Press release

Sensorion receives European Medicines Agency agreement on the Pediatric Investigation Plan (PIP) for Arazasetron (SENS-401) in two indications

This agreement paves the way for the submission of a marketing authorization application in Europe

Montpellier, 28 June 2019 – 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, announces today that the European Medicines Agency (EMA) has accepted its Pediatric Investigation Plan (PIP) for both development in the treatment of severe hearing loss (SSNHL) and for prevention of ototoxicity caused by cisplatin (CIO) in the pediatric population.

"We are delighted by this outcome which we regard as an important stage for Sensorion and young patients. Indeed, this approval will allow Sensorion to develop SENS-401 for pediatric patients suffering from severe hearing loss (SSNHL) but also in the prevention of ototoxicity caused by cisplatin. The loss of hearing in pediatric oncology patients often generates a lifelong handicap and is one of the main side effects of chemotherapy. We think that SENS-401 could be a safe and effective treatment for these severe lesions, a field in which there are substantial unmet medical needs. So we intend to continue discussions and propose a Phase 2 clinical trial protocol in order to investigate SENS-401 in this indication", states Nawal Ouzren, Sensorion CEO.

SENS-401 is under development in the treatment of Sudden Sensorineural Hearing Loss (or SSNHL). Sensorion initiated Phase 2 clinical trial in this indication at the start of 2019. The interim safety results are expected at the end of 2019. In November 2016, SENS-401 already received the orphan drug designation in Europe in SSNHL.
This data on otoprotection and the recovery of auditory capacity confirms the promising clinical potential of SENS-401 in sudden onset deafness, including when the treatment is not initiated immediately.

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 physiopathology and etiology of inner ear related diseases enabling us to select the best targets and modalities for drug candidates. We also identify biomarkers to improve diagnosis and treatment of these underserved illnesses. Sensorion is launching in the second half of 2019 two preclinical gene programs aiming to correct hereditary monogenic forms of deafness including Usher Type 1 and deafness caused by a mutation of the gene encoding for Otoferlin. 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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