



Sensorion Announces FDA Orphan Drug Designation Granted to SENS-401 for Treatment of Cisplatin-Induced Ototoxicity in Pediatric Patients

Company Intends to Initiate Phase 2 Clinical Trial for SENS-401 in this Indication in 2018

Montpellier, 22 August, 2017 – 8:00 am (CEST) - Sensorion (FR0012596468 – ALSEN), a biotech company pioneering novel treatments of inner ear diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to SENS-401, a therapy in development for the treatment of hearing disorders, for the prevention of Platinum-Induced Ototoxicity in pediatric patients. Platinum-based chemotherapies, in particular cisplatin, are commonly used to treat cancer, but induce severe hearing loss in 50-60% of treated patients. There is currently no approved pharmaceutical treatment available for this pathology.

Nawal Ouzren, CEO of Sensorion, commented: *“The FDA’s decision to grant Orphan Drug Designation to SENS-401 is another important milestone for our company, as we continue to advance our clinical and regulatory strategy. Hearing loss in pediatric oncology patients is one of the most frequent and side effects of Cisplatin treatment, and may disable them for the rest of their lives. Based on its unique profile and the data generated to date, we believe SENS-401 has the potential to be a safe and effective treatment for this serious medical condition where a significant unmet need exists. As such, we look forward to working with the FDA and EMA to set up an IND and design a Phase 2 clinical trial in order to evaluate SENS-401 in this indication.”*

Under the U.S. Orphan Drug Act, FDA's Office of Orphan Products Development grants Orphan Drug Designation to investigational drugs and biologics that are intended for the treatment of rare diseases that affect fewer than 200,000 people in the U.S. Orphan Drug status provides incentives for companies to develop products for rare diseases, including tax credits related to clinical trial expenses, an exemption from the FDA user fee, FDA assistance in clinical trial design, and potential market exclusivity for seven years following approval.

SENS-401 is currently also in development for the treatment of Sudden Sensorineural Hearing Loss (SSNHL). Sensorion expects to initiate a Phase 2 clinical trial in this indication in the US and Europe in the first half of 2018. SENS-401 previously received Orphan Drug Designation in Europe in SSNHL.

About SENS-401

SENS-401, R-azasetron besylate, is a drug candidate that aims to protect and preserve inner ear tissue when lesions can cause progressive or sequellar hearing impairments. SENS-401 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. SENS-401 is a small molecule that can be taken orally or via an injection and has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss.

About Sensorion

Sensorion is a biotech company specializing in the treatment 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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