Press release

Sensorion Reports Promising Preliminary Data from SENS-401 Phase 2a Clinical Study

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- **SENS-401 first-in-class drug candidate showed promising preliminary data in POC Phase 2a study to prevent residual hearing loss after cochlear implantation**
- **Preliminary results demonstrated 100% patients treated with SENS-401 showed presence of SENS-401 in perilymph at therapeutic concentrations, confirming that the oral presentation of SENS-401 passed through the labyrinth barrier to the cochlea**
- **Sensorion to host a KOL Webinar on July 5, 2023**

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

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 announces promising preliminary results from its Proof of Concept (POC) Phase 2a clinical trial of SENS-401 for residual hearing preservation following cochlear implantation. Sensorion will communicate further analysis of SENS-401 study during the KOL webinar it will host on July 5, 2023.

The Phase 2a trial is a multicentric, randomized, controlled, open-label trial aimed at evaluating the presence of SENS-401 in the cochlea (perilymph) after 7 days of twice-daily oral administration in adult participants prior to cochlear implantation due to moderately severe to profound hearing impairment. Patients start treatment with SENS-401 7 days before implantation and continue to receive SENS-401 for a further 42 days. The study also assesses a number of secondary endpoints, including the change of hearing threshold from baseline to the end of the study in the implanted ear at several frequencies.

Preliminary results

In 5 out of 5 patients, the presence of SENS-401 in the perilymph at a level compatible with therapeutic efficacy has

been confirmed, 7 days after the start of the study. These results confirm that SENS-401 crosses the labyrinth barrier and may have an effect on the preservation of the residual hearing.

Géraldine Honnet, M.D., Sensorion's Chief Medical Officer, declared: "Presence of SENS-401 in the cochlea in 100% of patients having undergone cochlear implantation surgery confirms our confidence in the potential of our small molecule. These preliminary results support Sensorion's ambition to provide solutions for people with hearing loss disorders. We will report further data from our Phase 2a study of SENS-401 in association with cochlear implants during our KOL webinar to be held on July 5, 2023."

Professor Yann Nguyen, M.D., Ph.D., ENT Surgeon at the Otolaryngology Department at the Hospital Pitié Salpêtrière, Paris, France, said: "The SENS-401 preliminary data suggests a compelling clinical profile for patients scheduled for cochlear implantation. These results are very promising, and I look forward to seeing further data of SENS-401, which has the potential to produce clinical benefits to patients suffering from hearing loss."

Sensorion's KOL webinar, held on July 5, 2023, will feature a presentation by KOL Professor Yann Nguyen M.D., Ph.D., who will provide an overview on the importance of residual hearing preservation and the surgical procedure developed for perilymph sampling.

Sensorion's management team will communicate further analysis of the preliminary results of the POC Phase 2a study of SENS-401 for the residual hearing preservation in patients who, due to moderately severe to profound hearing impairment, are scheduled for cochlear implantation. The study has been developed with Sensorion's partner, Cochlear Ltd., the global leader in implantable hearing devices.

A Q&A session will follow the formal presentations and the webinar will be subtitled live. A replay of the call will also be available.

Dr Yann Nguyen is an ENT professor at the Otolaryngology Department, at the Hospital Pitié Salpêtrière (Sorbonne Université, AP-HP), in Paris, France. His clinical activities are focused on middle ear surgery, cochlear implantation and lateral skull base surgery. He has a Ph.D. on "robot-based surgery for cochlear implantation". He is now working on robotics at the Hearing Institute (Institut Pasteur/Inserm) and he leads the "RobOtol project". Prof Nguyen's goal is to design and evaluate surgical solutions from lab bench to operating room for hearing loss.

Sensorion's KOL Webinar Wednesday July 5th, 2023

11am – 12pm ET / 5pm – 6pm CET

To register for the KOL Webinar, please click **here**

About SENS-401

SENS-401 (Arazasetron), Sensorion's clinical stage lead drug candidate, is an orally available small molecule that aims to protect and preserve inner ear tissue from damage responsible of progressive or sequelae hearing impairment. Sensorion currently develops SENS-401 in a Phase 2a for the prevention of residual hearing loss in patients scheduled for cochlear implantation. In addition, Sensorion expects to evaluate SENS-401 in a Phase 2 clinical trial for the prevention of Cisplatin-Induced Ototoxicity. SENS-401 has been granted Orphan Drug Designation by the EMA in Europe for the treatment of sudden sensorineural hearing loss, and by the FDA in the U.S. for the prevention of platinum-induced ototoxicity in pediatric population.

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 mechanisms of action for drug candidates.

It has two gene therapy programs aimed at correcting hereditary monogenic forms of deafness, developed in the framework of its broad strategic collaboration focused on the genetics of hearing with the Institut Pasteur. OTOF-GT targets deafness caused by mutations of the gene encoding for otoferlin and GJB2-GT targets hearing loss related to mutations 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.

Sensorion's portfolio also comprises clinical-stage small molecule programs for the treatment and prevention of hearing loss disorders.

Sensorion's clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) progressing in a planned Phase 2 proof of concept clinical study of SENS-401 in Cisplatin-Induced Ototoxicity (CIO) and, with partner Cochlear Limited, in a study of SENS-401 in patients scheduled for cochlear implantation. A Phase 2 study of SENS-401 was also completed in Sudden Sensorineural Hearing Loss (SSNHL) in January 2022.

www.sensorion.com

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