



## Sensorion Receives Orphan Drug Designation in Europe for SENS-401 in Sudden Sensorineural Hearing Loss

**Montpellier, November 24, 2016 - Sensorion (FR0012596468 – ALSEN), a biotech company specializing in the treatment of inner ear diseases, today announces that it has received Orphan Drug Designation from the European Commission for SENS-401, its drug candidate for the treatment of sudden sensorineural hearing loss. This decision validates the positive opinion issued by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA), as announced by Sensorion on October 17, 2016.**

**Laurent Nguyen, CEO of Sensorion, says:** *“The European Commission’s decision to grant SENS-401 orphan drug status is of strategic importance for Sensorion. Firstly, it allows us to position this molecule as the first orally-active candidate for treating sudden sensorineural hearing loss in Europe. Secondly, it represents a key element within the framework of our ongoing discussions with the regulatory authorities on the defining of the clinical development plan for this high-potential molecule.”*

Orphan Drug Designation is granted to drug candidates under development with potential activity in a condition based on the following criteria:

- the severity and rarity of the condition (affecting no more than 5 in 10,000 people in the EU);
- the absence of alternative methods of prevention or treatment.

SENS-401, a small molecule 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 (see the Press Release of November 17, 2016).

This condition 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 irreversible deterioration or destruction of neurons and certain hair cells in the inner ear. Approximately 4 in 10,000 Europeans are currently affected by this condition (i.e. approx. 205,000<sup>1</sup> patients), for which no efficient drug exists.

SENS-401’s orphan drug status provides Sensorion with a number of strategic advantages during its development cycle through to its marketing phase:

- certain incentives such as subsidies and tax credits, clinical protocol assistance and exemptions or reductions in regulatory fees during the product’s development or registration;
- a 10-year marketing exclusivity period once European marketing approval is granted.

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<sup>1</sup> For the purpose of the designation, the number of patients affected by the condition is estimated and assessed on the basis of data from the European Union (EU 28), Norway, Iceland and Liechtenstein. This represents a population of 513,700,000 (Eurostat 2016).

## 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 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 Acute 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.

## 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)

## Contacts

### Sensorion

Laurent Nguyen  
CEO

[contact@sensorion-pharma.com](mailto: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](mailto: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](mailto:chris@lifesciadvisors.com)

Tel.: +41 79 367 6254

## Disclaimer

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