



## Sensorion Obtains a Positive Opinion on Granting of Orphan Medicinal Product Designation for SENS-401 in Europe

SENS-401 is in Development for Treatment of Sudden Sensorineural Hearing Loss

**Montpellier, October 17, 2016 - Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announces that it has received, from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA), a positive opinion on the granting of Orphan Medicinal Product Designation for SENS-401, its drug candidate in development for the treatment of sudden sensorineural hearing loss.**

Sudden sensorineural hearing loss is a brutal affliction involving a hearing loss of more than 30dB, usually unilateral and occurring rapidly over just a few days. It is perceptive deafness following the deterioration or destruction of neurons and certain hair cells in the inner ear. As these cells do not spontaneously regenerate, their lesions lead to irreversible hearing impairments. There is currently no efficient drug available for treating acute hearing loss resulting from lesions of the inner ear.

SENS-401 administered orally has been shown to have a protective effect on hearing in a model of noise-induced hearing loss that has been established as a benchmark test in studying sudden sensorineural hearing loss.

SENS-401 has received a positive opinion from the EMA's Committee for Orphan Medicinal Products for the granting of Orphan Drug Designation in this indication. The definitive granting of this designation is now the responsibility of the European Commission. Sensorion expects to receive definitive notification in a few weeks, in line with usual procedures. This designation provides drugs and biologics intended to treat rare diseases and disorders with a special status. Notably it provides for 10-year marketing exclusivity period once European marketing approval is obtained, as well as certain incentives such as subsidies and tax credits, protocol assistance and possible exemptions or reductions in regulatory fees during the product's development or registration.

**Laurent Nguyen, CEO of Sensorion, concludes:** *“This positive opinion issued by the Committee for Orphan Medicinal Products for SENS-401 underscores the interest shown by the scientific community in the issue of acute hearing loss resulting from lesions of the inner ear such as those induced by acoustic trauma. This new molecule, recently identified using our screening platform, can potentially address a critical unmet need where there is currently no medical solution. We look forward to providing more details on the clinical development plan for SENS-401 in patients suffering from sudden sensorineural hearing loss as on-going talks with regulatory authorities get completed.”*

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### 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 sequellar 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 products 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 undertaken 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.

## 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](http://www.sensorion-pharma.com)

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