Press release

Sensorion Reports Positive Efficacy Data from SENS-401 Phase 2a Clinical Study

- ***Positive preliminary data showed SENS-401 has a clinically significant effect on the preservation of residual hearing after cochlear implantation in all adult patients treated so far***
- ***On the 19th of June, Sensorion announced that the patients treated with SENS-401 showed presence of SENS-401 in perilymph. Analysis suggests preservation of 21 dB of their residual hearing compared to the control group six weeks after cochlear implantation at 500 Hz***
- ***Data to be detailed at a webinar today Wednesday, July 5, 2023, led by Professor Yann Nguyen M.D., Ph.D and Sensorion's management team***

Montpellier, July 5, 2023, 7.30am CET – 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 further analysis from its Proof of Concept (POC) Phase 2a clinical trial of SENS-401 for residual hearing preservation in adult patients following cochlear implantation. Analysis of the preliminary data will be presented at the Company's KOL webinar taking place today, Wednesday, July 5, 2023 (event details below).

On June 19th, 2023, Sensorion announced that in preliminary data from the Phase 2a study, SENS-401 was detected in the perilymph of all 5 adult patients treated with the product. Levels of SENS-401 were considered consistent with potential therapeutic effects after seven days of repeated oral treatment.

The data unveiled today shows that the study also assessed a number of secondary endpoints, including the change of hearing threshold from baseline to the end of the treatment period in the implanted ear at several frequencies. Study entry criteria required patients to have a pure tone audiometry (PTA) threshold of 80 dB or better (i.e., ≤80 dB) at 500 Hz, defined as indicating a minimal level of residual hearing. Further analysis suggests SENS-401 treated patients demonstrated the preservation of 21 dB of their residual hearing compared to the control group six weeks after cochlear implantation at 500 Hz.

In the SENS-401-treated group (N=5), the loss of residual hearing was only 12 dB, contrasting with a larger loss of 33 dB observed in the control group of four participants not treated with SENS-401. This resulted in a difference of clinical significance of 21 dB between the two groups, suggesting SENS-401 provided a protective effect on early residual hearing loss after cochlear implantation. These original and promising findings reinforce the hypothesis that SENS-401, by crossing the labyrinthine barrier to reach the cochlear compartment, has a positive effect on the preservation of residual hearing.

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 patients 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.

Nawal Ouzren, Chief Executive Officer of Sensorion, stated: "We are very excited to see such promising new preliminary data for our ongoing Phase 2a clinical study of SENS-401. This is great news for our program and supports our confidence in the potential of our innovative therapy to prevent residual hearing loss in adult patients suffering from moderately severe to profound hearing disorders. This level of residual hearing preservation means patients have a better chance of understanding speech against background noise and perceiving more natural sound quality with speech and sounds."

Géraldine Honnet, M.D., Sensorion's Chief Medical Officer, added: "Two weeks ago we demonstrated that SENS-401 crossed the labyrinthine barrier to the cochlea. Today, following further analysis, we have gone much further and have shown SENS-401 potential to preserve early residual hearing six weeks after cochlear implantation. Patients treated with SENS-401 showed improved hearing preservation compared to the patients in the control group, corroborating the otoprotective potential of the molecule. We believe SENS-401 is a ground-breaking therapy with great potential in an area of significant unmet need and we are looking forward to seeing the final results of the study."

KOL Webinar

Sensorion's KOL webinar, held today on Wednesday, 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 Limited., 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 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.
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