Press release

Sensorion Updates on SENS-401 Phase 2 trial in Sudden Sensorineural Hearing Loss

- ***Safe and well tolerated in 115-patient SSNHL study; primary endpoint not met***
- ***Sensorion will continue to analyze the data from the AUDIBLE-S study and update the market mid-March following the analysis of the secondary endpoints***
- ***Sensorion continues to develop SENS-401 in other indications***
- ***Three preclinical gene therapy programs, aimed at correcting hereditary monogenic forms of deafness, are in progress***

Montpellier, 17 January 2022 – Sensorion (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, today reports results from the 115-patient Phase 2 AUDIBLE-S study of SENS-401 (Arazasetron), for the treatment of sudden sensorineural hearing loss ('SSNHL').

SENS-401 was safe and well tolerated, however, it did not meet the primary endpoint of 15 dB, a significant improvement in pure tone audiometry (PTA, dB) in the affected ear from baseline in comparison to placebo at the end of the four-week treatment period.

A sub-analysis in participants with hearing threshold $\geq$ 80dB, representing those with severe hearing loss, showed a better response compared to placebo at the two doses. This subgroup accounted for 30% of the overall study population. These results confirm the data we obtained in our preclinical model of severe noise induced hearing loss.

Sensorion will continue to evaluate the data from the AUDIBLE-S study and the secondary endpoints results will be released mid-March. We will outline plans for the development of SENS-401 SSNHL at that point.

"We are encouraged by the SENS-401 activity data that showed a continuous improvement from day 7 until day 28. We will review the full data as soon as possible and explore in particular the PTA comparisons at day 84 and the other secondary endpoints in the trial to determine the best development path for SENS-401," **commented Géraldine Honnet, CMO of Sensorion**.

"*We're naturally disappointed that the Phase 2 AUDIBLE-S trial of SENS-401 did not meet the primary endpoint of the study. However, we are looking forward to reviewing the secondary endpoints once these become available by mid-March. Sensorion is committed to continuing to develop novel therapies in indications to restore, treat and prevent hearing loss disorders. Through our pioneering R&D technology platform and with a number of promising new therapeutic approaches, including gene therapy programs, we are confident in our mission,"* **Nawal Ouzren, CEO of Sensorion, commented.** *"We would like to express our gratitude to the investigators, collaborators and partners who have worked with us and particularly the patients who participated in the trial."*

Mauricio Cohen-Vaizer, ENT, Department of Otolaryngology, Head and Neck Surgery, Rambam Health Care Center, Haifa, Israel, commented: "*Sudden sensorineural hearing loss is a debilitating condition for which there are no therapeutic treatments currently available. Although the trial did not meet the primary endpoint, Sensorion and its investigators have acquired a wealth of knowledge around this poorly understood*

condition and are in a good position to explore further development options. Sensorion is doing valuable work in raising awareness and understanding of this condition."

Sensorion is continuing to develop novel therapies in other indications to restore, treat and prevent within the field of hearing loss disorders. Sensorion submitted a clinical trial application for a proof of concept (POC) study of SENS-401 clinical study in cisplatin-induced ototoxicity (CIO) in December 2021. Separately, Sensorion and its partner Cochlear Limited plan to submit a clinical trial application for SENS-401 in patients scheduled for cochlear implantation by the end of January 2022. Sensorion has also 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 caused by *GJB2* gene mutations as well as Usher Syndrome Type 1 to potentially address important hearing loss segments in adults and children.

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent hearing loss disorders, a significant global unmet medical need.

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. Its portfolio combines both small molecule programs and a preclinical portfolio of inner ear gene therapies.

Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) progressing in a planned Phase 2 study of SENS-401 clinical study in cisplatin-induced ototoxicity (CIO) and, with partner Cochlear Limited, a study of SENS-401 in patients scheduled for cochlear implantation.

Sensorion has entered into a broad strategic collaboration with Institut Pasteur focused on the genetics of hearing. It has three gene therapy programs aimed at correcting hereditary monogenic forms of deafness including deafness caused by a mutation of the gene encoding for Otoferlin, Usher Syndrome Type 1 related deafness and hearing loss related to mutation in *GJB2* gene to potentially address important hearing loss segments in adults and children. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.
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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 were 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 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).

Press release

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