Press release

Sensorion Announces the Completion of Patient Inclusion in Phase 2a Clinical Trial of SENS-401 for Residual Hearing Preservation After Cochlear Implantation

Montpellier, February 1st, 2024, 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 announces the recruitment of the last patient in its Phase 2a clinical trial of SENS-401 for residual hearing preservation in adult patients following cochlear implantation.

A total of 33 patients have been screened to enroll at least 27 patients in the multicentric, randomized, controlled open-label Phase 2a 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. The study has been developed with Sensorion's partner, Cochlear Limited, the global leader in implantable hearing devices.

Géraldine Honnet, M.D., Chief Medical Officer of Sensorion, said: "We are delighted to announce the completion of recruitment in the Phase 2a clinical trial of SENS-401 for the residual hearing preservation, a key milestone in a study which is instrumental in the development plan of SENS-401. I would like to thank the patients and physicians involved in the study for their trust and commitment. The first preliminary efficacy data from this clinical trial were very promising and reinforce our confidence in the potential of SENS-401 in hearing loss prevention."

The first SENS-401 results published in July 2023 by Sensorion indicated positive efficacy and safety preliminary data showing that SENS-401 has a clinically significant effect on the preservation of residual hearing after cochlear implantation in all adult patients treated to date. Sensorion plans to publish the primary endpoint data readout in H1 2024.

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 assesses 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. SENS-501 (OTOF-GT) targets deafness caused by mutations of the gene encoding for otoferlin and is currently developed in a Phase 1/2 clinical study, 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:

Press release

SENS-401 (Arazasetron) progressing in two Phase 2 proof of concept clinical studies evaluating its efficacy to prevent Cisplatin-Induced Ototoxicity (CIO) and, with partner Cochlear Limited, to prevent residual hearing loss 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

Contacts

Investor Relations
Noemie Djokovic, Investor Relations and Communications Associate
ir.contact@sensorion-pharma.com

International Media Relations
Ulysse Communication
Pierre-Louis Germain / 00 33 (0)6 64 79 97 51
plgermain@ulysse-communication.com

Nicolas Entz / 00 33 (0)6 33 67 31 54
nentz@ulysse-communication.com

Bruno Arabian / 00 (0)6 87 88 47 26
barabian@ulysse-communication.com

Label: **SENSORION**
ISIN: **FR0012596468**
Mnemonic: **ALSEN**

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 2022 full year financial report published on March 30, 2023, 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.