

Sensorion Inner Ear Disease Product Candidates and Technology Subject of Multiple Presentations at ARO MidWinter Meeting 2017

Key R&D Initiatives Highlighted in One Podium and Three Poster Presentations

Montpellier, February 15, 2017 - Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today provided details of the podium and poster presentations given at the 40th Association for Research in Otolaryngology (ARO) annual meeting held in Baltimore, MD, from February 11 to 15, 2017.

Pierre Attali, Sensorion's Chief Medical Officer, comments: "The ENT scientific community's keen interest in our studies presented at the ARO MidWinter Meeting 2017, a major event in this field, again reveals a substantial need for innovation in the inner ear domain. Our industry leading research aims to improve preclinical and clinical investigation methods, and to provide patients with new orally-administered drugs to treat vertigo, hearing loss and tinnitus. Confirmation in humans of the efficacy and pharmacokinetic data observed in animals is an illustration of the predictive nature of our tools, a fundamental quality of all translational research, for ongoing and future developments."

Translational research:

 Translational Predictivity of Preclinical Model Studies of the Anti-Vertigo Drug SENS-111 for Clinical PK/PD Relationships (podium presentation)

Sensorion has developed a mechanism-based model of vestibular lesions that generates established vertigo symptoms, such as spontaneous nystagmus, an uncontrolled repetitive movement of the eyes, and postural deviations. Using a combination of preclinical and clinical pharmacodynamic and pharmacokinetic data, Sensorion's researchers have established a clear correspondence between effective concentrations of SENS-111, the Company's drug candidate currently in a phase 2 clinical trial, in animals and humans. This preclinical model addresses the need for a predictive model to steer the translational research of new drugs.

 Comparative Characterization of Vertigo Associated Symptoms in a Preclinical Model Using Videonystagmography and Wireless Inertial Measurement of Head Kinematics (poster)

In the treatment of vestibular disorders in humans, the assessment of vertigo is subjective, and therefore difficult to evaluate in animal models, emphasizing the need for surrogate markers. On this basis, Sensorion studied the symptoms of vertigo in an acute unilateral vestibular loss model in rats by using infrared videonystagmography and wireless inertial measurements of head kinematics.

The frequency of nystagmus remained detectable up to ~48 hours after the lesion, but postural deviations continued until the end of the 14-day study, thus providing additional information about the evolution of vestibular symptoms and recovery time. These results are consistent with the clinical observations

described in the literature and confirm the potential of the vestibular disorder quantification preclinical tools for Sensorion's R&D activities.

Other results presented on compounds in development:

 SENS-111, a new H₄R antagonist, concentration dependently reduces vertigo sensation in healthy volunteers (HV) (poster)

Sensorion conducted a randomized double-blind placebo-controlled phase 1 clinical trial on 100 healthy volunteers to assess the global tolerance, pharmacokinetic profile and effects of SENS-111 on nystagmus and the vertigo induced by a caloric test. The results of this trial demonstrated that SENS-111 was well-tolerated and diminished the symptoms of vertigo in a plasma concentration dependent manner of the compound of up to 500-700 ng/mL. This data helped determine the doses to be evaluated in the phase 2 clinical trial in patients suffering from acute severe vertigo.

 Treatment Window for Oral Administration of the Clinical Drug Candidate SENS-401 after Acoustic Trauma in Rat (poster)

SENS-401, Sensorion's drug candidate currently in a phase 1 clinical trial, was assessed in comparison with placebo via a noise-induced hearing loss model that is currently a benchmark test in the study of acute sensorineural hearing loss. The results showed that daily oral administration of SENS-401 initiated up to 48 hours following the acoustic trauma leads to a significant recovery in hearing ability in rats.

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About SENS-111

SENS-111 is the first histamine type 4 receptor antagonist tested in inner-ear pathologies. This drug candidate displays a neuromodulation effect of the sensorineural inner ear cell function and is being developed for the symptomatic treatment of vertigo crises and tinnitus. SENS-111 is a small molecule that can be taken orally or via a standard injection, and has been successfully assessed in humans in phase 1b. Sensorion has set up a phase 2 clinical trial to assess this drug candidate in 207 patients with acute unilateral vestibulopathy, with enrolment due to begin during the first quarter of 2017.

About SENS-401

SENS-401, R-azasetron besylate, is a drug candidate that aims to protect and preserve inner ear tissue when lesions are present that can cause progressive or sequelar hearing impediments. It is one of the two enantiomer forms of SENS-218, azasetron, a racemic molecule belonging to the family of setrons marketed in Asia under the name Serotone. Enantiomers are molecules that have an identical chemical structure but a different configuration in space, i.e. they are mirror images of each other, like a person's left and right hands. The pharmacological and pharmacokinetic tests completed to date have shown a superior drug candidate profile for SENS-401 compared with the other enantiomer or the racemic form. SENS-401 is a small molecule that can be taken orally or via an injection and has received Orphan Drug Designation in Europe for the treatment of sudden sensorineural hearing loss.

About Sensorion

Sensorion specializes in the treatment of pathologies of the inner ear such as acute vertigo, tinnitus and hearing loss. The company was founded by Inserm (the French Institute of Health and Medical Research) and is utilizing its pharmaceutical R&D experience and comprehensive technology platform to develop first-in-class easy-to-administer, notably orally active, drug candidates for treating and preventing hearing loss and the symptoms of bouts of vertigo and tinnitus. The first two programs are respectively in phase 1 (SENS-401) and phase 2 (SENS-111) clinical testing. Based in Montpellier, Southern France, Sensorion has received financial support from Bpifrance, through the InnoBio fund, and Inserm Transfert Initiative.

Sensorion has been listed on the Euronext Alternext Paris exchange since April 2015.

www.sensorion-pharma.com

Contacts

Sensorion Laurent Nguyen

contact@sensorion-pharma.com

Tel: +33 (0)4 67 20 77 30

Name: **SENSORION** ISIN code: **FR0012596468**

Ticker: ALSEN



Investor Relations - France NewCap

Dusan Oresansky / Emmanuel Huynh sensorion@newcap.eu

Tel: +33 (0)1 44 71 94 92

Investor Relations – Rest of the World

LifeSci Advisors LLC

Chris Maggos – Managing Director, Europe

chris@lifesciadvisors.com Tel.: +41 79 367 6254

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