

# SENSORION

---

Unlocking The Potential Of Advanced Therapies  
For Hearing Loss

January 2025

# DISCLAIMER

- This document has been prepared by Sensorion (the “Company”) and is provided for information purposes only. This document does not purport to contain comprehensive or complete information about the Company and is qualified in its entirety by the business, financial and other information that the Company is required to publish in accordance with the rules, regulations and practices applicable to companies listed on Euronext Paris. No reliance may be placed for any purposes whatsoever on the information or opinions contained in this document or on its accuracy or completeness.
- This presentation does not constitute an offer to sell, a solicitation of, or an invitation to subscribe for or to buy, securities of Sensorion in any jurisdiction.
- The information and opinions contained in this document are provided as of the date of this document only and may be updated, supplemented, revised, verified or amended, and thus such information may be subject to significant changes. The Company is not under any obligation to update the information or opinions contained herein which are subject to change without prior notice.
- The information contained in this document has not been subject to independent verification. No representation, warranty or undertaking, express or implied, is made as to the accuracy, completeness or appropriateness of the information and opinions contained in this document. The Company, its subsidiaries, its advisors and representatives accept no responsibility for and shall not, under any circumstance, be held liable for any loss or damage that may arise from the use of this document or the information or opinions contained herein.
- This document contains information on the Company’s markets and competitive position, and more specifically, on the size of its markets. This information has been drawn from various sources or from the Company’s own estimates which may not be accurate and thus no reliance should be placed on such information.
- This document contains certain forward-looking statements. These statements are not guarantees of the Company’s future performance. These forward-looking statements relate to the Company’s future prospects, developments and marketing strategy and are based on analyses of earnings forecasts and estimates of amounts not yet determinable. Forward-looking statements are subject to a variety of risks and uncertainties as they relate to future events and are dependent on circumstances that may or may not materialize in the future. Forward-looking statements cannot, under any circumstance, be construed as a guarantee of the Company’s future performance and the Company’s actual financial position, results and cash flow, as well as the trends in the sector in which the Company operates, may differ materially from those proposed or reflected in the forward-looking statements contained in this document. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include those discussed or identified in the “Risk Factors” section of our 2023 Annual Report published on March 14, 2024, and available on our website ([www.sensorion.com](http://www.sensorion.com)). Even if the Company’s financial position, results, cash-flows and developments in the sector in which the Company operates were to conform to the forward-looking statements contained in this document, such results or developments cannot be construed as a reliable indication of the Company’s future results or developments. The Company does not undertake any obligation to update or to confirm projections or estimates made by analysts or to make public any correction to any prospective information in order to reflect an event or circumstance that may occur after the date of this document.
- Certain figures and numbers appearing in this document have been rounded. Consequently, the total amounts and percentages appearing in the tables may not necessarily equal the sum of the individually rounded figures, amounts or percentages.
- All persons accessing this document must agree to the restrictions and limitations set out above.

# Sensorion

## Establishing Global Leadership In Hearing Loss With Strong And Diversified Pipeline



**Market:** Euronext Growth

**Ticker:** ALSEN


**Market Cap:** €207M

**Cash balance:** c.€87M\*

\*as of June 30th 2024; provides runway until end of 2025

# Sensorion

## Portfolio Of Advanced Hearing Loss Therapies

	Product	Indication	Discovery	In-vivo POC	Preclinical	Phase 1	Phase 2	Phase 3	Milestones (estimated)
Gene Therapies RESTORE	SENS-501*	Otoferlin Deficiency	Phase 1/2						2nd Cohort Completed in H1 2025
	GJB2-GT*	Adult Onset (presbycusis)							CTA/IND Enabling Activities
	GJB2-GT*	Pediatric Progressive							CTA/IND Enabling Activities
	GJB2-GT*	Congenital Onset							CTA/IND Enabling Activities
Small Molecule TREAT & PREVENT	SENS-401	Hearing Preservation after CI							Ph2a Primary Endpoint Met
	SENS-401	Cisplatin-Induced Ototoxicity							Recruitment Completed H1 2025
	SENS-401	SSNHL							Exploring Partnering Opportunities

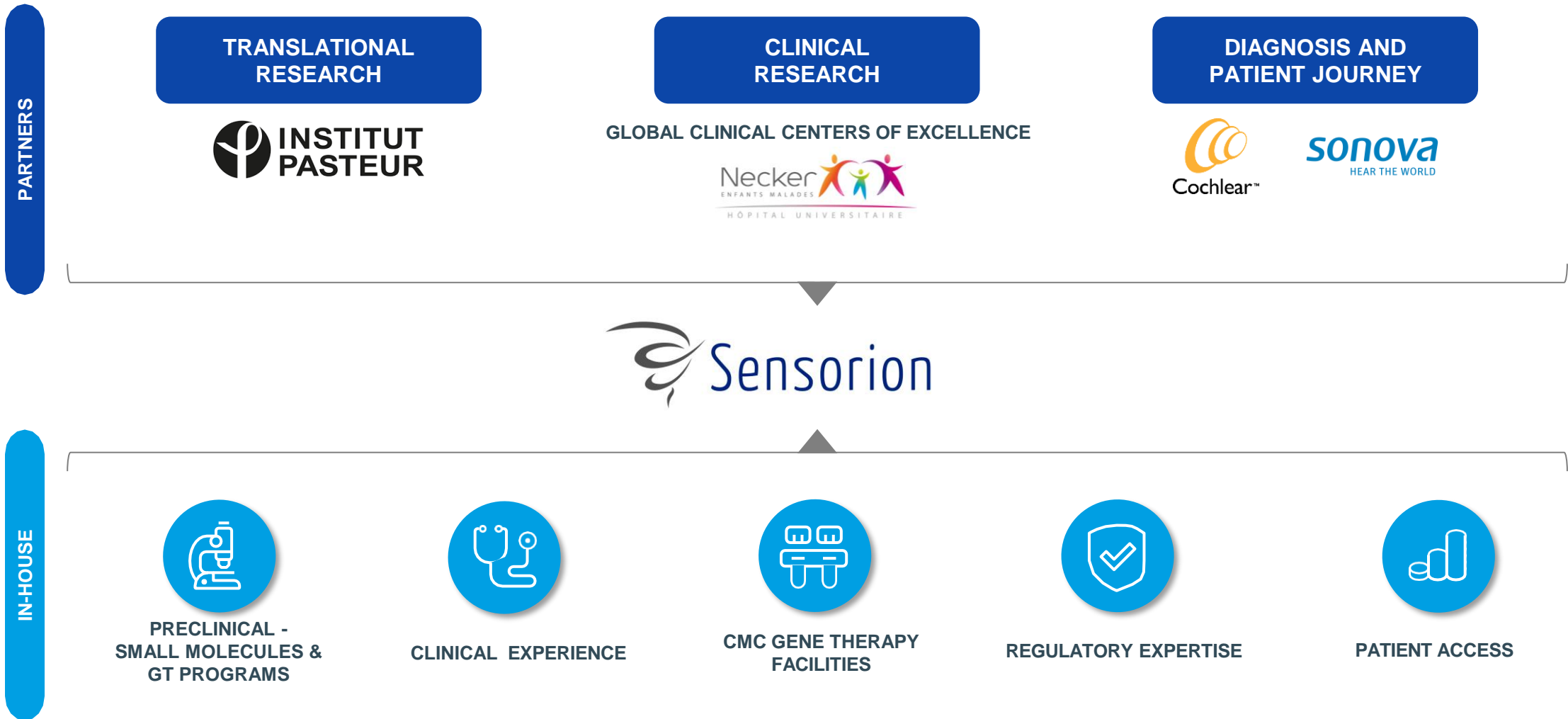
3SBio has a right of first refusal with respect to licensing in Greater China of SENS-401 (except in combination with cochlear implants) and SENS-501 OTOF-GT

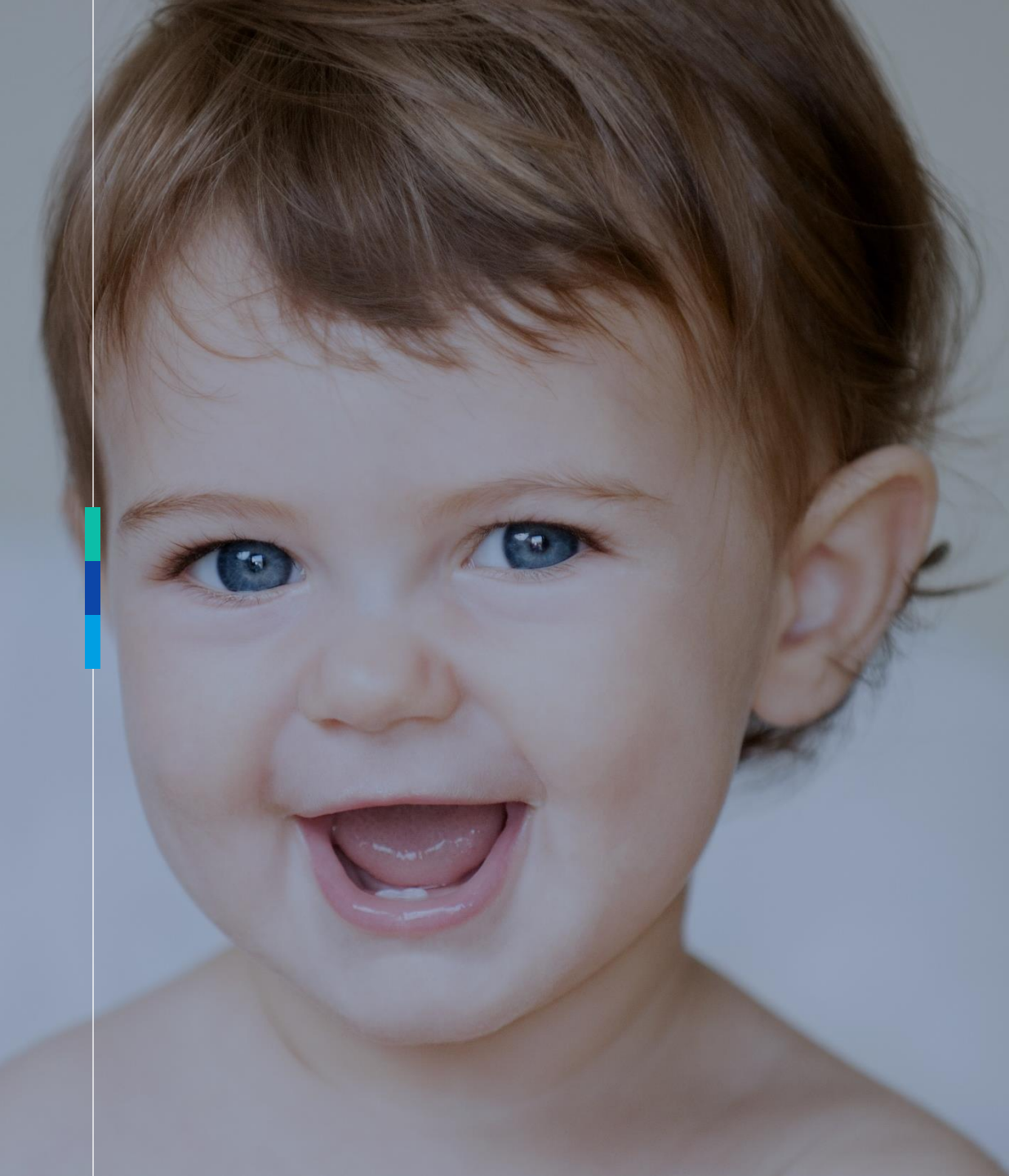
\*Option to obtain a licence from the Institut Pasteur (pre-defined financial terms and other terms to be negotiated)

Copyright by **Sensorion** - 2025 - All Rights Reserved

# Sensorion

Best-In-Class Partners And Internal Capabilities To Transform Standard Of Care





# 1

## GENE THERAPY PROGRAMS

---



# Sensorion

## Gene Therapy Programs Target Rare Auditory Diseases

### FIRST PROGRAMS RESULTING FROM THE INSTITUT PASTEUR COLLABORATION

#### OTOFERLIN DEFICIENCY

- Pediatric patients with mutations in OTOF suffer from severe to profound sensorineural prelingual non-syndromic hearing loss
- Otoferlin deficiency could be responsible for up to 8% of all cases of congenital hearing loss
- Prevalence ~20,000 in the USA + EU
- Incidence ~1,100 per year in USA + EU
- EU and US Orphan Disease Designation, US Rare Pediatric Disease Designation
- Pediatric Investigational Plan Agreed in EU

#### GJB2-RELATED HEARING LOSS

We have identified three forms of hearing loss associated with GJB2 gene mutations:

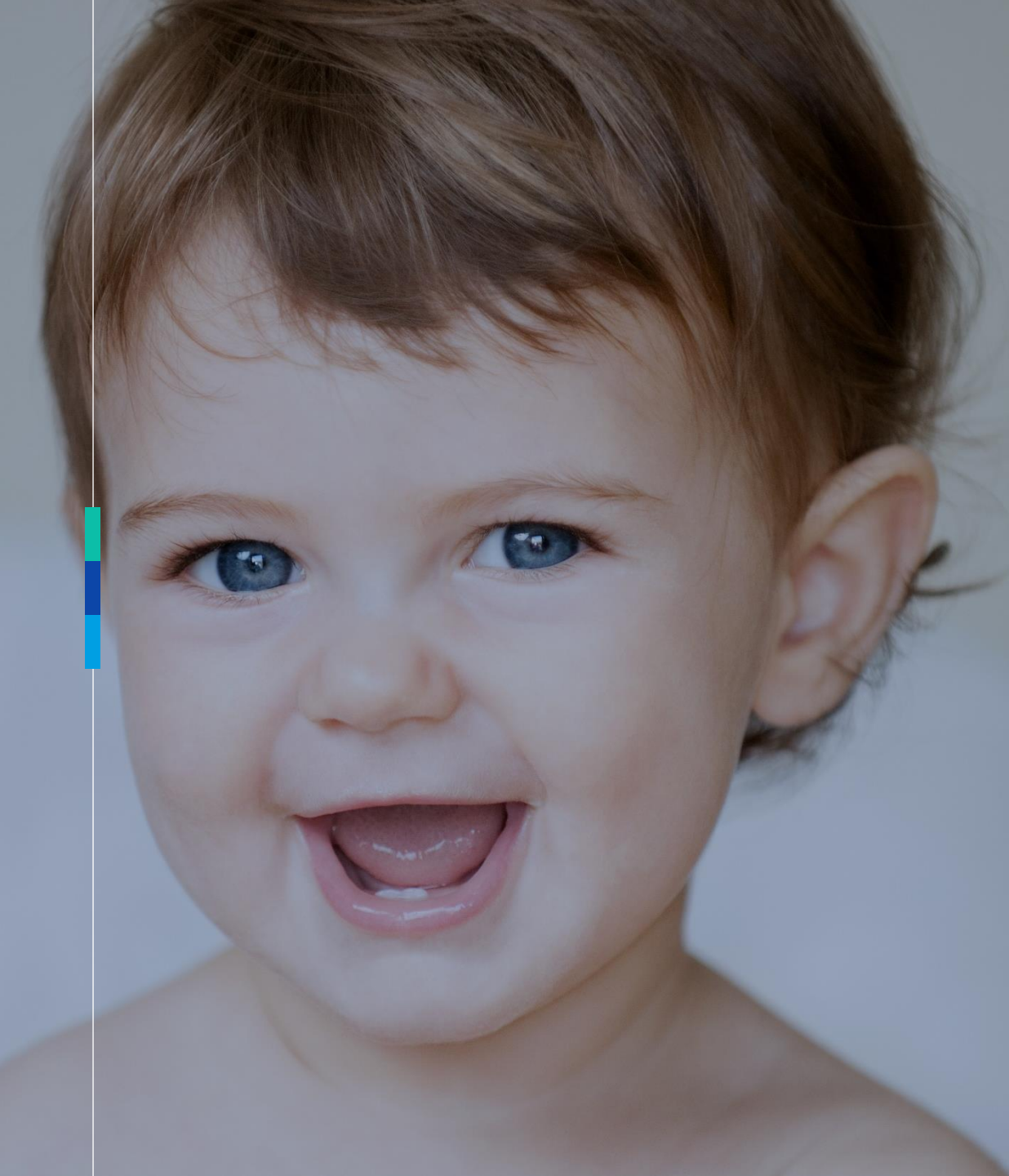
- Early onset of severe presbycusis (adult population)
- Childhood onset (pediatric population)
- Congenital onset (pediatric population)
- ~100,000 patients between 30- and 69-years old thought to be affected by a monogenic form of presbycusis due to GJB2 mutations
- Prevalence of congenital and childhood onset forms are estimated to be around 200,000 patients as around 50% of autosomal recessive non syndromic hearing loss cases are thought to be from GJB2 mutations



Current Standard Of Care Is Cochlear Implantation

**Gene Therapy Has A Life-Changing Potential For These Auditory Diseases**

Sources: Akil et al. 2019 ([link](#)), Orphanet ([link](#)), NIH ([link](#)), company estimates based on publicly available population data, Chardan 2020 report, Bryan, Garnier & Co 2019 report, Institut Pasteur, Boucher et al. 2020 ([link](#))



# 2

## OTOFERLIN DEFICIENCY

---

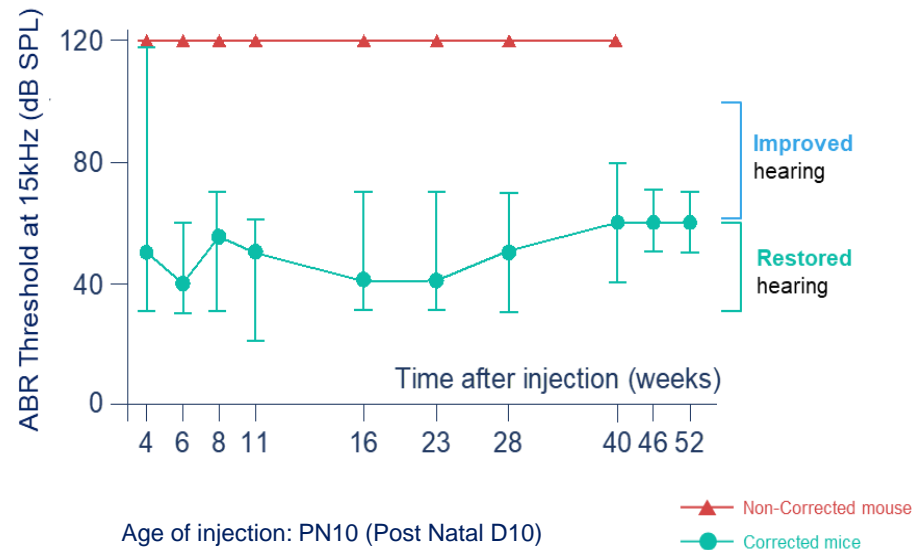


# SENS-501

## Long-Term Hearing Recovery In A Standardized Translational Model Of Otoferlin Deficiency

### Long-Term Hearing Restoration

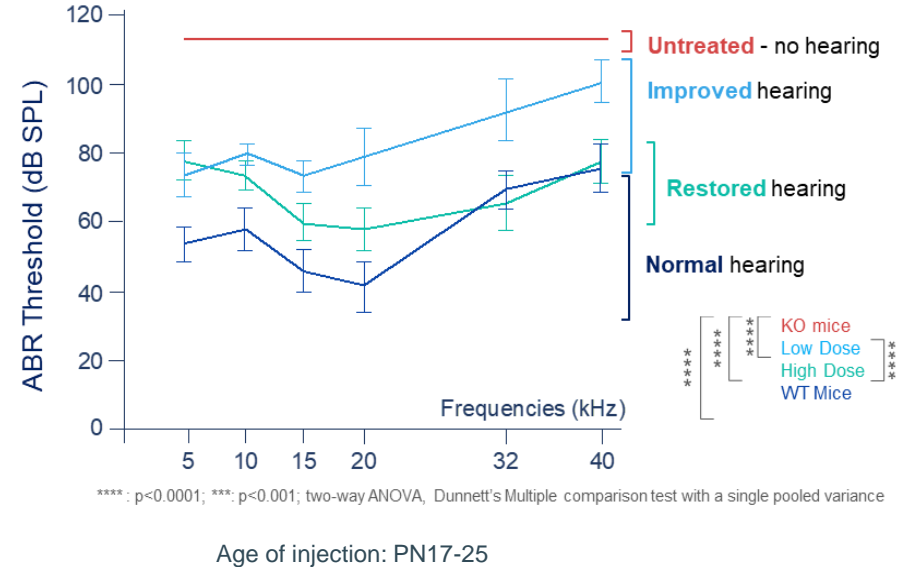
AAV-mOTOF injected in mice before hearing onset



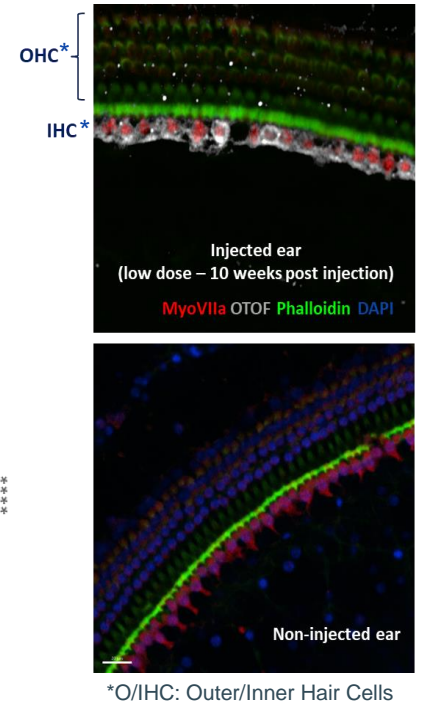
- **Durable hearing restoration** in *Otof*<sup>-/-</sup> mice by dual AAV-OTOF directly delivered to the inner ear up to one year post-injection

### Hearing Restoration Correlates with de novo OTOF Expression

SENS-501 injected in mice after hearing onset  
10 months after injection



- Both doses of SENS-501 demonstrated efficacy in **improving hearing in KO mice**
- SENS-501 leads to **otoferlin expression in Inner Hair Cells**



# SENS-501

## Dedicated Surgical Approach for Gene Therapy

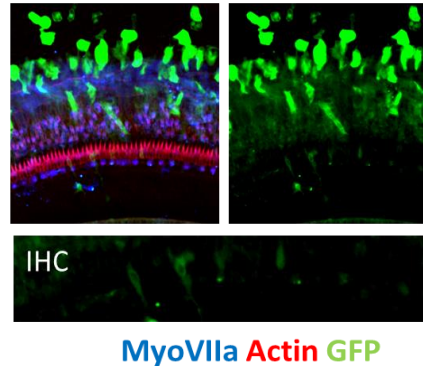
Non-Human Primates injected through the round window membrane (RWI) with or without stapedotomy (stap)

### 1 Fenestration

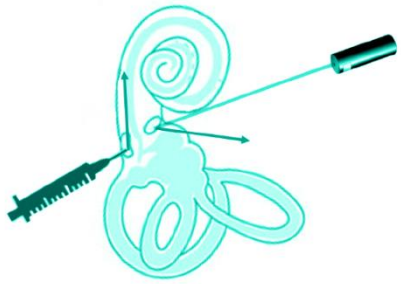


Used for cochlear implant

- Overpressure
- Limited volume
- Backflow
- Irregular transduction rate

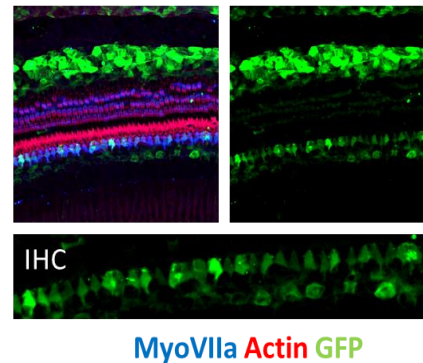


### 2 Fenestrations



Combining 2 common surgical techniques: cochlear implant and stapedotomy

- No overpressure
- No backflow
- Homogenous and efficient transduction rate



### Surgical approach

- Surgical procedure is **similar to cochlear implantation and well mastered by ENTs surgeons**
- Optimized surgery uses **stapedotomy procedure** to maximize target cells exposure along the full length of the tonotopic axis
- **Proprietary injection device developed** to inject a defined volume at a controlled flow rate

# SENS-501

## Raising The Bar With The SENS-501 Audiogene Study

**We wanted to generate a compelling value story showing that SENS-501 treatment is able to:**

- Demonstrate by itself **hearing restoration in toddlers**
- Enable infants to have **normal language acquisition** and **development**
- Improve **Patient Reported Outcomes & QoL** to allow infants **social development**

**Critical parameters that Audiogene have to demonstrate to be competitive:**

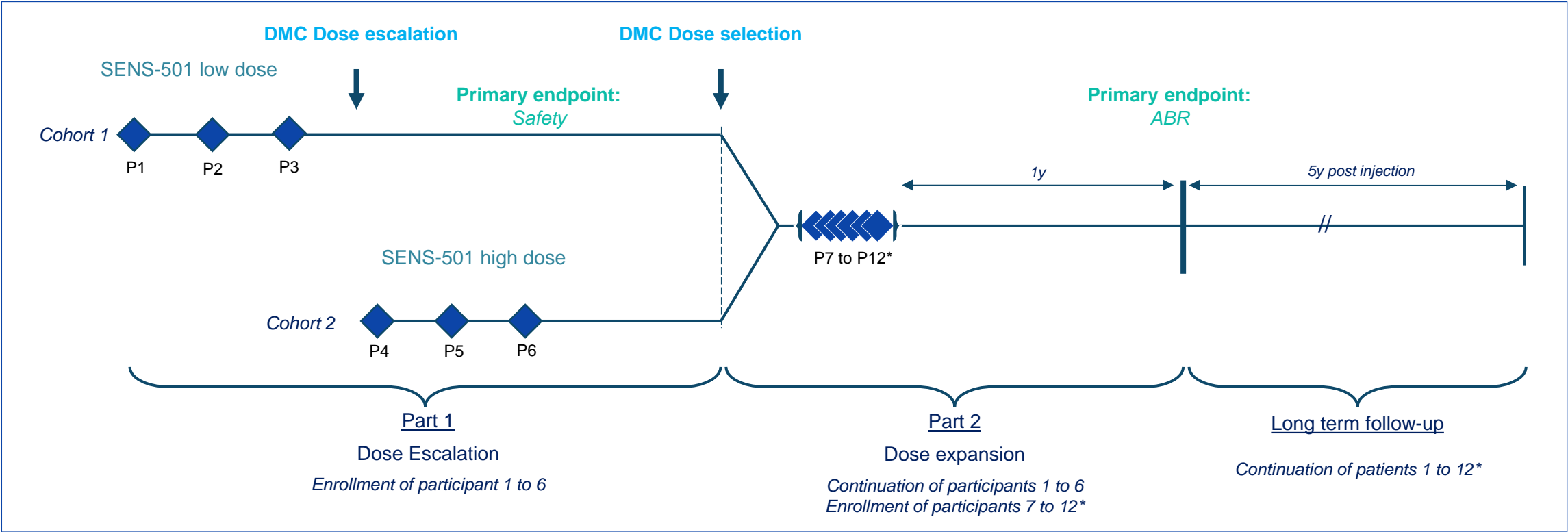
- A **homogeneous** clinical study population in the right target age for **speech acquisition** (ie: below 3 years old)
- **No concomitant cochlear implantation**
- **No previous cochlear implantation** to be able to document the contribution of the GT in speech development
- Global clinical study **leveraging the natural history network**

# SENS-501

## Phase 1/2 Audiogene Study



Audiogene, a Phase 1/2 clinical trial in homogenous population of infants and toddlers, aged 6 to 31 months, naive of cochlear implants, to assess safety, tolerability, and efficacy of SENS-501 following unilateral injection into the cochlea



\*Further participants may be recruited if required, who will be assessed in the same way as P7 to P12.  
Copyright by **Sensorion** - 2025 - All Rights Reserved

### FIRST COHORT INJECTED

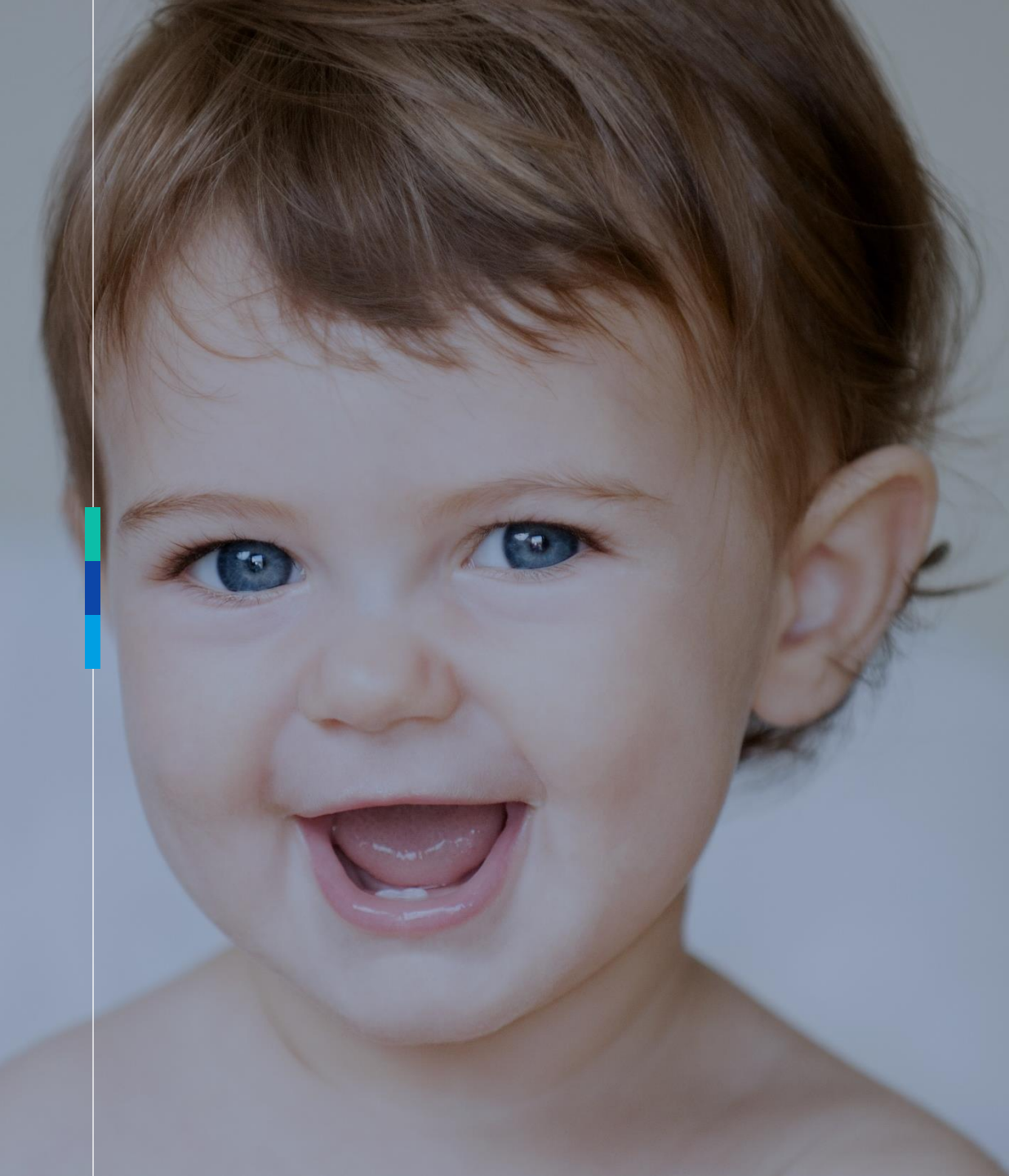


- **First cohort of infants and toddlers (3 patients) injected in H2 2024**
- **Surgical administration procedure was uneventful in the 3 patients**
- **Initial safety reported in first two patients**
  - No dose-limiting toxicities, no Serious Adverse Events
  - Vestibular function remained intact and unchanged from baseline
  - Otoacoustic Emissions (OAEs) remain present
- **Encouraging behavioral improvements in first two patients assessed for efficacy**

### STUDY UPDATE



- **Patient recruitment going as planned:**
  - 1<sup>st</sup> cohort completed by year-end 2024
  - 2<sup>nd</sup> cohort of patients to be recruited in H1 2025
- **Ongoing Natural History Study Otoconex supports eligible patients' identification**
- **KOL event to be held in early 2025**
- **Engage FDA in pre-IND Discussions in H1 2025**



# 3

## **GJB2-RELATED HEARING LOSS**

---



# GJB2-GT

## Leveraging SENS-501 Program For GJB2-GT Program Success

SENS-501 Is Paving The Way For GJB2-GT

SENS-501

GJB2-GT

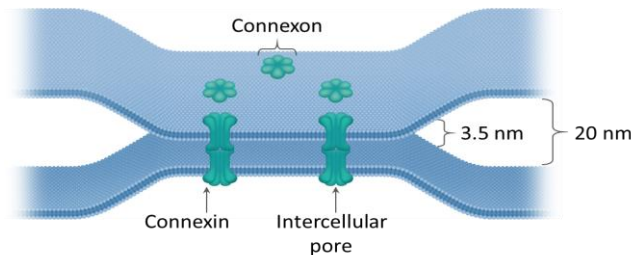
Aiming To Develop Best-In Class And First-In Class Gene Therapy

- **AAV capsid selected for high-level of target cells specificity**
- **GT product showing high level of target cells transduction**
- **Limited off-target tissue biodistribution**
- **Surgical approach developed and mastered by ENTs surgeons**

# GJB2-GT Connexin 26 Is A Gap-junction Protein Encoded By *GJB2* Gene And Is Responsible For Tissue Homeostasis

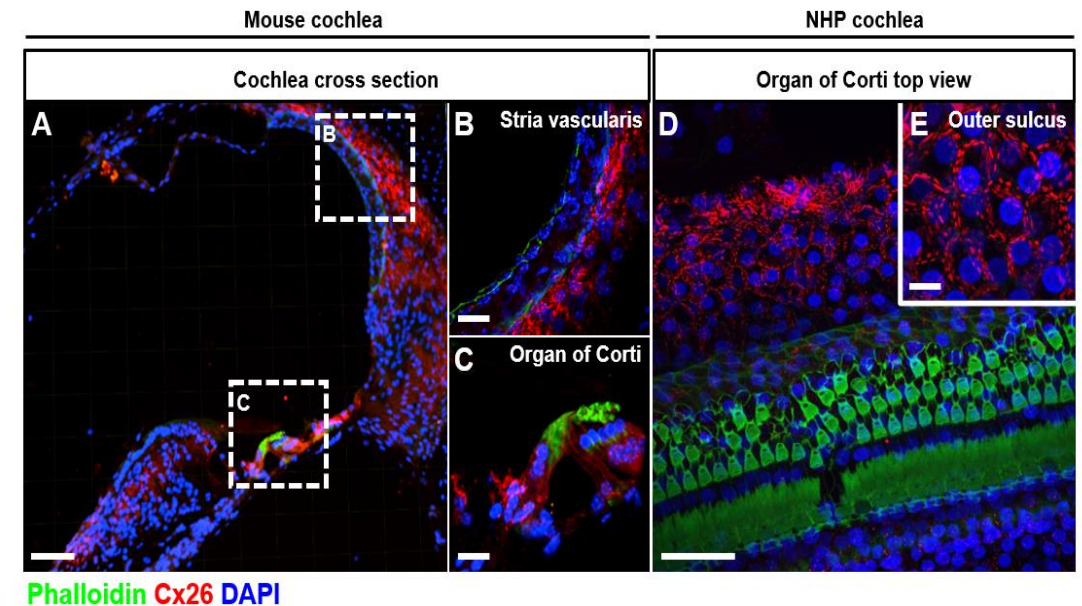
## Mutations in the *GJB2* gene Lead to Deafness

- *GJB2* is the gene encoding for the Connexin 26 protein; one of 20 known connexins
- Cx26 and Cx30 proteins are the dominating connexins in the cochlea; heteromeric or heterotypic hexamers forming Gap Junctions
- Gap Junctions are key for the intercellular exchange of molecules (miRNA, glucose, ions, etc.) hence responsible for tissue homeostasis
- More than 100 recessive mutations origin Cx26 truncation / deletion leading to non-syndromic hearing loss and deafness, most are addressable via gene replacement
- Severity of hearing loss correlates with degree of loss of *GJB2* function



Schematic representation of a gap junction – adapted from Kemperman, Hoefsloot and Cremers J R Soc Med 2002;95; 171-177

## *GJB2* Expression in the Cochlea

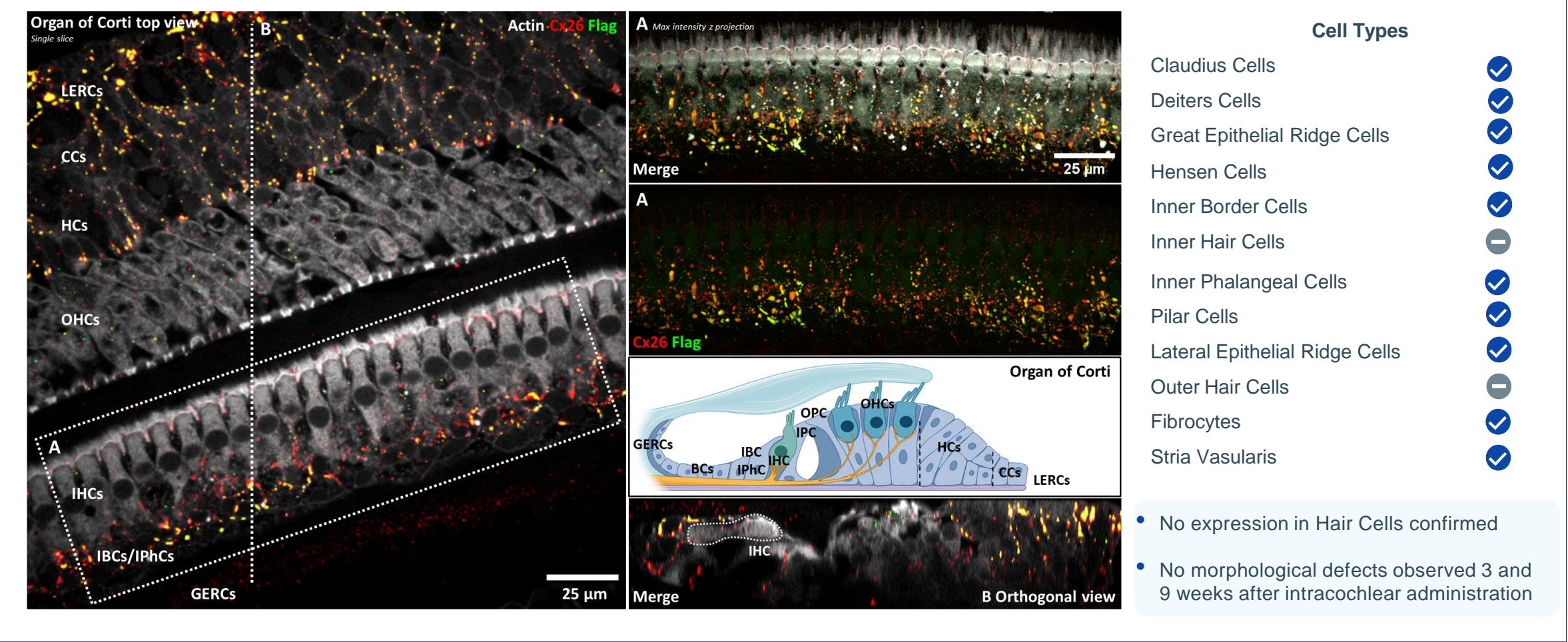


- Supporting cells of the organ of Corti
- Fibrocytes of the spiral limbus and the lateral wall
- Intermediate and basal cells of the stria vascularis
- Not expressed in hair cells

# GJB2-GT

## Lead Candidate Can Deliver Cx26 In The Appropriate Target Cells

Correct Delivery Of Cx26 Using Lead Candidate Flag In Non-Human Primate Cochlea





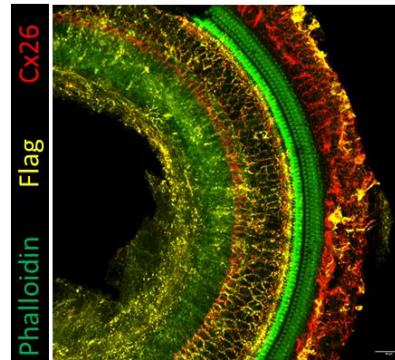
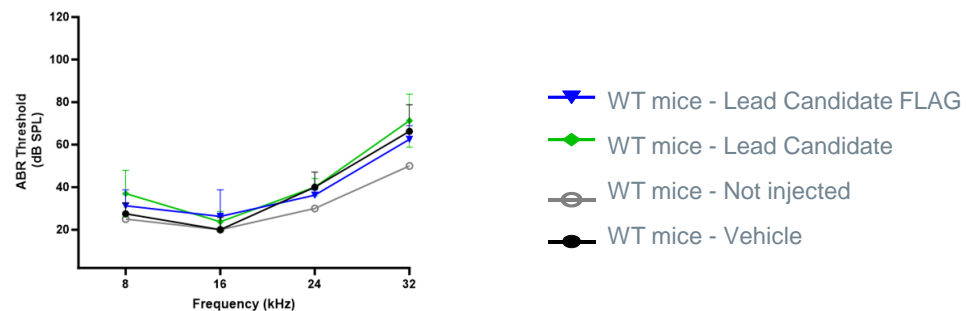
# GJB2-GT Lead Candidate Demonstrates Adequate Safety and Biodistribution Profile - Including Long-Term Local Tolerability in Mice and NHP

## Acute toxicity in WT Mice - High Dose IV injection

- Study performed in preparation of upcoming GLP-toxicity in mice after IV injection
- GJB2-GT does not interfere with normal growth and don't elicit elevated transaminase levels 4 and 8 weeks after injection
- Behavioral evaluation (Functional Observation Battery, exploratory behavior (videotracking) 3 and 7 weeks after injection: no findings

## 6-Month Exploratory Safety and Transgene Expression in WT Mice – Intracochlear Injection

### 6 months after injection



GT-GJB2-Flag imaging – 6 months post intracochlear injection in mice

- No impact on ABR up to 6 months following Lead Candidate injection
- Normal histology maintained, transgene expression persistence
- Hair cells detargeted
- Clinical pathology: no findings

## 3-Month Exploratory Toxicity and Biodistribution in Non-Human Primate – Intracochlear Injection

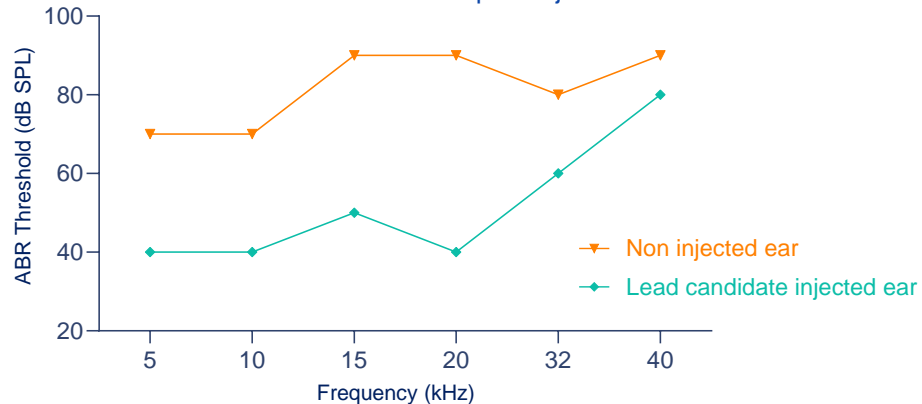
- Lead Candidate is well tolerated and did not induce any macroscopic/organ weight changes or local/systemic microscopic findings
- Normal cochlear histology
- No lab and clinical findings
- Biodistribution: the vast majority of the vector remains in injected ears, no dissemination observed in gonads, main organs, dorsal root ganglion (DRG)

# GJB2-GT

## Lead Candidate Prevents Hearing Loss In Relevant Mouse Model

### Proof Of Concept In Mice with Progressive Hearing Loss

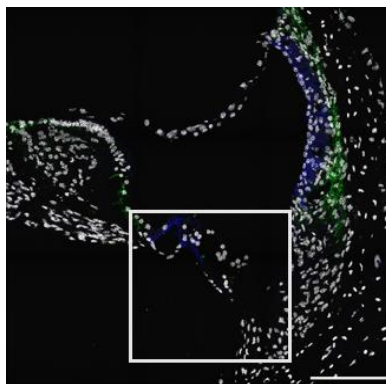
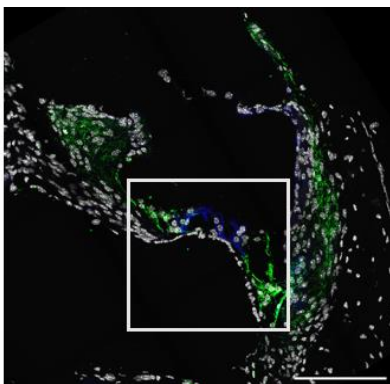
Example of One Mouse Injected After Hearing Onset  
ABR threshold - 10 weeks post-injection



### Hearing Loss Prevention Correlates With Connexin 26 Expression

Lead candidate injected ear

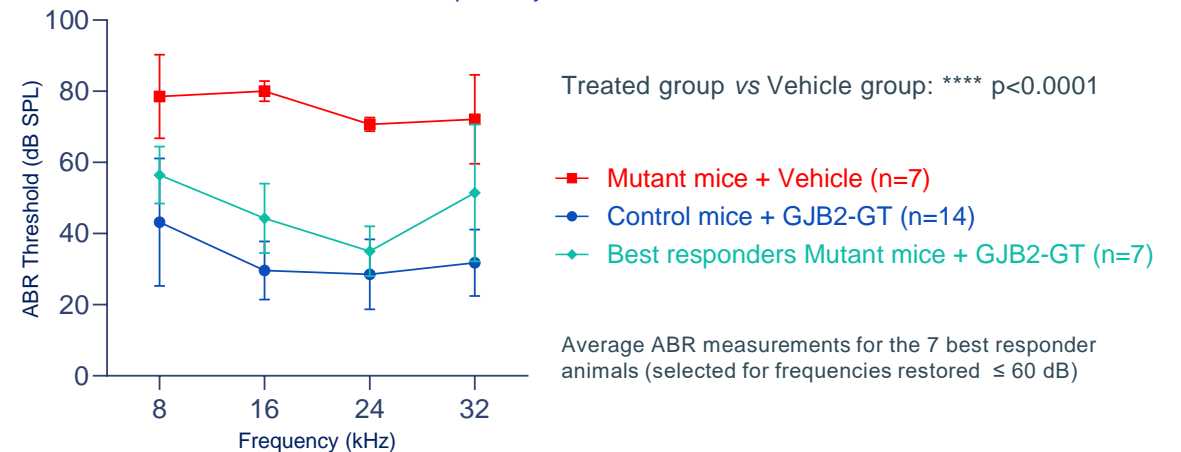
Non injected ear



Left: Green staining demonstrates efficient Cx26 re-expression in target cells, which are otherwise depleted (right) in Cx26 in the GJB2 deficient model

### Proof Of Concept In Mice with Congenital Hearing Loss

ABR threshold - 7 weeks post-injection



- In progressive model: ongoing work indicates that hearing loss prevention correlates with Connexin 26 re-expression in target cells
- In congenital model: ongoing studies indicate that lead candidate GJB2-GT induced a statistically significant hearing recovery
  - as early as 3 weeks after injection
  - evidence of dose-response

Tran Van Ba et al., ESGCT 2024 ([link](#))

Additional data on two models: GJB2 gene therapy-response of two pre-clinical mouse models of the most frequent form of human deafness, DFNB1. Heritier et al., ESGCT 2024 ([link](#))

# GJB2-GT

## Program Status

Ongoing  
European  
Natural History  
Study  
OTOCONEX



Ongoing  
Natural History  
Study  
in Collaboration  
with Sonova



Update on  
Additional  
PoC Efficacy  
and Safety Data  
Oct 2024  
(ESGCT)



IND/CTA  
Enabling  
Studies



Clinical Trial  
Applications  
H2 2025





A close-up photograph of a woman with blonde hair, looking slightly to the side. She is touching her right ear with her hand. The image is partially obscured by a blue and white vertical bar on the left side.

# 4

## **SENS-401 PROGRAMS**

---

Multiple Indications To Treat  
And Prevent Hearing Loss

# SENS-401 To Preserve Residual Hearing After Cochlear Implantation

## COMBINATION OF COCHLEAR IMPLANT WITH SENS-401 TO PREVENT CELL-DEATH POST COCHLEAR IMPLANT PROCEDURE

### HEALTHY AGEING

Growing understanding of the link between  
healthy hearing and healthy ageing

Cognitive  
decline



Isolation

Depression



Ability  
to work

Falls



Loss of  
independence

Source: Cochlear® 2018 investor day ([link](#))

### KEY FIGURES

**48,040**

Implants sold by Cochlear® globally in 2024<sup>1</sup>  
(representing ~60% of global market share)

**\$1.8bn**

Cochlear implant market in 2020<sup>2</sup>

**3%**

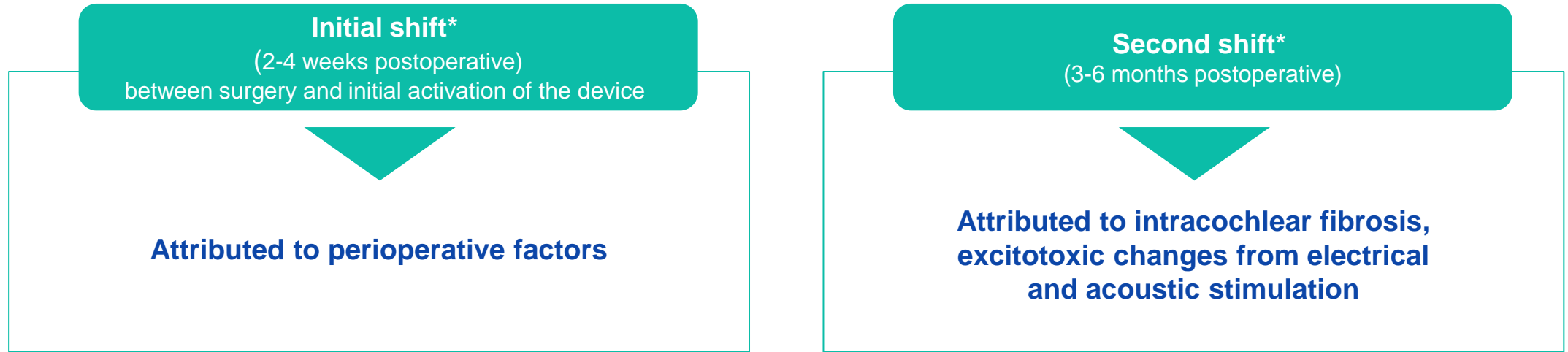
Market penetration in adults eligible to CI  
in developed markets<sup>1</sup>

1. Cochlear® FY24 Result Presentation ([link](#))

2. Global Hearing, the highest growth hearing market, a primer on cochlear implants, Bernstein 2023

# CI

## Residual Low Frequency Hearing Benefits for Cochlear Implant Users

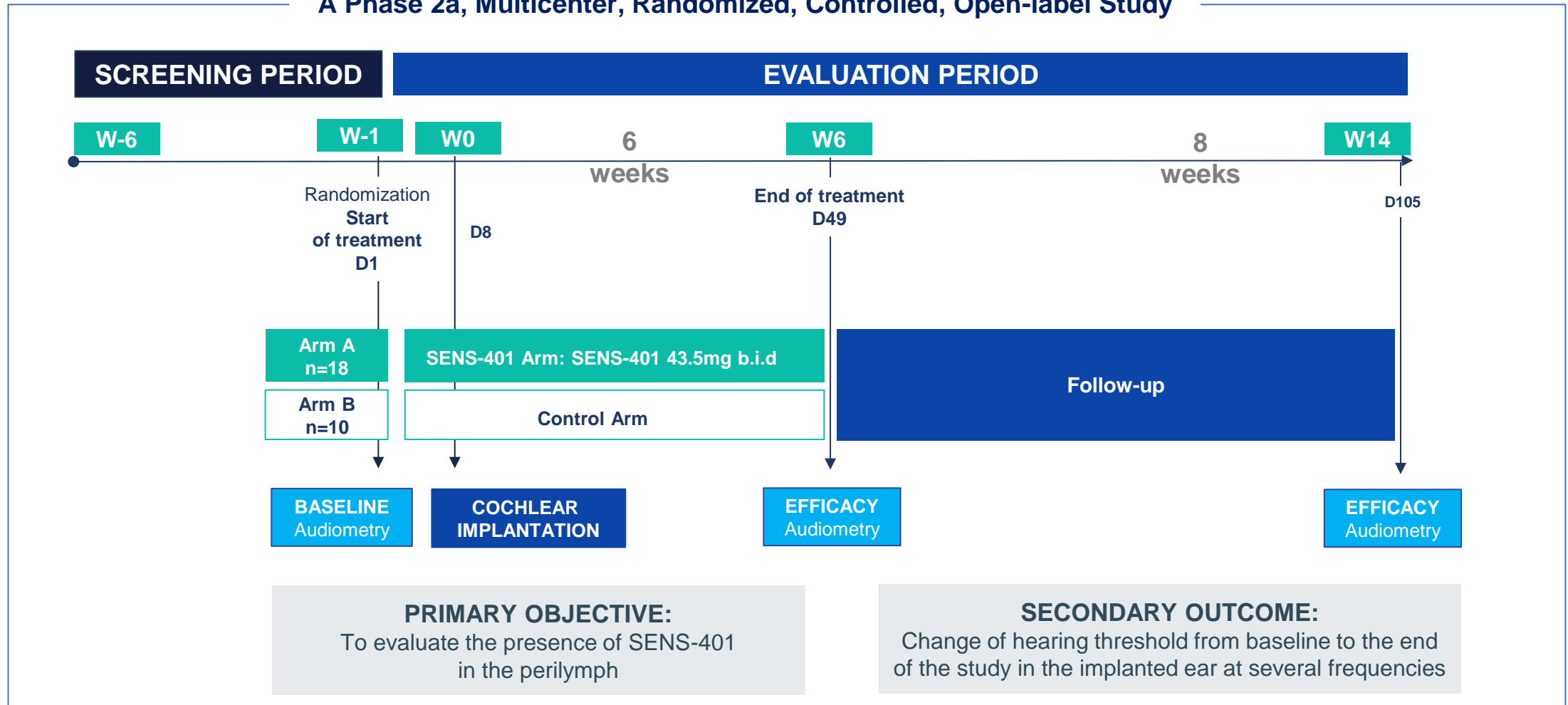


*\*Jensen et al., Hearing Preservation After Cochlear Implantation, 2021*

**Postoperative hearing preservation** defined as:  
unaided air-conduction **thresholds < 85 dB HL** at 125, 250, and 500 Hz

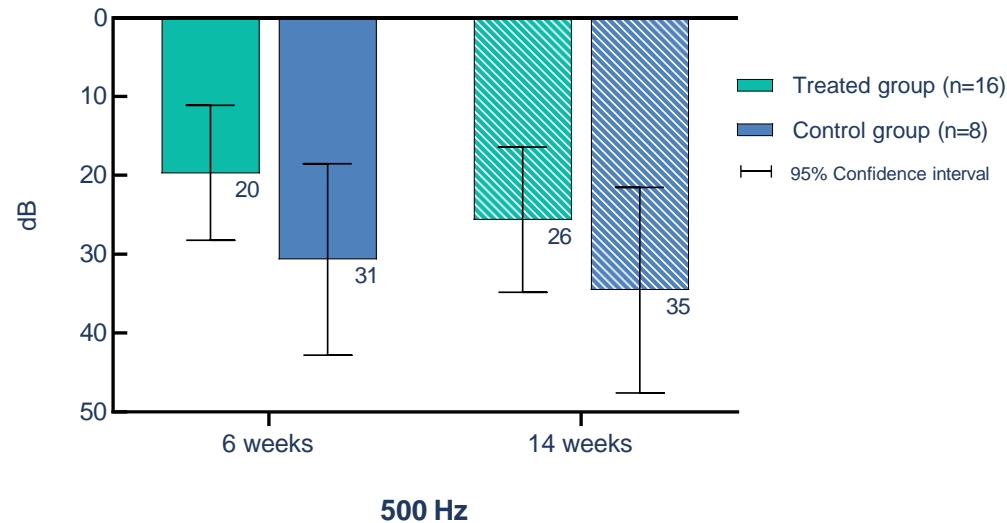
## SENS-401 CI Study Design - Study completed

## A Phase 2a, Multicenter, Randomized, Controlled, Open-label Study

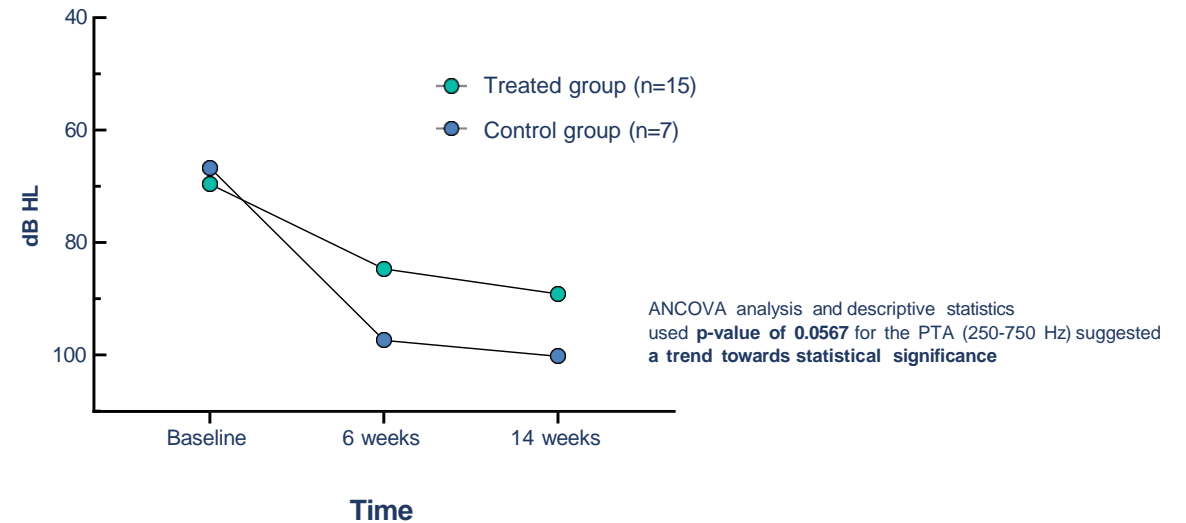


## SENS-401 Provides Hearing Protection 6 & 14 Weeks Post-Cochlear Implantation

LS Mean change from baseline of hearing threshold values at 6 and 14 weeks post CI



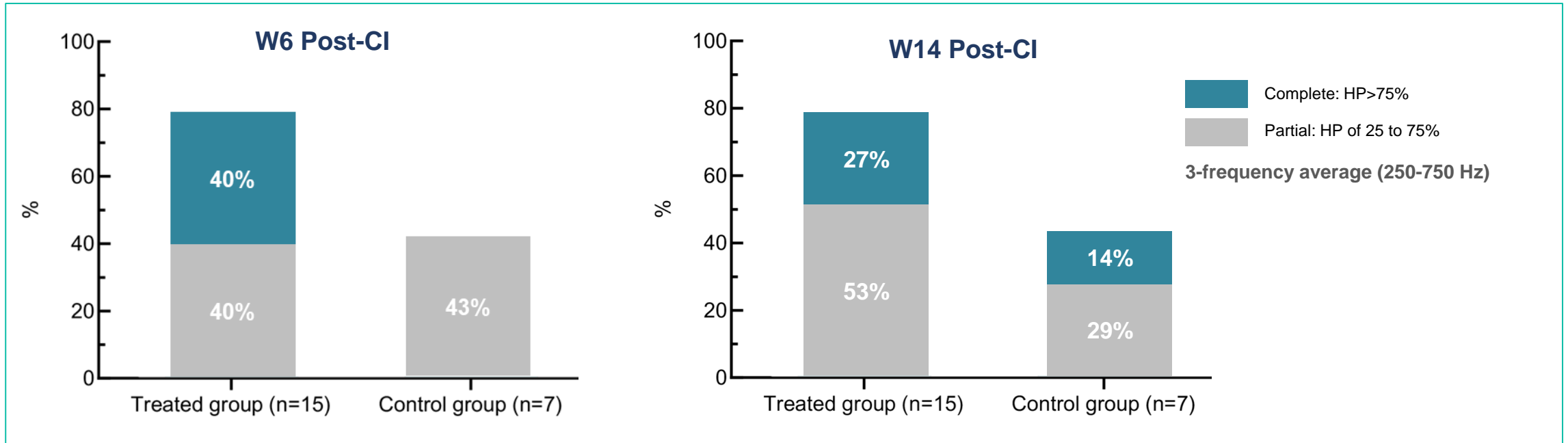
Mean of the 3-frequency average (250-750 Hz) hearing threshold values at baseline, 6 weeks and 14 weeks post CI



- Residual hearing loss is lower in patients treated with SENS-401 compared to control group 6 weeks after cochlear implantation
- This preservation effect is maintained 8 weeks after SENS-401 discontinuation (14 weeks post-CI)

# CI

## SENS-401 Provides Residual Hearing Preservation\* 6 & 14 Weeks Post-Cochlear Implantation



- Patients in the SENS-401 treated group are **twice as likely to show complete or partial hearing preservation** compared to control group after 7 weeks of continuous treatment
- Only SENS-401 treated group show a **complete hearing preservation with 40%** of treated patients compared to 0% in the control group at 6 weeks post-CI
- **These results are maintained 8 weeks** after SENS-401 discontinuation (14 weeks post-CI)

\*Skarzynski H, van de Heyning P, Agrawal S, Arauz SL, Atlas M, Baumgartner W, et al. Towards a consensus on a hearing preservation classification system. Acta Otolaryngol Suppl. 2013(564):3-13.



# CI

## SENS-401 CI Final Results - Conclusion



**SENS-401 can cross the labyrinthine barrier to target cochlear hair cells in all patients sampled, confirming primary endpoint is met. SENS-401, present in the perilymph fluid, reaches concentrations that are pharmacologically active.**



A **complete hearing preservation** is exclusively observed in 40% of patients treated with SENS-401 at 6 weeks post cochlear implantation



Eight weeks after discontinuation of SENS-401, the **hearing protective effect is maintained**



**Residual hearing loss is reduced in the SENS-401 treated group** compared to the untreated group at 6 weeks post-cochlear implantation



SENS-401 taken for 8 weeks confirms it has a **good safety profile**



**SENS- 401 has the potential to modify the outcome of CI while preserving residual hearing by improving speech perception in quiet and noise, music perception, spatial localization and maintaining more natural sound quality**



These results support the SSNHL phase 2 data and further development of SENS-401

# CIO

## Cisplatin Administration For Chemotherapies Damages The Inner Ear And Leads To Hearing Loss, Tinnitus And Dizziness

### WHAT IS CIO?

**Hearing loss caused by cisplatin administration as chemotherapeutic treatment.**

Risk factors include young age as well as individual and cumulative cisplatin doses.

CIO leads to permanent inner ear problems in 40-60% of adult cases and up to 90% of pediatric cases.

**These complications significantly impact patients' quality of life due to:**

- Hearing loss, tinnitus and dizziness impacting daily life activities
- Problems in language acquisition and learning for pediatric patients
- Difficulties in communicating, social isolation, cognitive decline

Potential treatments must not interfere with cisplatin efficacy.

**Incidence of cisplatin treated patients:** 570,000 patients in 2025 in G7 countries<sup>1</sup>

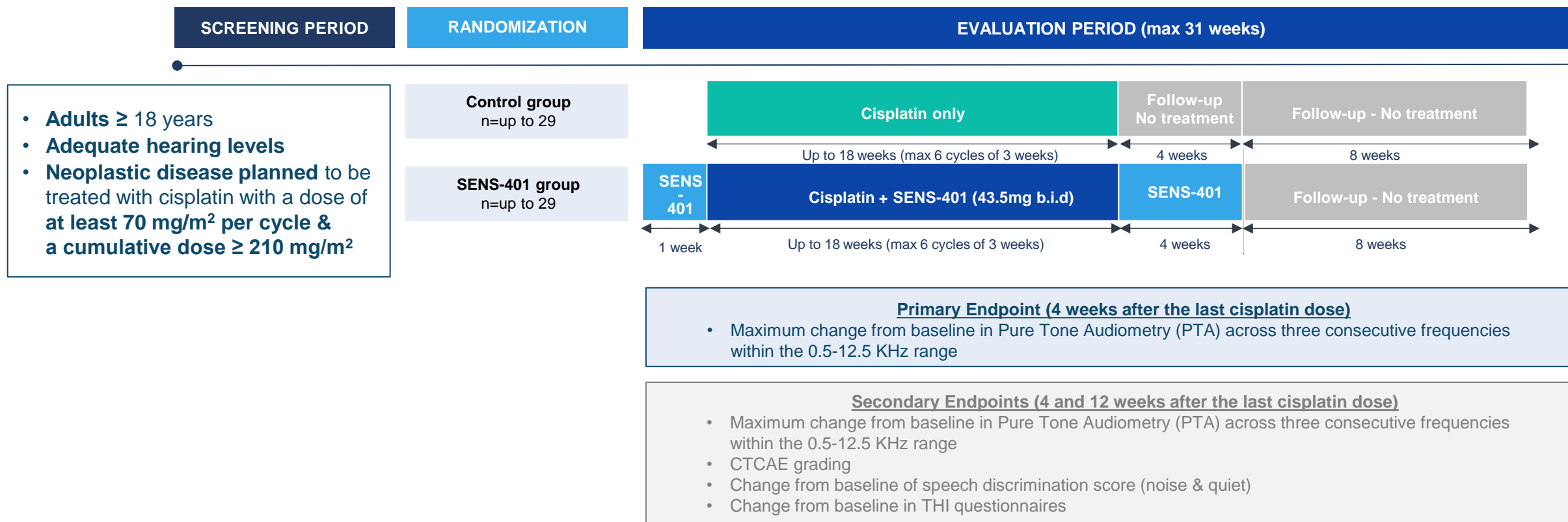


1. Company/ estimates based on publicly available data (in the US, Japan, Germany, France, the UK, Italy and Spain)

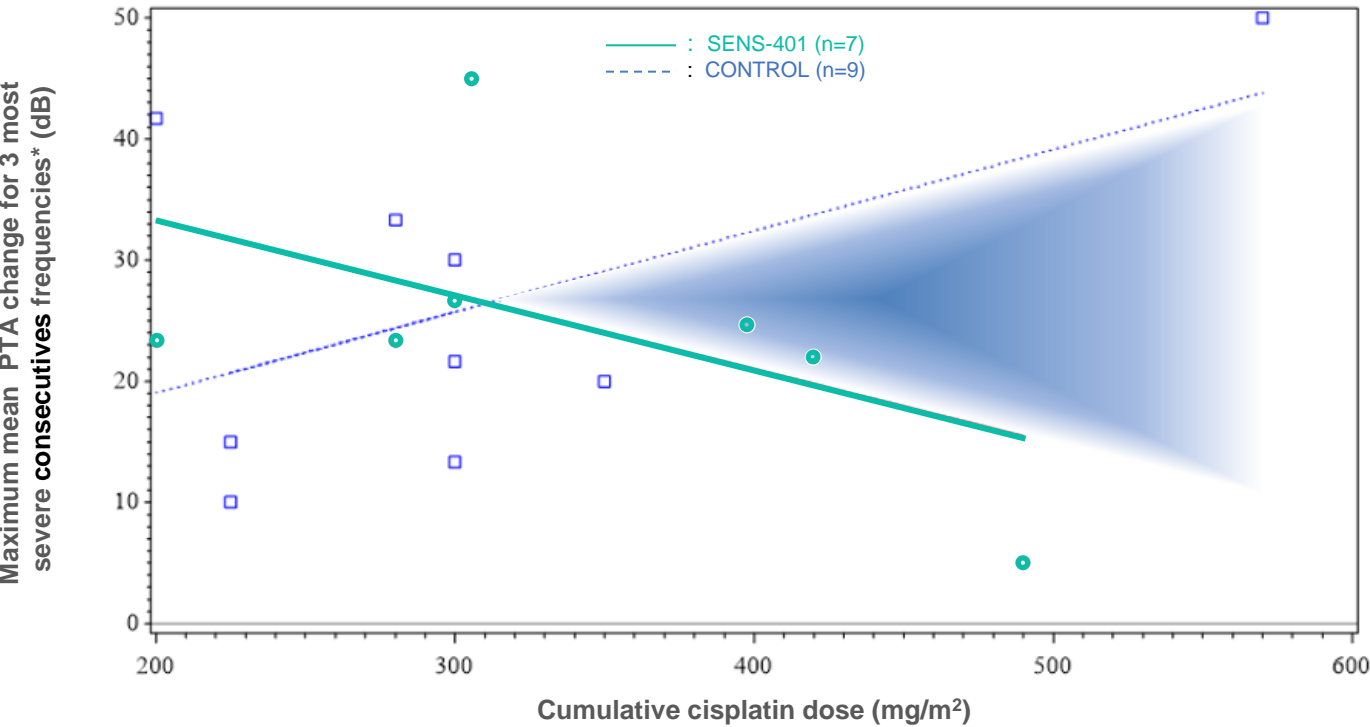
# SENS-401 Phase 2a Proof-Of-Concept Study NOTOXIS

## Positive Preliminary Safety Data

**A Phase 2a, Multicenter, Randomized, Controlled, Open-label Study to Evaluate the Efficacy of SENS-401 to Prevent the Ototoxicity Induced by Cisplatin in Adult Subjects with a Neoplastic Disease**



# Preliminary Results Show Patients with High Exposure to Cisplatin May Benefit the Most from SENS-401's Otoprotective Effects



Groups	n	Variables	Mean	SD
Control	9	Cisplatin dose	305	110.0
		PTA change	26	13.6
SENS-401	7	Cisplatin dose	342	98.7
		PTA change	24	11.7

- Hearing loss is similar between SENS-401 and control group
- SENS-401 subjects were exposed to significantly more cisplatin than control

- As the cumulative dose of cisplatin increases, severity of ototoxicity observed in the control group escalates  $r=0.42$
- **Benefit of SENS-401 increases with higher cisplatin doses**
- **SENS-401 treatment group outperforms the control group at cisplatin doses > 300 mg/m<sup>2</sup>**

## Key Takeaways From Preliminary Study Data



**Cumulative dose** of cisplatin is a **key factor** of ototoxicity severity



SENS-401 has a **favorable safety profile** when administered continuously for up to **23 weeks** in adult patients undergoing cisplatin-based chemotherapy



Recruitment is progressing well



Based on preliminary data, **no significant difference** observed on ototoxicity measured by **PTA change** or CTCAE grading, **however SENS-401 treated group received higher cumulative dose of cisplatin compared to control**



Patients with **higher exposure to cisplatin** may benefit the most from **SENS-401's otoprotective effect**



The preliminary results suggest a trend toward an otoprotective effect of SENS-401 beyond a cisplatin dose of 300 mg/m<sup>2</sup>



- **Developing hearing loss therapeutics to treat, prevent and restore hearing – an area of high unmet clinical need**



- **Combining extensive internal capabilities with world-leading exclusive partnerships**



- **Advancing a robust and diversified pipeline with multiple upcoming milestones in 2025**



- **Completion of patient recruitment of the second cohort in Audiogene in H1 25**
- **Completion of patient recruitment in SENS-401 CIO in H1 25**
- **Clinical Trial Application for GJB2-GT in H2 25**



# THANK YOU

---

E:contact@sensorion-pharma.com

# Appendix

---

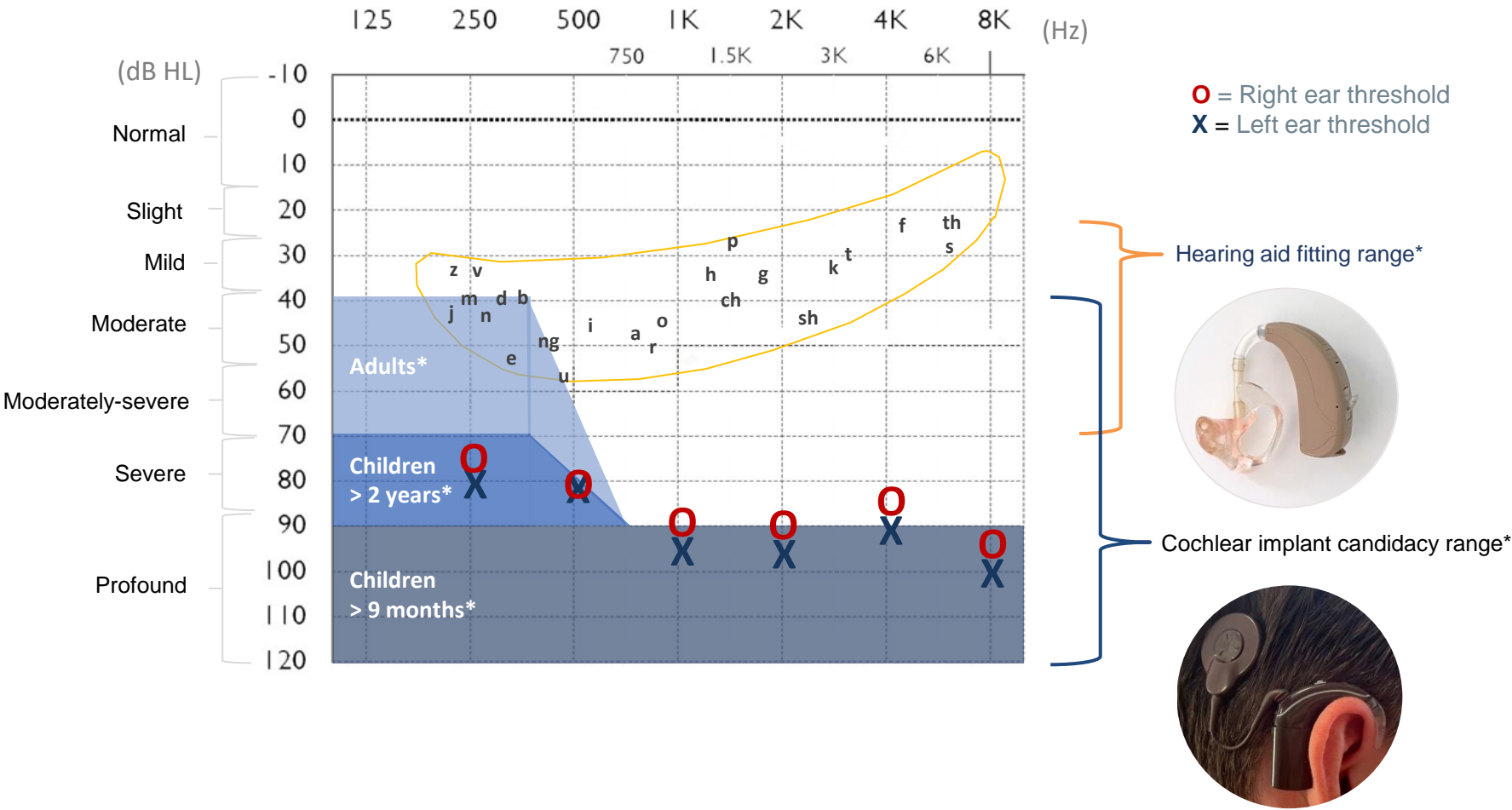


# HEARING LOSS

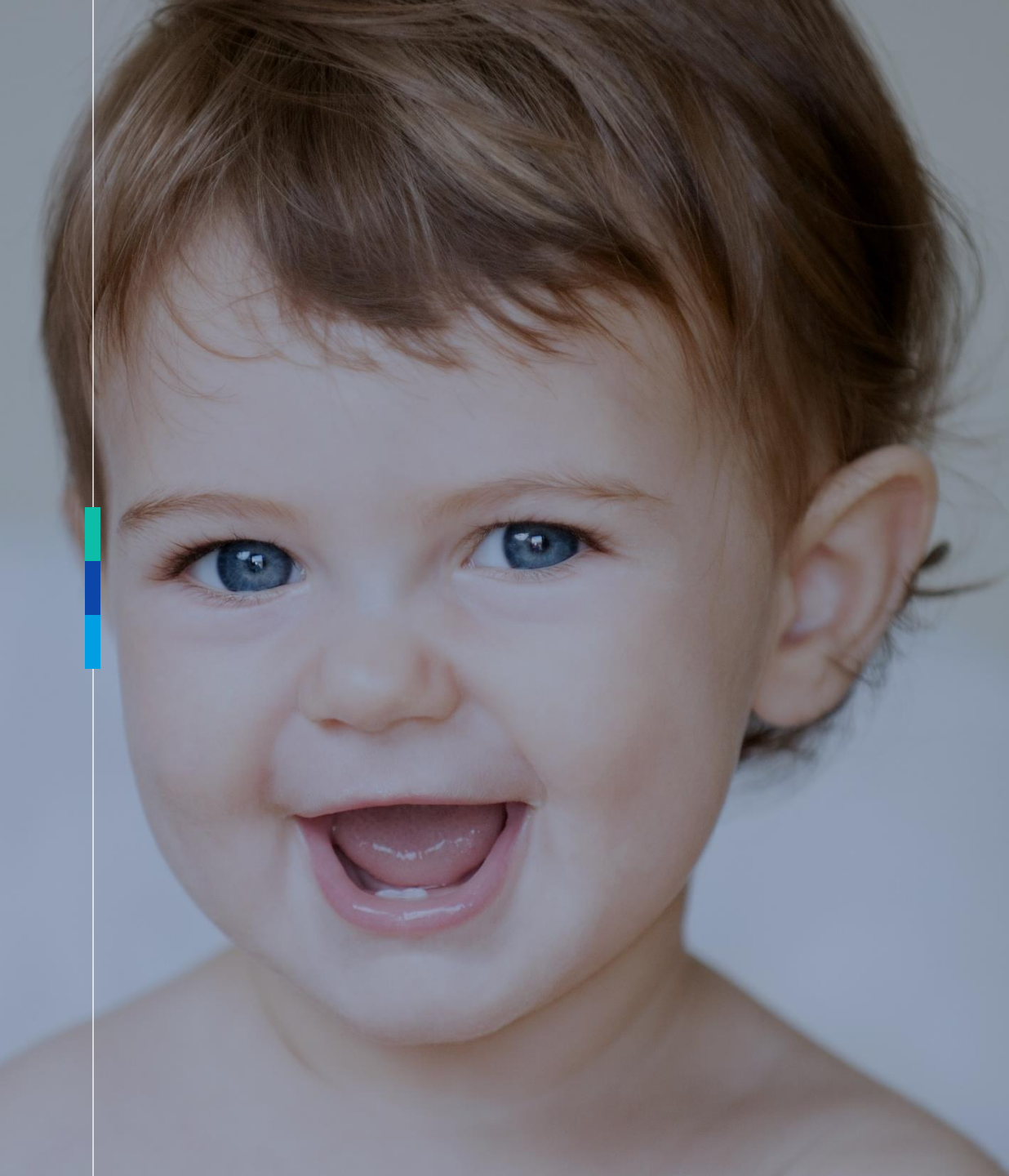
---

# HEARING

Access And Clarity Are Mandatory For Optimal Outcomes



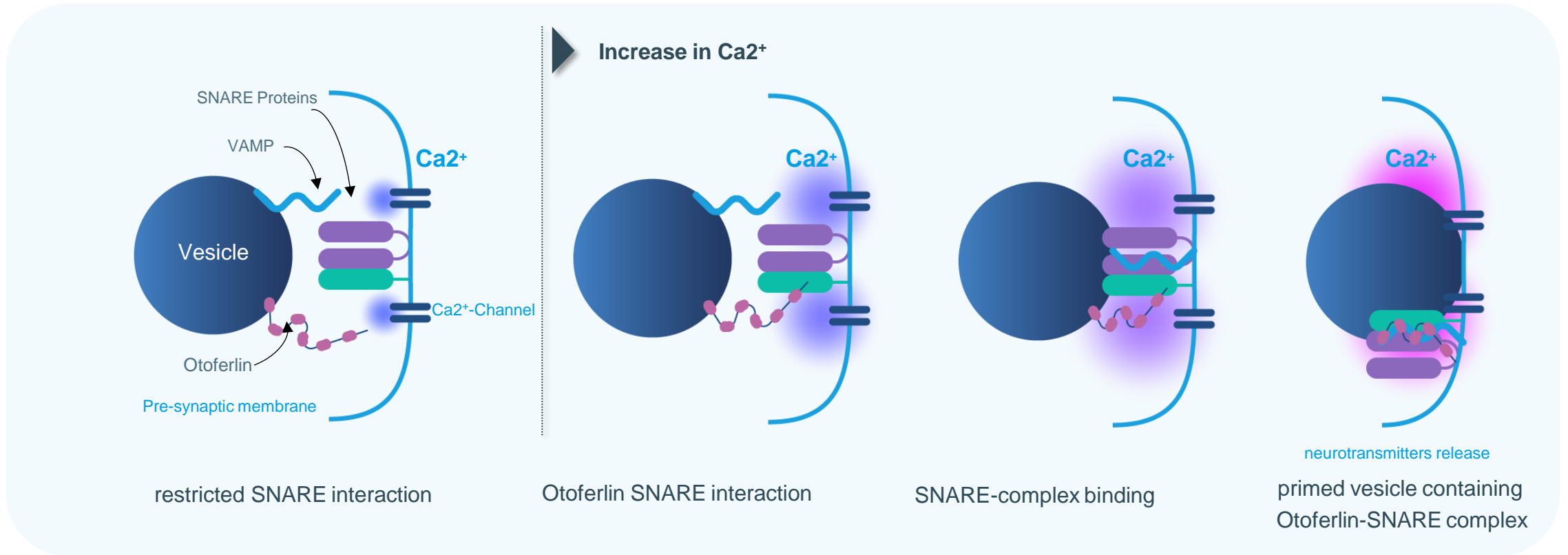
\*Guideline criteria may vary slightly by manufacturer, device, and/or country  
Image of hearing aid: [https://commons.wikimedia.org/wiki/File:Unitron\\_Ziel\\_photo\\_2.jpg](https://commons.wikimedia.org/wiki/File:Unitron_Ziel_photo_2.jpg)  
Image of cochlear implant sound processor on ear: [https://commons.wikimedia.org/wiki/File:Cochlear\\_Nucleus%C2%AE\\_7\\_Sound\\_Processor.jpg](https://commons.wikimedia.org/wiki/File:Cochlear_Nucleus%C2%AE_7_Sound_Processor.jpg)  
Copyright by **Sensorion** - 2025 - All Rights Reserved



# GENE THERAPY PROGRAMS BACK-UP

## SENS-501

### OTOF Gene Encodes Otoferlin, a Key $\text{Ca}^{2+}$ Sensor Protein

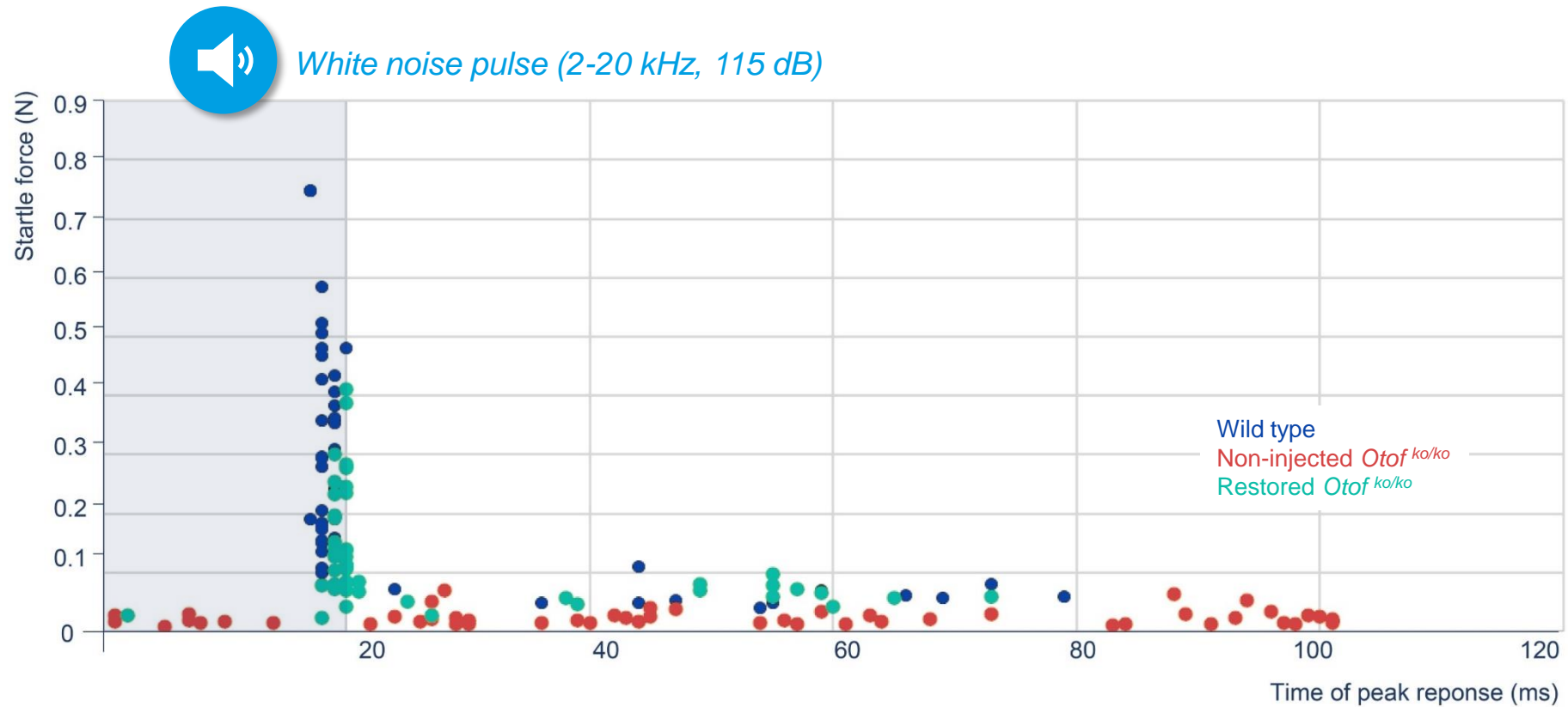


**OTOF is the gene coding for the otoferlin protein, a  $\text{Ca}^{2+}$  sensor key for vesicle fusion and vesicle pool replenishment at auditory hair cell ribbon synapses**



# SENS-501 Leads to Restoration of Efficient Sound Processing in Behavioural Test

Behavior Test Based on Hearing Recovery Implemented in Mouse



Olivier et al. ASGCT 2023

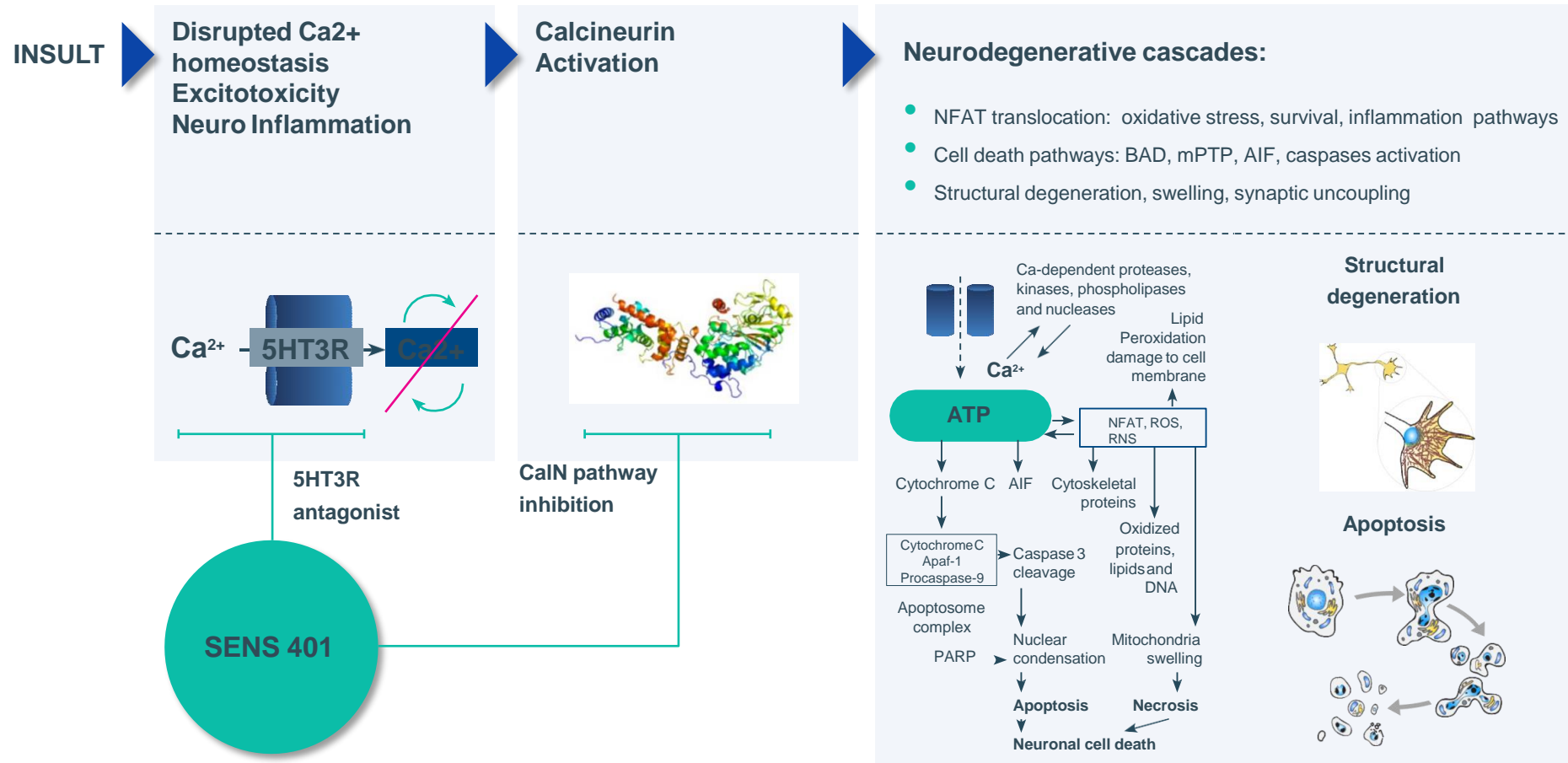
A close-up photograph of a woman with blonde hair, wearing a red top and a gold necklace. She is gently touching her right ear with her hand. The image is partially obscured by a blue and white vertical bar on the left side.

# **SENS-401 PROGRAMS BACK-UP**

---

Multiple Indications To Treat  
And Prevent Hearing Loss

100





# **SSNHL**

Sudden Sensorineural  
Hearing Loss

# Sudden Sensorineural Hearing Loss (SSNHL) is a Severe Disease Affecting more than 200,000 Patients Per Year

## WHAT IS SSNHL?

**The sudden onset of a significant hearing loss due to dysfunction of the cells of the cochlea and central auditory structures.**

Hearing loss develops over less than 72 hrs, hearing sensitivity is reduced by at least 30 dB (1,000 fold) in the affected ear(s).

>90%<sup>1</sup> of cases are idiopathic, known causes include noise/head trauma, ischemia, infection.

>33%<sup>2</sup> of patients suffer from permanent disabling hearing loss, mostly those with initial severe/profound hearing loss.

**Complications significantly impact quality of life due to:**

- Difficulties in communicating, social isolation, cognitive decline
- Accompanying tinnitus

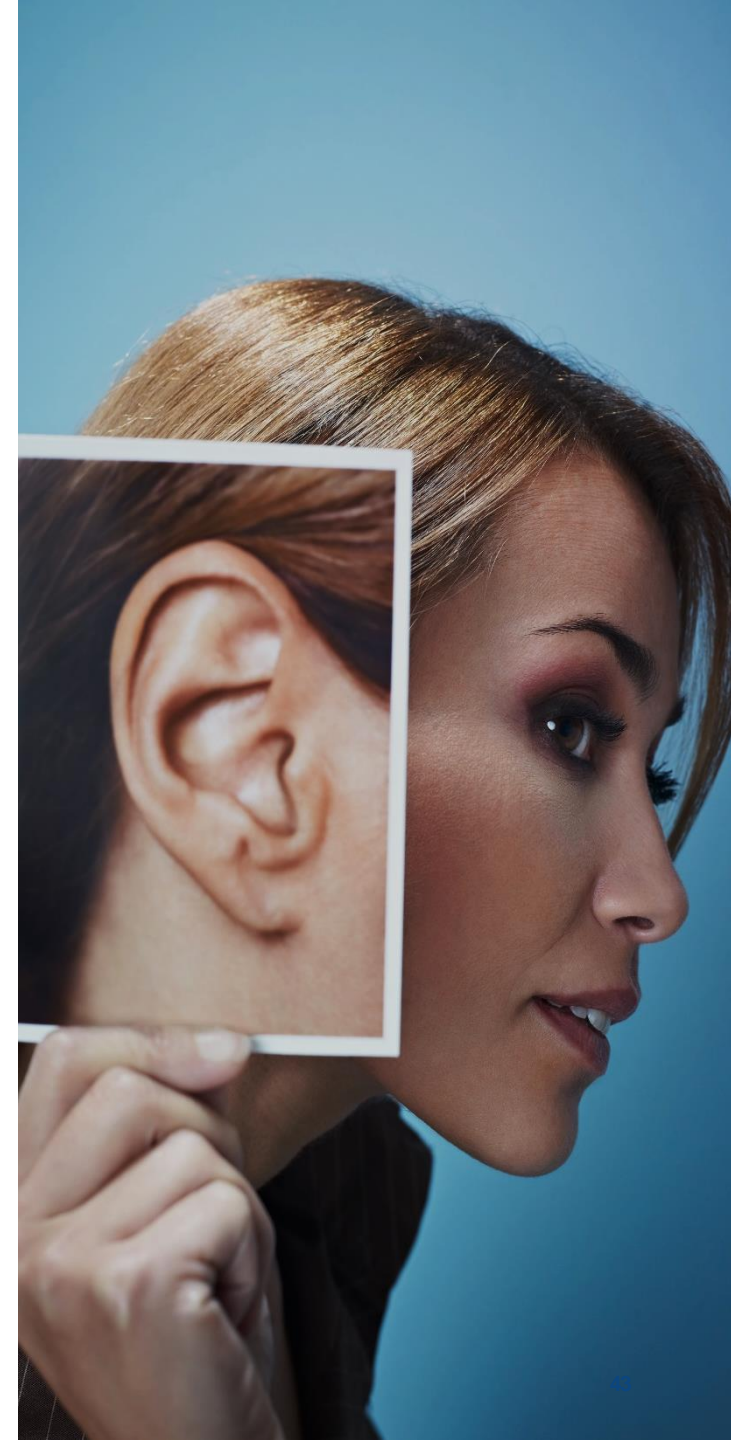
**Incidence:** 27-35 per 100,000 (c.200,000 patients in 2017 in G7 countries)<sup>1</sup>

1. American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) Clinical Practice Guidelene

2.Kearny Interviews

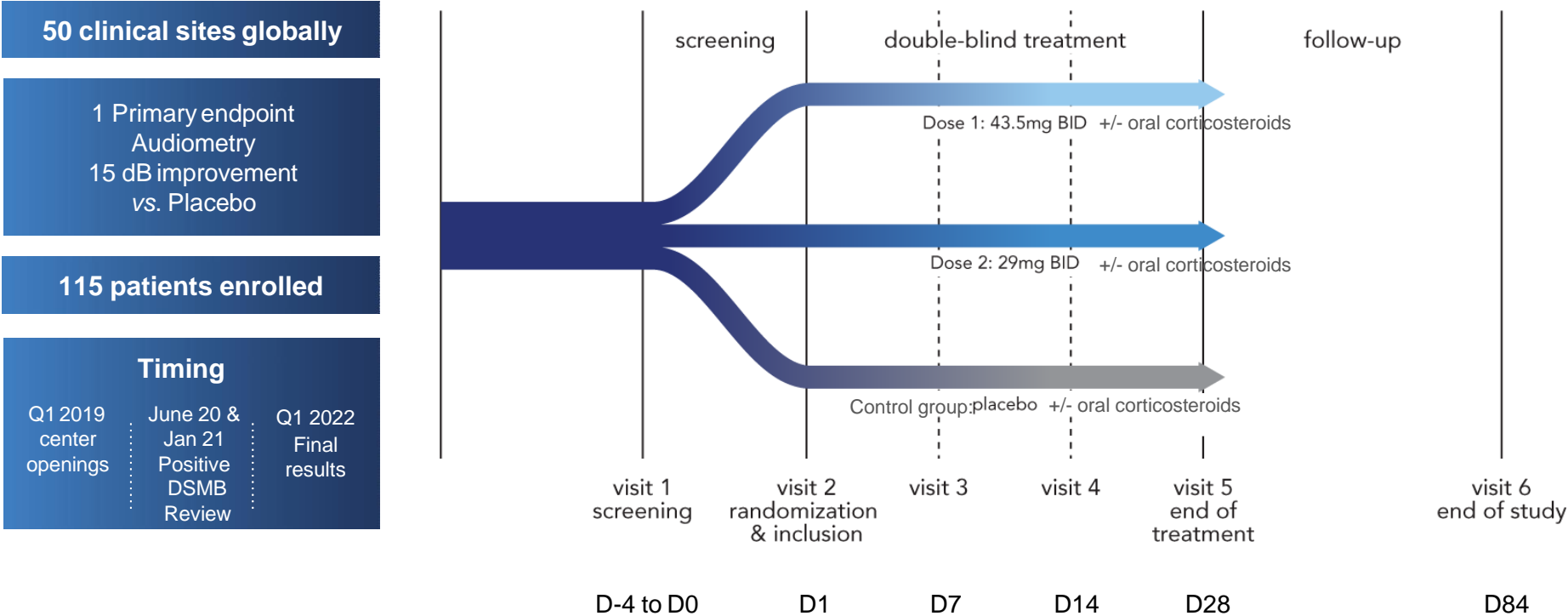
3. Company/ estimates based on publicly available data (in the US, Japan, Germany, France, the UK, Italy and Spain)

Copyright by **Sensorion** - 2025 - All Rights Reserved



SENS-401 SSNHL Program: AUDIBLE-S Phase 2 Design

A RANDOMIZED, MULTICENTER, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

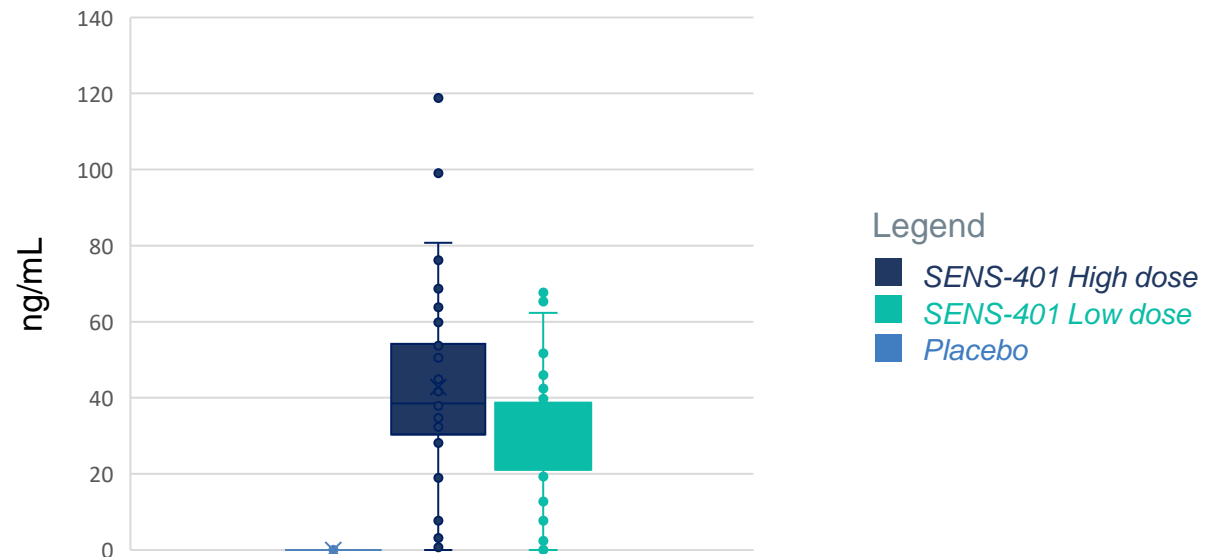


**Primary endpoint definition:**

“...change in pure tone audiometry (PTA); average of the hearing threshold of 3 contiguous most affected hearing frequencies in decibels in the affected ear from baseline to the end of treatment visit (Visit 5/D28±3)”

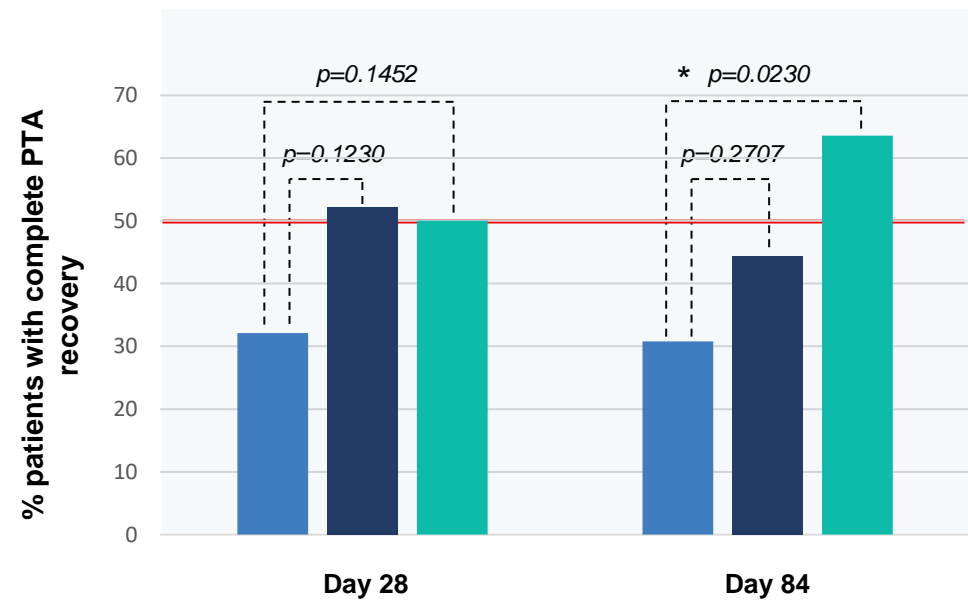


### PLASMATIC CONCENTRATION (Pre-dose at Day 14 and Day 28)



SENS-401 Induces Complete PTA Recovery In 50% Of Patients

COMPLETE PTA RECOVERY



Complete PTA recovery (n/n total)	Placebo	High Dose	Low Dose
Day 28	9/28	12/23	13/26
Day 84	8/26	8/18	14/22

- Legend
- SENS-401 High dose
  - SENS-401 Low dose
  - Placebo

- Complete hearing recovery is defined as patients with hearing loss at baseline who will revert to PTA < 20 dB, considered as “normal” hearing.

### AUDIBLE-S SECONDARY ENDPOINT RESULTS

- **Complete PTA recovery is achieved in 50% of the SENS-401 treated patients**
- SENS-401 shows a **clinically meaningful and statistically significant effect on PTA change** (at least 10 dB) over time in a **large homogeneous idiopathic population of patients treated with corticosteroids**
- SENS-401 induces a **significant PTA change of at least 19 dB at day 28 and up to 25 dB at Day 84 allowing a reduction of the hearing loss degree from profound to mild, in large profound hearing loss sub-group**
- A better response was observed in both treatment groups with a **continuous improvement between Day 28 and Day 84**
- **The change in PTA translates into functional improvement evidenced with speech audiometry tests**
- Safe and well tolerated in 115-patient SSNHL study; although primary endpoint not met data supports and informs further clinical development
- **Responder rate is always better in the treated group** compared to Placebo and difference with Placebo increases over time