

# Sensorion Surpasses Enrollment Target for SENS-401 in SSNHL, Results Available in January 2022

10/27/2021

MONTPELLIER, France--(BUSINESS WIRE)-- Regulatory News:

**Sensorion (Paris:ALSEN) (FR0012596468 – ALSEN)** a pioneering clinical-stage biotechnology company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, announces 115 patients have been enrolled for treatment in the company's AUDIBLE-S study of the company's first-in-class small molecule drug SENS-401 in patients with sudden sensorineural hearing loss (SSNHL). Recruitment is now closed and the evaluation of the last recruited patients is ongoing.

With 115 patients enrolled, Sensorion has surpassed its target of 111 required under the revised statistical analysis plan for the AUDIBLE-S study. Enrolled patients receive 28 days of treatment and are followed for two additional months to complete the study. The release of preliminary data is expected in January 2022 broadly in line with the expectations of top line data release around year end, as communicated in our press release in September.

"AUDIBLE-S is an important part of the development of SENS-401 as a pipeline asset for Sensorion and we are looking forward to sharing the top line results of the study in January 2022. As SENS-401 progresses through multiple clinical programs, Sensorion is building a clear picture of the clinical utility and market potential in treating and preventing diverse forms of hearing loss" said **Géraldine Honnet, CMO of Sensorion**.

Patients included in AUDIBLE-S have experienced severe sudden sensorineural hearing loss. The imminent completion of the AUDIBLE-S trial in SSNHL follows the acceptance by regulatory authorities of an amendment to the statistical analysis plan for the study announced with Sensorion's H1 results on September 27th, 2021.

SENS-401 is also progressing in other indications. Sensorion and its partner Cochlear Limited, will submit a clinical

trial application for SENS-401 in patients scheduled for cochlear implantation before year end. Separately, Sensorion will also submit a clinical trial application for a Phase 2 study of SENS-401 clinical study in cisplatin-induced ototoxicity (CIO) in Q4 2021.

## About SENS-401

SENS-401 (Arazasetron), is a drug candidate that aims to protect and preserve inner ear tissue from damage that can cause progressive or sequela 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. It has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA).

## About AUDIBLE-S

The Phase 2 AUDIBLE-S study is a randomized, double-blind, placebo-controlled multi-center Phase 2 study. Primary objective of the study is to assess the efficacy of SENS-401 on hearing loss in comparison to placebo at the end of the 4-week treatment period. Patients with severe or profound sudden sensorineural hearing loss are being recruited within 96 hours after onset of a sudden and severe hearing loss and randomized to either two treatment arms (29mg and 43.5mg twice a day oral dosing) or placebo. Change in pure tone audiometry PTA (dB) in the affected ear from baseline to the end of treatment visit is the primary outcome measure of the study.

## About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL). Sensorion has built a unique R&D technology platform to expand its understanding of the pathophysiology and etiology of inner ear related diseases enabling it to select the best targets and modalities for drug candidates. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses. Sensorion has launched three gene therapy programs, currently at preclinical stage, aimed at correcting hereditary monogenic forms of deafness including deafness caused by a mutation of the gene encoding for Otoferlin, hearing loss related to gene target GJB2 as well as Usher Syndrome Type 1 to potentially address important hearing loss segments in adults and children. The Company is potentially uniquely placed, through its 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 medical need.

**[www.sensorion.com](http://www.sensorion.com)**

Label: **SENSORION**

ISIN: FR0012596468

Mnemonic: **ALSEN**

## 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 2020 annual financial report published on April 9, 2021 and available on our website 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. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Sensorion shares in any country. The communication of this press release in certain countries may constitute a violation of local laws and regulations. Any recipient of this press release must inform oneself of any such local restrictions and comply therewith.

## Press Relations

Sophie Baumont

LifeSci Advisors

**sophie@lifesciadvisors.com**

+33 6 27 74 74 49

## Investor Relations

Catherine Leveau

Head of Investor Relations & Communication

**ir.contact@sensorion-pharma.com**

+33 6 72 18 00 22

Source: Sensorion