Press release

Regulators approve Sensorion's amendment to Phase 2 AUDIBLE-S trial of SENS-401 in Sudden Sensorineural Hearing Loss

- ***New recruitment target at 111 patients for Phase 2 SENS-401 AUDIBLE-S trial protocol***
- ***112 patients enrolled; recruitment expected to close by end of October 2021***
- ***Amendment approved by 9 out of 10 participating countries, the last one remains pending***

Montpellier, France, September 24, 2021 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company specialising in the development of novel therapies to restore, treat and prevent hearing disorders, announces that regulatory authorities of 9 out of 10 participating countries have approved Sensorion's amendment to the Phase 2 AUDIBLE-S study protocol with SENS-401 (Arazasetron) in Sudden Sensorineural Hearing Loss (SSNHL). The last one is still being reviewed and we hope to provide an update as soon as possible.

As announced with our full year results on March 18, 2021, Sensorion had submitted to the regulatory authorities an amendment to the statistical analysis plan for the AUDIBLE-S study that significantly reduced the sample size without compromising the quality or potential outcome of the trial. The study has now a recruitment target of 111 patients and has enrolled 112 patients. Since not all patients have yet completed their 28-day end of treatment visit, Sensorion will continue the recruitment until the end of October 2021. Top line data continues to be expected around year end.

The original statistical analysis plan (which was based on a combined phase 2 & phase 3 study) had required a much larger number of patients based on assumptions derived from scientific literature. Sensorion's revised approach has now been widely accepted by the regulatory authorities and follows the planned interim analysis reviewed by the independent Data Monitoring Committee. The primary outcome measure of the study remains unchanged.

"The continuing progress of SENS-401 in treating hearing loss in SSNHL is immensely gratifying and a testament to the skills and dedication of our clinical teams and their collaborators" said **Géraldine Honnet, CMO of Sensorion.** "We look forward to presenting the top line data from the study, and to conducting further clinical studies on SENS-401 in additional indications."

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 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. 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 (NCT03603314) is a randomized, double-blind, placebo-controlled Phase 2 study conducted across 50 sites in Europe, Canada, Israel, and Turkey. 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.

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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

Follow us on Twitter and LinkedIn

For further information, please contact

Press Relations
Sophie Baumont
LifeSci Advisors
sophie@lifesciadvisors.com
+33 6 27 74 74 49

Investor Relations
Catherine Leveau
Head of Investor Relations & Corporate Communications
Ir.contact @sensorion-pharma.com
+33 6 72 18 00 22

Label: **SENSORION**
ISIN: **FR0012596468**
Mnemonic: **ALSEN**

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