Press release



# Sensorion Announces Publication of SENS-401 Data in Otology & Neurology Journal

Improvement of hearing recovery above threshold for clinical relevance when SENS-401 was administered daily for 28 days delayed as much as 96 hrs after acoustic trauma in a preclinical model

**Montpellier, December 21, 2018 – Sensorion (FR0012596468 – ALSEN),** a pioneering clinical-stage biopharmaceutical company, which specializes in the development of novel therapies to restore, treat and prevent inner ear diseases such as hearing loss, tinnitus and vertigo, today announced the publication online, (<u>O&N journal</u>) ahead of print of data in the Otology & Neurology journal, showing the otoprotective potential of twice-daily oral SENS-401 in preclinical models.

The Sensorion pre-clinical team tested the efficacy of SENS-401 against severe acoustic trauma-induced hearing loss in a male rat model using auditory brainstem response (ABR), distortion product otoacoustic emissions (DPOAE) and histology. Results showed that twice daily, lower doses of SENS-401 for 28 days was the optimal dosing regimen for hearing protection using all outcome measures. Further experiments demonstrated that this treatment regimen was able to deliver clinically relevant and statistically significant otoprotection and hearing recovery when the administration was delayed by as much as 96 hours after acoustic trauma (the latest treatment initiation time-point tested). A responder analysis showed that oral SENS-401 treatment not only strongly increased the percentage of subjects with clinically significant hearing recovery compared to placebo, but also enhanced the degree of individual hearing recovery observed.

These data on otoprotection and hearing recovery supports SENS-401 as a promising clinical candidate for acute onset sensorineural hearing loss, including when treatment is not initiated immediately.

"These results provide support for the translational development of SENS-401 in sudden sensorineural hearing loss (SSNHL) and publication in the respected Otology & Neurology journal also provides additional important peer-validation," says Nawal Ouzren, Sensorion's Chief Executive Officer. "SENS-401 offers the potential to make a real difference to patients' lives as a potential first-in-class treatment, and we look forward to starting the Phase 2 of SENS-401 in SSNHL for which we received the authorization in Europe and Canada."

## About SENS-401

SENS-401, R-azasetron besylate, is a drug candidate that aims to protect and preserve inner ear tissue from damage that can cause progressive or sequelar hearing impairment. 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 pioneering clinical-stage biopharmaceutical company, which specializes in the development of novel therapies to restore, treat and prevent inner ear diseases such as hearing loss, vertigo and tinnitus. Our clinical-stage portfolio includes two phase 2 products: Seliforant (SENS-111) under investigation for acute unilateral vestibulopathy and Arazasetron (SENS-401) for sudden sensorineural hearing loss (SSNHL). We have built a unique R&D technology platform to expand our understanding of the pathophysiology and etiology of inner ear related diseases enabling us to

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select the best targets and modalities for drug candidates. We also identify biomarkers to improve diagnosis and treatment of these underserved illnesses.

In its drive to continue to deliver additional groundbreaking therapeutic solutions for inner ear patients, Sensorion entered into exclusive negotiations, in November 2018, with Pasteur Institute for hearing loss gene therapy programs including among others the Usher Syndrome Type1 and Otoferlin-deficiency.

We are uniquely placed through our platforms and pipeline of potential therapeutics to make a lasting positive impact on hundreds of thousands of people with inner ear related disorders; a significant global unmet need in medicine today.

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