Press Release

Sensorion Announces New Positive Clinical Data Across its Gene Therapy and Small Molecule Programs at the World Congress of Audiology in Paris

Montpellier, September 20, 2024, 7.30 am 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 announces new positive medical data from its clinical programs SENS-501 and SENS-401 during a symposium (12.30-1.30pm CET) and in an oral presentation on SENS-401 (11.15am CET) organized as part of the 36th World Congress of Audiology (WCA), held in Paris at the CNIT, La Défense, France.

The Company reports today new data across its pipeline of gene therapy (SENS-501) and small molecule (SENS-401) programs. Details of these medical advances will be presented by **Professor Natalie Loundon**, ENT Surgeon in the pediatric Hospital Necker-Enfants malades in Paris, France, **Professor Catherine Birman** (Otorhinolaryngologist, Director of the Sydney Cochlear Implant Centre, Australia), **Professor Yann Nguyen** (ENT Surgeon, Pitié Salpétrière Hospital, Paris, France), **Professor Stephen O'Leary** (Head of Otorhinolaryngology, University of Melbourne, Australia) and **Professor Christophe Vincent** (Head of Otology and Otoneurology, ENT surgeon, Salengro Hospital, Lille, France).

Gene Therapy

- Audiogene (OTOF-GT): Professor Catherine Birman will report initial positive safety results on the first patient injected in Sensorion's Phase 1/2 gene therapy clinical trial of SENS-501, dedicated to restoring hearing in patients suffering from otoferlin deficiency, one of the most common forms of congenital deafness. The surgery was well tolerated by the patient and no safety signals were reported. From early observations, changes in the child's behaviour and vocalisations were noted.
- Audiogene, aims to evaluate the safety, tolerability, and efficacy of intra-cochlear injection of SENS-501 for the treatment of *OTOF* gene-mediated hearing impairment in paediatric patients aged 6 to 31 months at the time of gene therapy treatment. Targeting the first years of life, the time period when the auditory system plasticity is optimal, will maximize the chances of these young children with pre-lingual hearing loss to acquire normal speech and language. The design of the study consists of two cohorts of two doses followed by an expansion cohort at the selected dose. While the safety will be the primary endpoint for the dose escalation cohort, the auditory brainstem response (ABR) will be the primary efficacy endpoint of the dose expansion cohort.

Small Molecule

- NOTOXIS, (SENS-401 in Cisplatin-Induced Ototoxicity): Professor Yann Nguyen will report preliminary safety and efficacy data in Sensorion's Phase 2a clinical trial of SENS-401 for the prevention of hearing loss caused by cisplatin ototoxicity in patients undergoing chemotherapy. The preliminary data show that a cumulative dose of cisplatin is a key factor of ototoxicity severity. A good safety profile of SENS-401 is confirmed in the long term, with the drug being administered for the first time for an average duration of up to 23 weeks. The preliminary results suggest a trend toward an otoprotective effect of SENS-401 beyond a cisplatin dose of 300 mg/m*2.*
  The NOTOXIS Proof-of-Concept (POC) Phase 2a trial is a multicenter, randomized, controlled, open-label study designed to assess the efficacy of SENS-401 in preventing cisplatin-induced ototoxicity in adult patients with neoplastic disease, four weeks after completion of cisplatin-based chemotherapy. The trial assesses several endpoints, including the rate and severity of

ototoxicity, changes in pure tone audiometry (PTA) (dB) throughout the study compared to before cisplatin treatment, and tolerability.

- SENS-401 for the prevention of residual hearing loss following cochlear implantation: Professor Stephen O'Leary during the symposium and Professor Christophe Vincent in a dedicated session on auditory implants for adults will report the final data analysis of Sensorion's Phase 2a clinical trial of SENS-401 for the preservation of residual hearing after cochlear implantation. Analysis of the final data of SENS-401 showed clinically significant effects on the preservation of residual hearing in patients treated with the small molecule compared to the control group. Sensorion's Phase 2a clinical trial of SENS-401 in association with cochlear implantation 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.

Details of these presentations will be available on Sensorion's website at the close of the symposium, at 1.30pm CET (7.30am ET). A video recording of the symposium will also be available shortly after.

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. SENS-501 (OTOF-GT) currently being developed in a Phase 1/2 clinical trial, 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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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.