial screening of candidate targets and compounds. In this study, live cell imaging was used to quantify the effects and lesion time-course of cisplatin exposure in Organ of Corti explant cultures and differential sensitivity of hair and supporting cells to ototoxic insult. Data from this study showed that this model may be useful for future drug target and compound screening for the treatment of ototoxicity.

Press release

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 sequellar 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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