Press release

Sensorion Receives Ethics Committee Approval to Include New Military Sites in SENS-401 Phase 2 study

- ***New sites to recruit voluntary military personnel in ongoing Phase 2 study in Sudden Sensorineural Hearing Loss***

Montpellier, February 17, 2020 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotech company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, announces that the Independent Ethics Committee of Strasbourg (France) has reviewed and approved a list of additional centers that will participate in the ongoing Phase 2 study for SENS-401 in Sudden Sensorineural Hearing Loss (SSNHL). Inclusion of voluntary military patients on these new sites will start after final administrative steps are carried out.

The new centers will recruit volunteer military personnel exposed to impulse noise during their professional activities and suffering from hearing loss. The participation of the French Army in the Phase 2 study makes this the largest military trial ever conducted in France.

The PATRIOT consortium - led by Sensorion and also comprising the French Biomedical Research Center (IRBA), Institut Pasteur and Electronique du Mazet[1] - has been awarded €10.8m non-dilutive funding from the French government, with Sensorion eligible to receive up to €5.6m to support SENS-401 clinical development for SSNHL. The commitment and active involvement of the French Ministry of Armed Forces in the project emphasizes that SSHNL is a clear and important unmet medical need and that efficient diagnostics and therapeutic solutions are required.

About SENS-401

SENS-401 (Arazasetron), is a drug candidate that aims to protect and preserve inner ear tissue from damage that can cause progressive or sequelar hearing impairment. A small molecule that can be taken orally or via an injection, SENS-401 has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss, and Orphan Drug Designation from the US FDA for the prevention of platinum-induced ototoxicity in the pediatric population. It has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA).

About SENS-401 Phase 2 trial

The AUDIBLE-S Phase 2 is a multi-center, randomized, double-blind, placebo-controlled study of SENS-401 in subjects with severe or profound sudden sensorineural hearing loss (SSNHL). Included patients will receive twice a day for 4 weeks one of the following: a 43,5mg dose, a 29mg dose or a placebo. The primary endpoint is change in pure tone audiometry PTA (dB) in the affected ear from baseline to the end of treatment visit (day 28).

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders. Its clinical-stage portfolio includes one Phase 2 product: SENS-401 (Arazasetron) for sudden sensorineural hearing loss (SSNHL). 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 modalities for drug candidates. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses. Sensorion has launched in the second half of 2019 two preclinical gene therapy programs aiming at correcting hereditary monogenic forms of deafness including Usher Type 1 and deafness caused by a mutation of the gene encoding for Otoferlin. The Company is uniquely placed through its platforms and pipeline of potential therapeutics to make a lasting positive impact on hundreds of thousands of people with inner ear related disorders; a significant global unmet medical need.
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[1] Through its subsidiary named ECHODIA

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