*Press release*

# Sensorion receives FDA IND Approval for Arazasetron (SENS-401)

**Montpellier, July 11th, 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 it has received the Investigational New Drug (IND) approval from the US Food and Drug Administration (FDA) to proceed with SENS-401, based on preclinical data and clinical development plan.

SENS-401 is under development in the treatment of Sudden Sensorineural Hearing Loss (or SSNHL). Sensorion initiated the Phase 2 clinical trial in this indication beginning of 2019 in Europe, Canada, Israel and Turkey. The interim safety results are expected at the end of 2019 and top line data will be announced mid-2020. In November 2016, SENS-401 received the orphan drug designation in Europe in SSNHL.

The European Medicines Agency (EMA) has accepted on the 28th of June 2019 the Pediatric Investigation Plan (PIP) for both developments in the treatment of severe sudden sensorineural hearing loss (SSNHL) and for prevention of ototoxicity caused by cisplatin (CIO) in pediatric populations.

## About SENS-401

SENS-401, arazasetron 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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## Disclaimer

This press release contains certain forward-looking statements concerning Sensorion and its business. Such forward looking statements are based on assumptions that Sensorion considers to be reasonable. However, there can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the 'Document de référence' registration document filed with the 'Autorité des Marchés Financiers' (AMF French Financial Market Authority) on September 7th, 2017 under n°R.17-062 and to the development of economic conditions, financial markets and the markets in which Sensorion operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Sensorion or not currently considered material by Sensorion. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Sensorion to be materially different from such forward-looking statements.
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