Press release

Sensorion Update on SENS-401

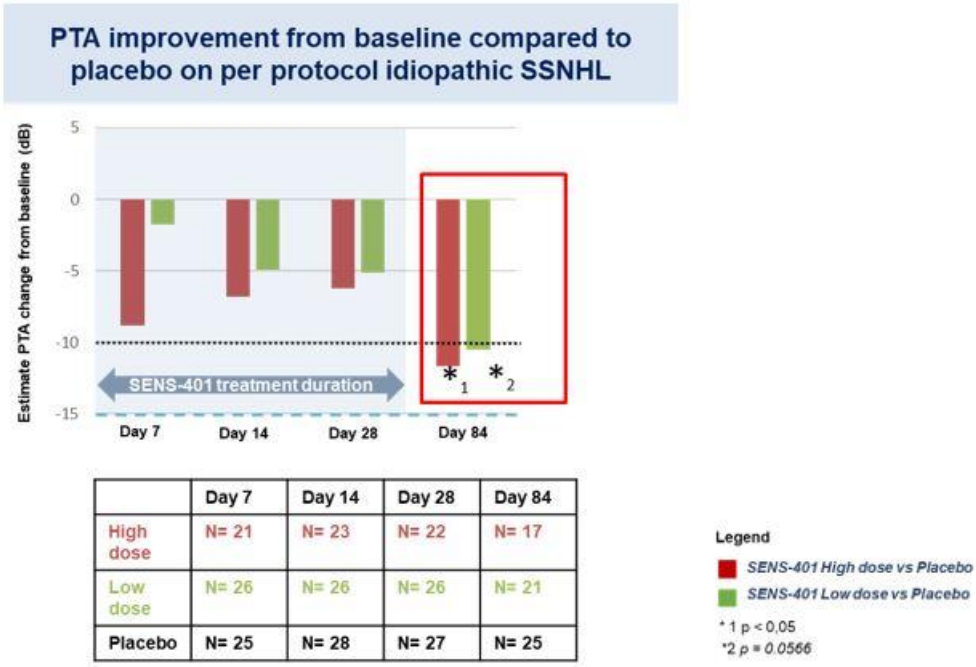
- ***Supplementary analysis of the Phase 2 AUDIBLE-S study data shows positive findings for certain trial population sub-groups within SSNHL***
- ***SENS-401 demonstrated a statistically significant effect with the high dose on pure tone audiometry (≥ 10 decibels improvement vs placebo) in Phase 2 AUDIBLE-S trial in SSNHL at Day 84 in per protocol idiopathic population (81 patients) treated with corticosteroids – (c. 70% of study population)***
- ***Sensorion will continue its joint development program with Cochlear Ltd for hearing preservation in patients following cochlear implantation***
- ***Sensorion is assessing next steps for SENS-401 in SSNHL and Cisplatin-Induced Ototoxicity (CIO) to balance clinical development priorities with efficient capital allocation and will update the market in due course***

Montpellier, 17 March 2022 – Sensorion (FR0012596468 – ALSEN) a pioneering clinical-stage biotechnology company which specializes in the development of novel therapies to restore, treat and prevent within the field of hearing loss disorders, today provides an update following supplementary analysis of the 115-patient Phase 2 AUDIBLE-S study of SENS-401 for the treatment of sudden sensorineural hearing loss (SSNHL).

As announced in January, SENS-401 for the treatment of SSNHL was safe and well tolerated but it did not meet the primary endpoint of 15 decibels (dB), a significant improvement from baseline in pure tone audiometry (PTA) in the affected ear in comparison to placebo at the end of the four-week treatment period.

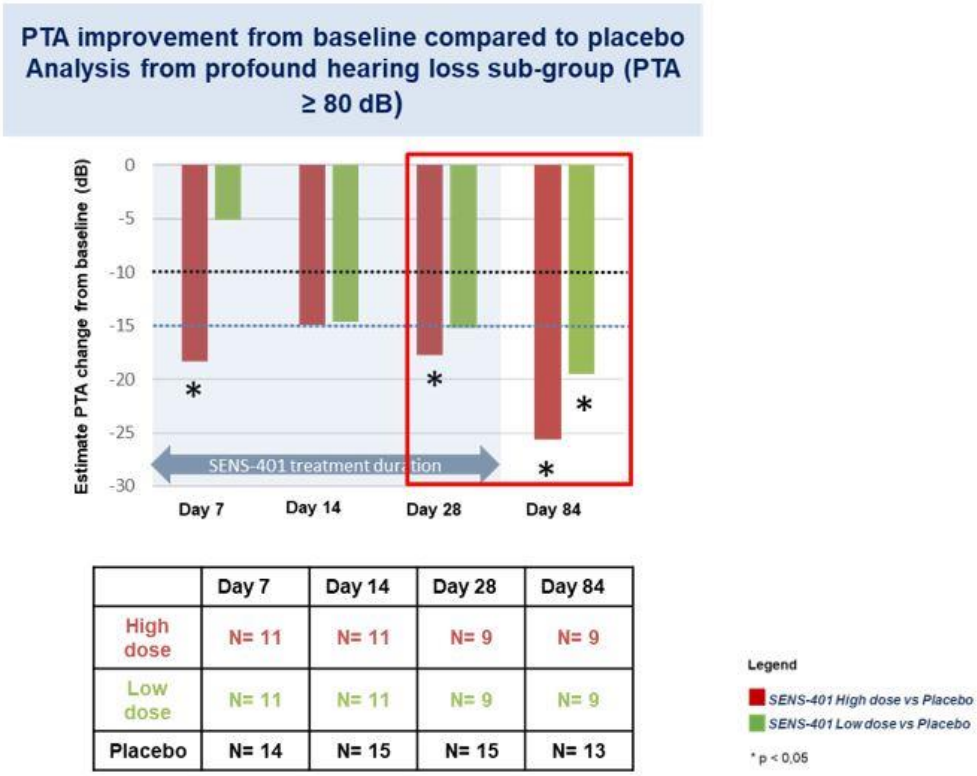
However, a review of exploratory endpoints identified a statistically significant treatment effect in a number of sub-group populations.

Firstly, a statistically significant and clinically meaningful treatment effect of at least 10 dB vs placebo was observed with the high dose at Day 84 (D84) in the per protocol idiopathic SSNHL population (81 patients) treated with corticosteroids (representing c. 70% of the Intent to Treat (ITT) population).



	Day 7	Day 14	Day 28	Day 84
High dose	N= 21	N= 23	N= 22	N= 17
Low dose	N= 26	N= 26	N= 26	N= 21
Placebo	N= 25	N= 28	N= 27	N= 25

Secondly, in a sub-group of idiopathic patients suffering from profound hearing loss (PTA ≥ 80 dB) treated with corticosteroids (36% of the overall study patient population), a significant response was observed at D28 and at D84, demonstrating a 19 to 26 dB significant improvement from baseline compared to placebo.



	Day 7	Day 14	Day 28	Day 84
High dose	N= 11	N= 11	N= 9	N= 9
Low dose	N= 11	N= 11	N= 9	N= 9
Placebo	N= 14	N= 15	N= 15	N= 13

In the ITT population, a better response (improvement ≥ 30 dB) was observed in both treated groups compared to placebo. Encouragingly, this difference improves over time between D28 and D84:

- At D28, 69% and 70% of patients in the treated groups showed a ≥ 30 dB improvement compared to 62.5% taking placebo
- At D84, 87.5% and 74%of patients in the treated groups showed a ≥ 30 dB improvement vs 60% in the placebo arm

The changes in Speech Discrimination Threshold and changes in Word Recognition Score are correlated with changes in PTA.

In light of the encouraging exploratory analysis and to ensure a disciplined approach to its R&D priorities in the context of challenging capital markets, Sensorion will explore options to finance the further development of SENS-401 in SSNHL and CIO.

Sensorion plans to provide an update on its clinical development plans for these indications in due course.

In addition, Sensorion and its partner Cochlear Limited (Cochlear) will advance with a trial of SENS-401 for hearing preservation in patients following cochlear implantation. Sensorion and Cochlear have submitted the proposed trial design for SENS-401 in patients scheduled for cochlear implantation to regulatory authorities in Australia and France.

Géraldine Honnet, Chief Medical Officer of Sensorion, commented: "An evaluation of the secondary and exploratory endpoints from the AUDIBLE-S study shows that SENS-401 demonstrated a statistically significant treatment effect in several subgroup populations and a superior responder rate to placebo in all treatment groups. In particular, we note many patients entering the study with profound hearing loss have emerged with mild hearing loss, meaning they do not have difficulty hearing what is said in quiet environments. This is the first time that this level of improvement has been demonstrated in profound hearing loss SSNHL patients."

Nawal Ouzren, CEO of Sensorion, added: "We are highly focused on the development of life-changing therapies to restore, treat and prevent hearing loss disorders. Following a rigorous evaluation of these data and our entire pipeline, we are focusing on what we believe to be the most promising development pathway for SENS-401 and across our R&D platform to create the greatest possible value for patients and investors. Along with our world-class partners, we remain excited about the potential of our gene therapy programs aimed at correcting hereditary monogenic forms of deafness, where we are pressing ahead with the most promising candidates."

About Sensorion

Sensorion is a pioneering clinical-stage biotech company, which specializes in the development of novel therapies to restore, treat and prevent hearing loss disorders, a significant global unmet medical need. 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, and has a pipeline of small molecule and gene therapy-based programs.
Sensorion is assessing next steps to advance clinical development of SENS-401 for SSNHL and for cisplatin-induced ototoxicity. Sensorion is advancing, with partner Cochlear Limited, a study of SENS-401 in patients scheduled for cochlear implantation.
Sensorion has entered into a broad strategic collaboration with Institut Pasteur focused on the genetics of hearing. It has gene therapy programs aimed at correcting hereditary monogenic forms of deafness including deafness caused by a mutation of the gene encoding for Otoferlin, Usher Syndrome Type 1 related deafness and hearing loss related to mutation in GJB2 gene to potentially address important hearing loss segments in adults and children. The Company is also working on the identification of biomarkers to improve diagnosis of these underserved illnesses.
www.sensorion.com

Press release

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 pediatric population. It has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA).

Contacts

Investor Relations
Catherine Leveau
Head of Investor Relations & Communication
ir.contact@sensorion-pharma.com
+ 33 6 72 18 00 22

International Media Relations
Consilium Strategic Communications
Mary-Jane Elliott/Jessica Hodgson
+ 44 7739 788014
+44 7561 424788
sensorion@consilium-comms.com

Label: **SENSORION**
ISIN: **FR0012596468**
Mnemonic: **ALSEN**

Disclaimer

This press release contains certain forward-looking statements concerning Sensorion and its business. Such forward looking statements are based on assumptions that Sensorion considers to be reasonable. However, there can be no assurance that such forward-looking statements will be verified, which statements are subject to numerous risks, including the risks set forth in the 2020 annual financial report published on April 9, 2021 and available on our website and to the development of economic conditions, financial markets and the markets in which Sensorion operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Sensorion or not currently considered material by Sensorion. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Sensorion to be materially different from such forward-looking statements. This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Sensorion shares in any country. The communication of this press release in certain countries may constitute a violation of local laws and regulations. Any recipient of this press release must inform oneself of any such local restrictions and comply therewith.