Press release

Sensorion Announces Positive Recommendation From the Data Safety Monitoring Board (DSMB) Regarding the Continuation of NOTOXIS, its Phase 2a Clinical Trial of SENS-401 in Cisplatin-Induced Ototoxicity

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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 that the independent Data Safety Monitoring Board (or DSMB) has undertaken a review of the safety data for the patients participating in the NOTOXIS Phase 2a Proof-of-Concept (POC) clinical study of SENS-401 for the prevention of Cisplatin-Induced Ototoxicity (CIO).

The DSMB has recommended the continuation of the study and confirmed the absence of any concern as to the safety of SENS-401 when administered in adult patients receiving a daily dose of 43.5 mg, administered twice daily, over a period of up to 23 weeks. Data previously published in December 2023, indicated a favorable safety profile when administered continuously for up to 11 weeks in patients receiving SENS-401.

The patient enrolment continues to progress at a steady pace, in 13 clinical centers open to date. Sensorion's management team will report preliminary safety and efficacy data of the Phase 2a POC clinical trial of SENS-401 CIO at the World Congress of Audiology, to be held on September 19-22, 2024, in Paris, France.

The NOTOXIS 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.

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 and 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. 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.
www.sensorion.com

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Disclaimer

This press release contains certain forward-looking statements concerning Sensorion and its business. Such forward looking statements are based on assumptions that Sensorion considers to be reasonable. However, there

can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the 2023 full year report published on March 14, 2024, and available 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.

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