Press release

Sensorion Obtains FDA Approval to Initiate a Clinical Study of SENS-111 in Acute Severe Vertigo

Expect to begin global phase 2 study, including the United States, in the second half of 2016

Montpellier, September 1st, 2016 - Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announces that it has obtained Investigational New Drug (IND) status from the FDA for SENS-111, enabling the Company to initiate a clinical study in acute severe vertigo.

The FDA's approval validates the preclinical and clinical trials led by Sensorion within the framework of its SENS-111 program, and notably the results obtained from 100 healthy volunteers in a phase 1b clinical trial. The latter helped confirm the compound's safety and pharmacokinetic profile and provided guidance regarding the caloric test's use within this population.

All the results of the phase 1b trial will be presented at two upcoming annual scientific conferences:

- The American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNSF), September 18-21, 2016, in San Diego, California
  Poster: SENS-111, H4 Antagonist for Treatment of Peripheral Vertigo, Is Safe

- The European Association for Clinical Pharmacology and Therapeutics (EACPT), October 6-9, 2016, in Opatija, Croatia
  Oral presentation: The effect of SENS-111, a new H_4R antagonist, on vertigo induced by caloric test in healthy volunteers is related to plasma concentrations

The aim of the phase 2 study, which is expected to begin during the second half of 2016, will be to prove SENS-111's efficacy in treating the symptoms in patients with acute severe vertigo. The international study will notably be undertaken in the United States and Europe.

Pierre Attali, Sensorion's Chief Medical Officer, comments: "*The FDA's approval to begin our first phase 2 clinical trial of SENS-111 is a major strategic milestone for Sensorion. It reflects a real need for easy-to-administer drugs to treat vertigo crisis and confirms Sensorion's ability to rapidly take its R&D programs to the clinical stage. Our technological platform, which is capable of identifying molecules of therapeutic interest for inner ear disorders, active through systemic administration, plays a pivotal role in this process. Given the results demonstrated by SENS-111 in preclinical trials and the phase 1b study, we are confident in the success of this new study, which we expect to initiate during the second half of this year.*"

There is currently a clear unmet medical need for new effective and well-tolerated treatments to alleviate the symptoms of vertigo crises that effect some 82 million patients worldwide[1].

[1] Source: Alcimed, Sensorion

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About SENS-111

SENS-111 is the first representative of the histamine type 4 receptor antagonist class tested in inner-ear pathologies. This drug candidate displays a neuromodulation effect of the neurosensorial inner ear cell function and is being developed for the symptomatic treatment of vertigo crises or 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.

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 candidate programs for treating hearing loss and the symptoms of vertigo and tinnitus, for preventing and treating complications associated with progressive lesions in the inner ear, and for preventing the toxicity of chemotherapy in the inner ear. Based in Montpellier, southern France, Sensorion received financial support from Bpifrance, through the InnoBio fund, and Inserm Transfert Initiative.

Sensorion is listed on Alternext Paris since April 2015. www.sensorion-pharma.com

Upcoming events

- Participation in the Rodman & Renshaw global investment conference, on September 11-13, 2016 (New York, USA)
- Participation in the Sachs Biotech Forum, on September 27-28, 2016 (Basel, Switzerland)
- Participation in the Midcap Event conference, on October 5-6, 2016 (Paris, France)
- Publication of 2016 first-half results, on October 31, 2016 (after market)
- Participation in the BIO Europe conference, on November 7-9, 2016 (Cologne, Germany)
- Participation in the Actionaria trade fair, on November 18-19, 2016 (Paris, France)

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