

# Corporate Presentation

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Unlocking The Potential Of Advanced Therapies  
For Hearing Loss

September 2025

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# 1

# SENSORION

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Our vision is to enable people with inner ear hearing disorders to live life with unlimited connections

# Sensorion

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



# Sensorion

## Experienced Leadership Team, Board of Directors and SAB



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**STEPHANIE FILIPE**  
Head of Business Ops &  
Portfolio Management



**LAURENT DESIRE**  
Head of Preclinical  
Development

**SENSORION**  
(Since 2017)

**SHIRE**  
(2016-2017)  
Head of the Global Genetic  
Diseases Franchise

**SENSORION**  
(Since 2020)

**GENETHON**  
(2011-2020)  
Director of Development

**SENSORION**  
(Since 2023)

**JP MORGAN / JEFFERIES**  
(2005-2021)  
Investment Banking / ECM

**SENSORION**  
(Since 2024)

**QUELL Tx**  
(2019-2023)  
SVP Product Delivery

**SENSORION**  
(Since 2020)

**CELLECTIS**  
(2016-2020)  
Program Leader &  
Preclinical Manager

**SENSORION**  
(Since 2020)

**YPOSKESI**  
(2017-2020)  
Head of Cellular &  
Molecular Biology Unit

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- **Dr. Diane Lazard**, France, Principal Associate Investigator, Hearing Institute (Paris)
- **Dr. Hernán López-Schier**, Germany, Senior Group Leader & Research Unit Director at the Helmholtz Center (Munich)

# Sensorion

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

PARTNERS

TRANSLATIONAL  
RESEARCH

INSTITUT  
pasteur

CLINICAL  
RESEARCH

GLOBAL CLINICAL CENTERS OF EXCELLENCE

Necker  
ENFANTS MALADES  
HÔPITAL UNIVERSITAIRE

DIAGNOSIS AND  
PATIENT JOURNEY

Cochlear™

sonova  
HEAR THE WORLD

Sensorion

IN-HOUSE



PRECLINICAL -  
SMALL MOLECULES &  
GT PROGRAMS



CLINICAL EXPERIENCE



CMC GENE THERAPY  
FACILITIES



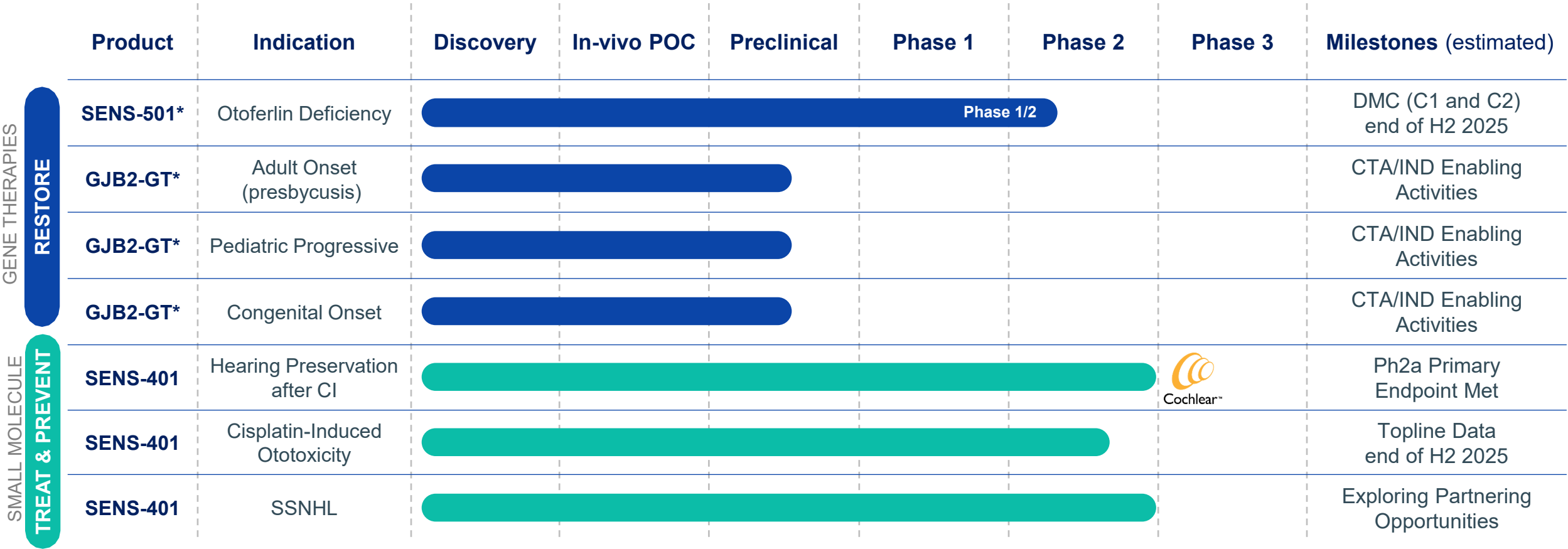
REGULATORY EXPERTISE



PATIENT ACCESS

# Sensorion

## Portfolio Of Advanced Hearing Loss Therapies



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 grant a licence from the Institut Pasteur (licence granted for SENS-501, pre-defined financial terms and other terms to be negotiated for GJB2-GT)  
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# 2

## GENE THERAPY PROGRAMS

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# Sensorion

## Gene Therapy Programs Target Rare Auditory Diseases

### FIRST PROGRAMS RESULTING FROM THE INSTITUT PASTEUR COLLABORATION

#### OTOFERLIN DEFICIENCY

- Pediatric patients with mutations in *OTOF* gene 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:

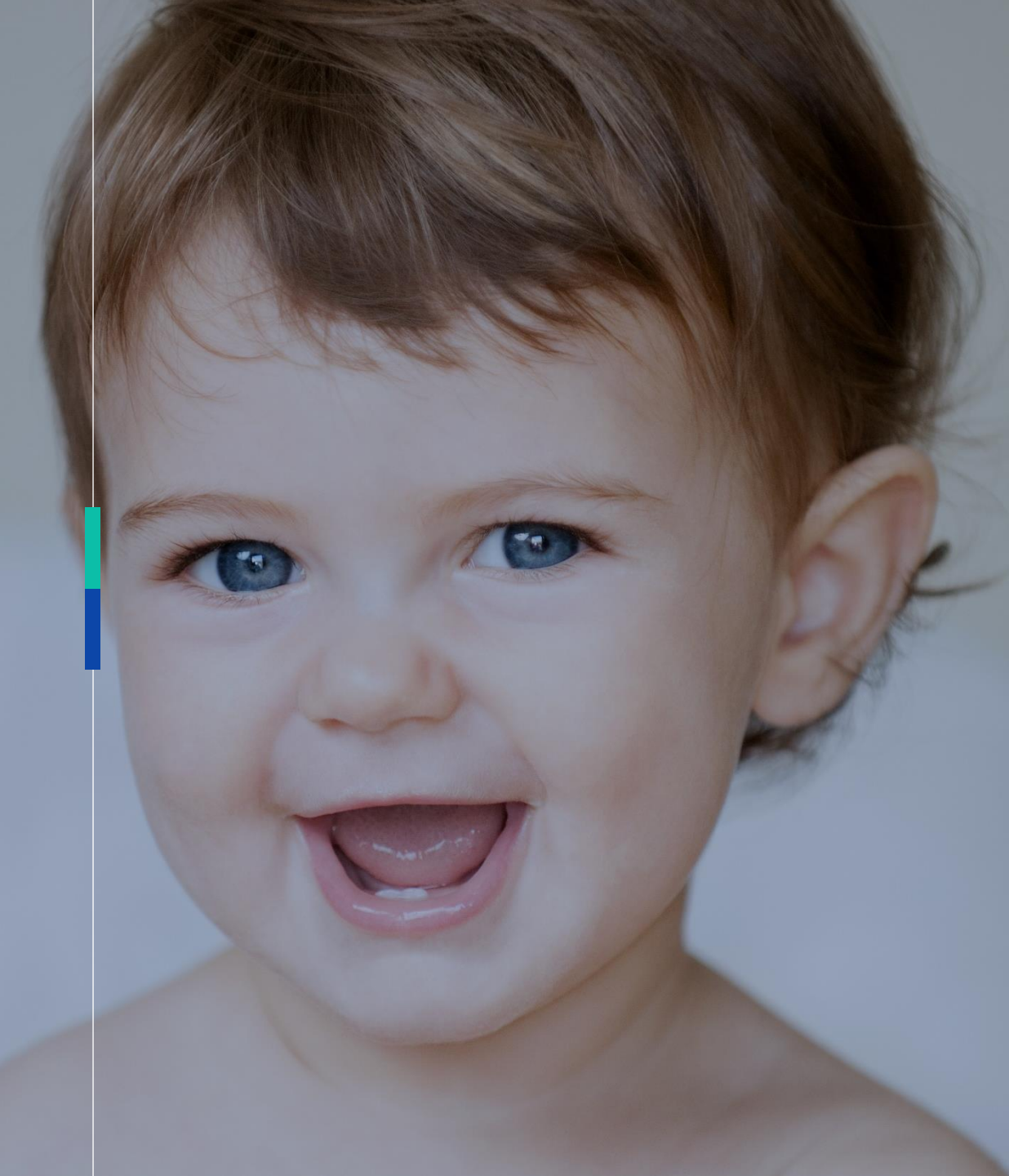
- Early onset of severe presbycusis (adult population)
- Childhood onset (pediatric population)
- Congenital onset (pediatric population)
- ~100,000 patients between 30- and 69-years old thought to be affected by a monogenic form of presbycusis due to *GJB2* mutations
- Prevalence of congenital and childhood 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](#)), company estimates based on publicly available population data  
Chardan 2020 report, Bryan, Garnier & Co 2019 report, Institut Pasteur, Boucher et al. 2020 ([link](#))

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# 2.1

## OTOFERLIN DEFICIENCY

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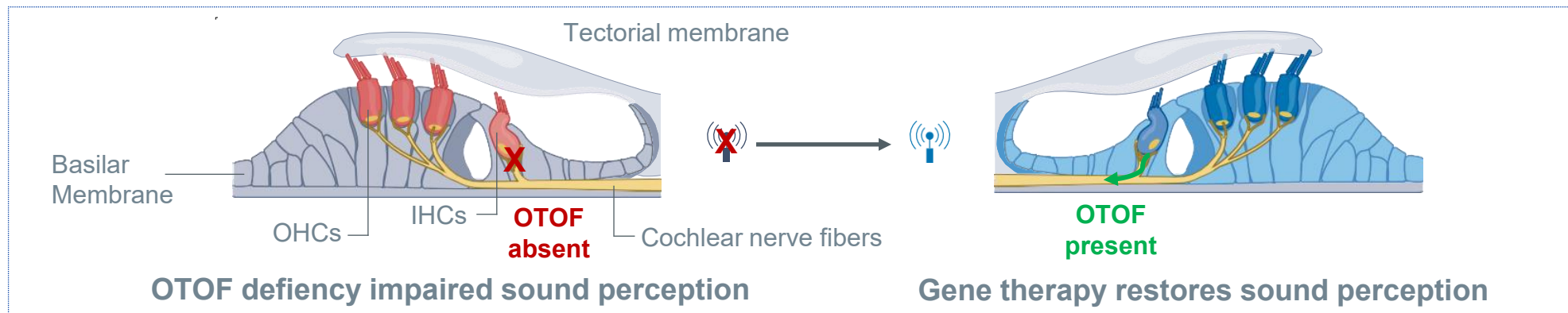
# SENS-501

## SENS-501 (OTOF-GT) Is The Perfect Pilot Program

- Well understood biology and pathology of the otoferlin deficiency
- Full functionality of the remaining hearing pathway components
- High specificity for the inner hair cells (IHCs), no off-target effect expected

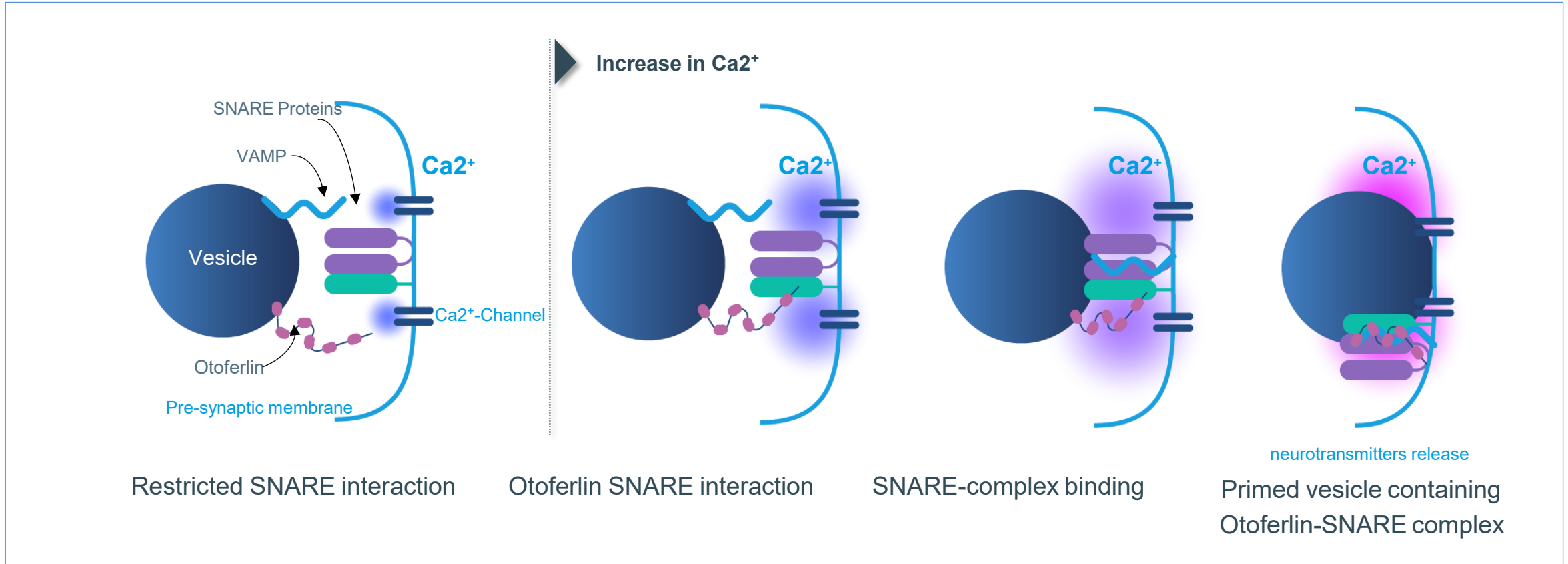


- SENS-501 is the pilot program that has the potential to demonstrate that GT is a relevant medical approach for the inner ear
- SENS-501 will establish understanding of GT in the inner ear by the Regulators and the Payers for future GT programs
- Medical plausibility and target population have been confirmed through:
  - ✓ ODD in the US and EU, RPDD with eligibility for voucher in the US
  - ✓ PIP agreed in EU
  - ✓ First and Second cohort completed



## SENS-501

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



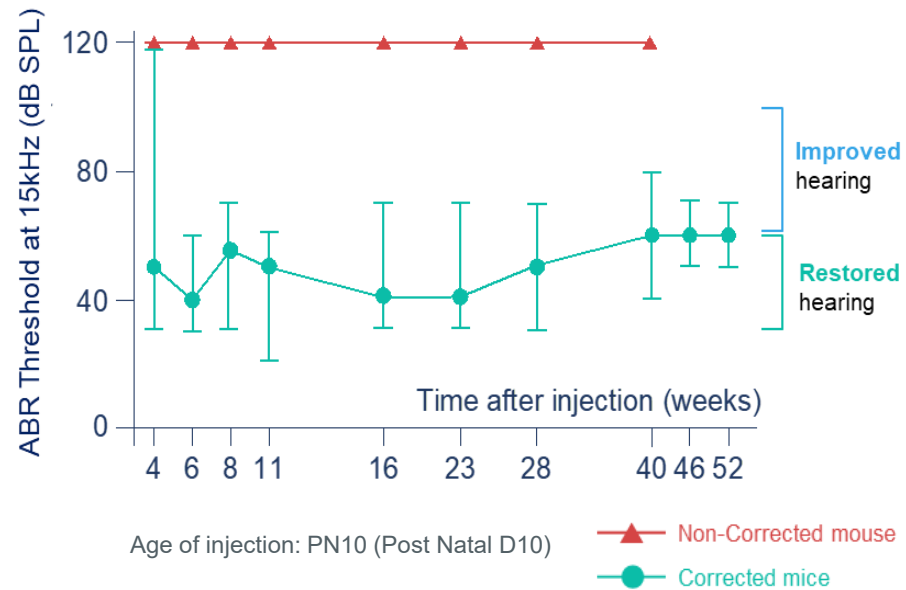
***OTOF* is the gene coding for the otoferlin protein, a  $\text{Ca}^{2+}$  sensor key for vesicle fusion and vesicle pool replenishment at auditory hair cell ribbon synapses**

# SENS-501

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

### Long-Term Hearing Restoration

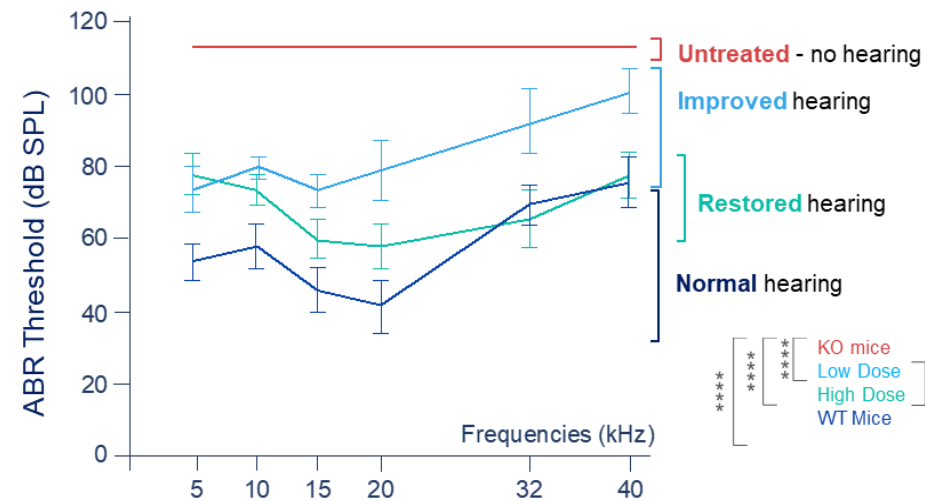
AAV-mOTOF injected in mice before hearing onset



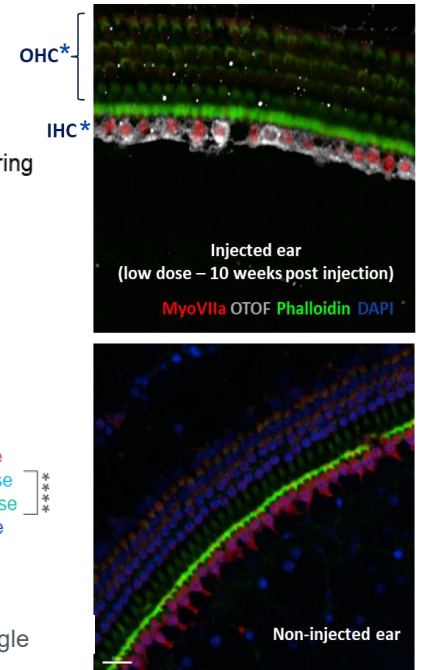
- **Durable hearing restoration** in *Otof*<sup>-/-</sup> mice by dual AAV-OTOF directly delivered to the inner ear up to one year post-injection

### Hearing Restoration Correlates With De Novo OTOF Expression

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



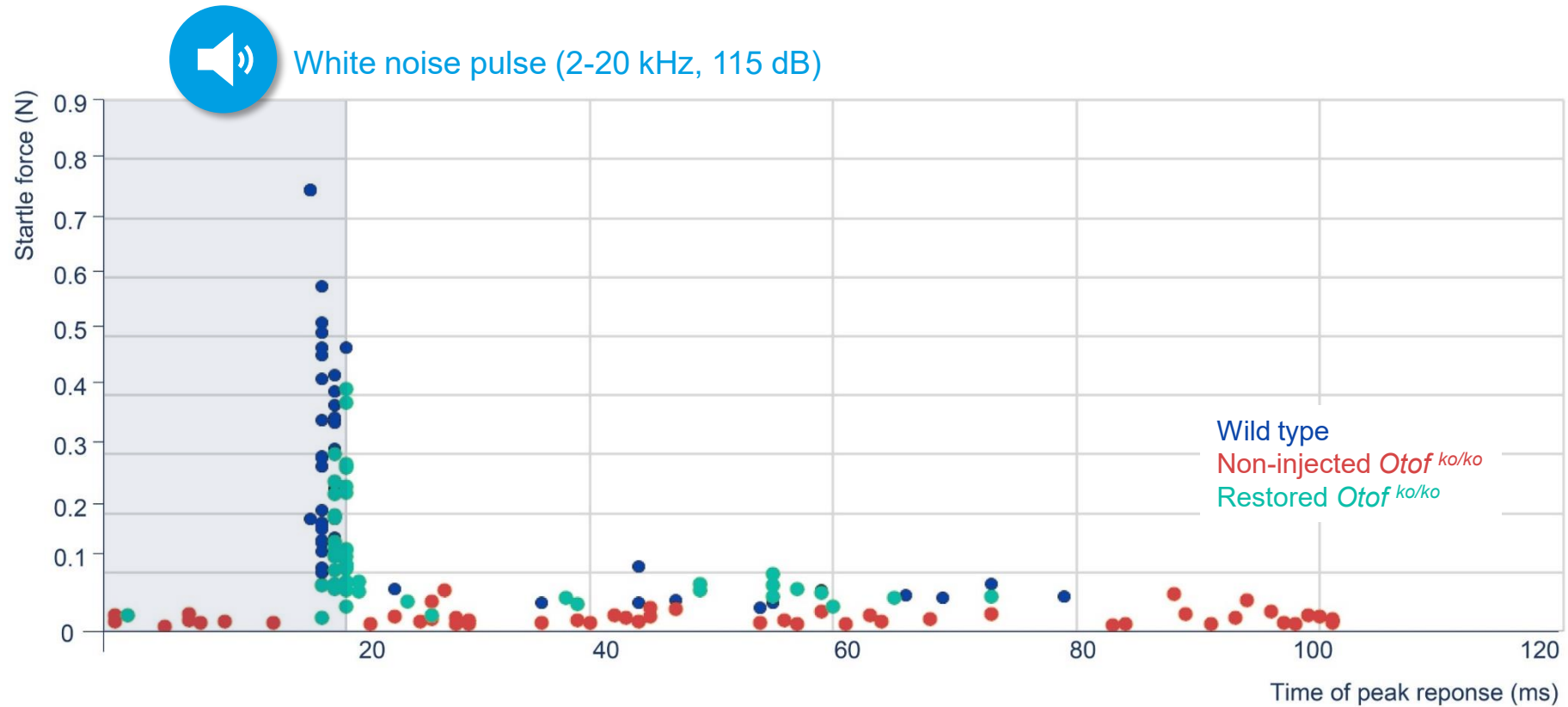
- Both doses of SENS-501 demonstrated efficacy in **improving hearing in KO mice**
- SENS-501 leads to **otoferlin expression in Inner Hair Cells**



# SENS-501

## Restoration Of Efficient Sound Processing In Behavioural Test

Behavior Test Based On Hearing Recovery Implemented In Mouse



# SENS-501

## Dedicated Surgical Approach For Gene Therapy

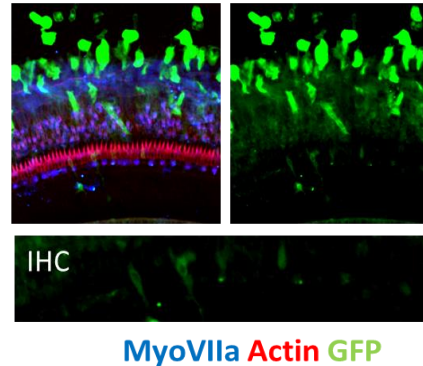
Non-Human Primates injected through the round window membrane with or without stapedotomy

### 1 Fenestration

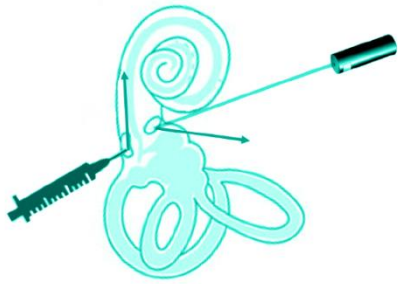


Used for cochlear implant

- Overpressure
- Limited volume
- Backflow
- Irregular transduction rate

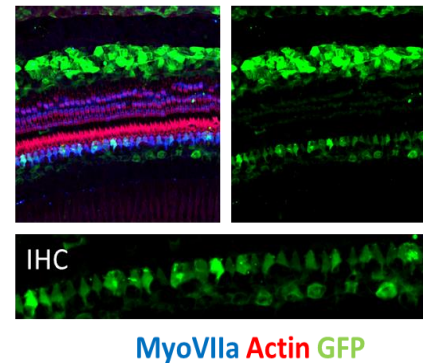


### 2 Fenestrations



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 ENT 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

**Generating 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 & Quality of Life** to allow infants **social development**

**Critical parameters leading Audiogene towards success:**

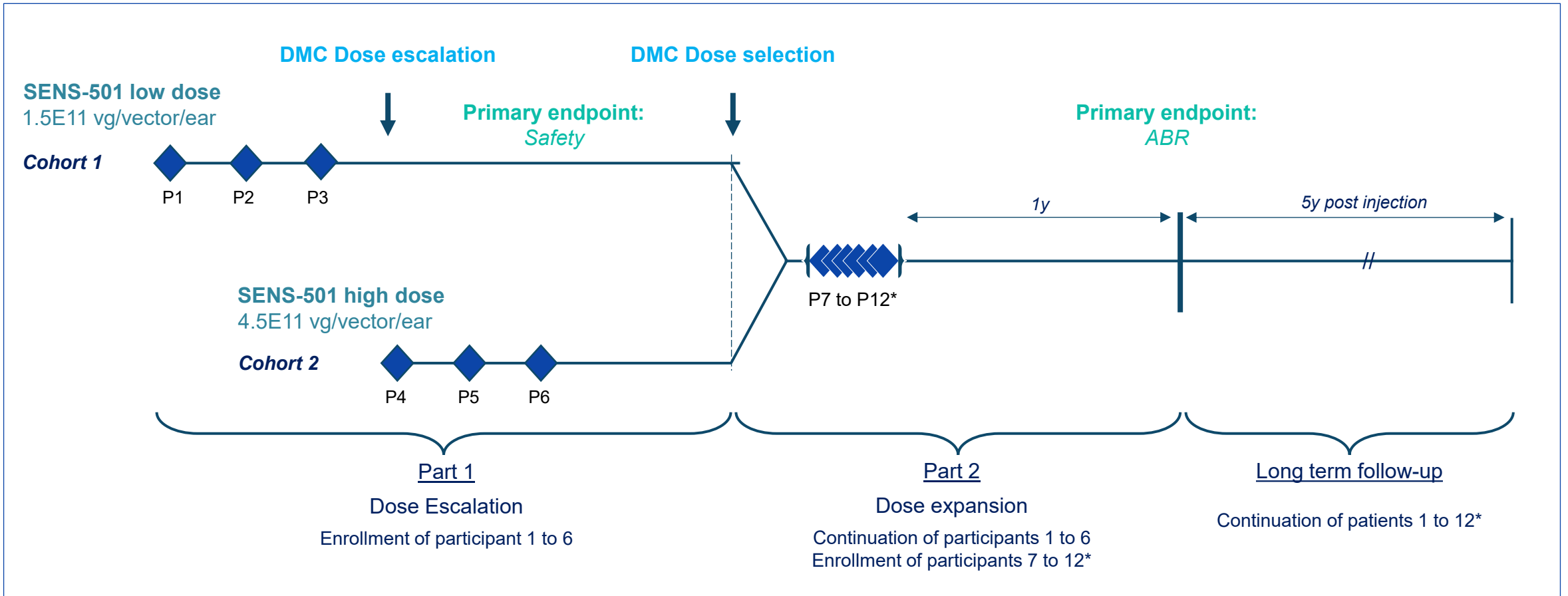
- A **homogeneous** clinical study population in the right target age for **speech acquisition** (ie: below 3 years old)
- **No concomitant or previous cochlear implantation at the time of the injection**, to be able to document the contribution of the GT in speech development
- Global clinical study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

# SENS-501



## Audiogene The First Phase 1/2 Study With A Homogeneous Population

**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.

### DOSE ESCALATION ON TRACK



- **Patient recruitment going as planned with First and Second Cohort completed**
- **Good initial safety to date at both doses**
  - Surgical administration procedure well tolerated
  - No dose-limiting toxicities, no Serious Adverse Events
  - Vestibular function and Otoacoustic Emissions (OAEs) remained intact and unchanged from baseline
- **Early promising hearing improvements observed in Patient 3** (Cohort 1, at low dose), a toddler aged 11 months at the time of injection

### PATIENT 3 DATA AT 3 MONTHS



- **Positive ABR responses at two frequencies**, with the best frequency reaching 70 dB
- **Improvement of hearing levels per PTA across two frequencies** with best frequency reaching 90 dB level
- **Meaningful changes in responses to sounds and voices** as reported by the parents with an **IT-MAIS** score increase of 16 points (145% relative improvement from baseline), and met expected auditory milestones based on an age-based parent questionnaire and according to the patient's age (**LittleEARS**)

# SENS-501

## Program Status





## 2.2

# ***GJB2*-RELATED HEARING LOSS**

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# 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

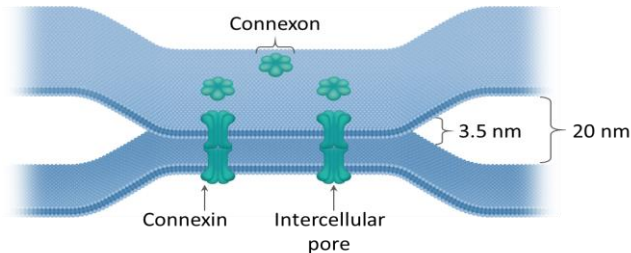
- **AAV capsid selected for high-level of target cells specificity**
- **GT product showing high level of target cells transduction**
- **Limited off-target tissue biodistribution**
- **Surgical approach developed and mastered by ENT surgeons**

# GJB2-GT

## Connexin 26 Is Encoded By *GJB2* Gene And Is Responsible For Tissue Homeostasis

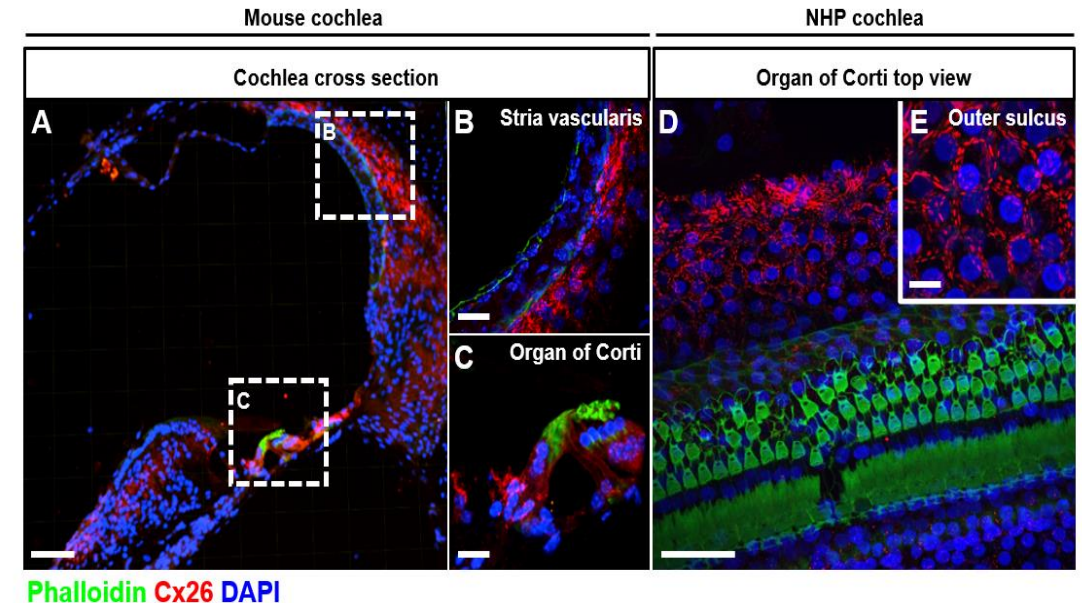
### Mutations In The *GJB2* gene Lead To Deafness

- Connexin 26 and Connexin 30 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 Was Selected To Answer Specific Development Criteria

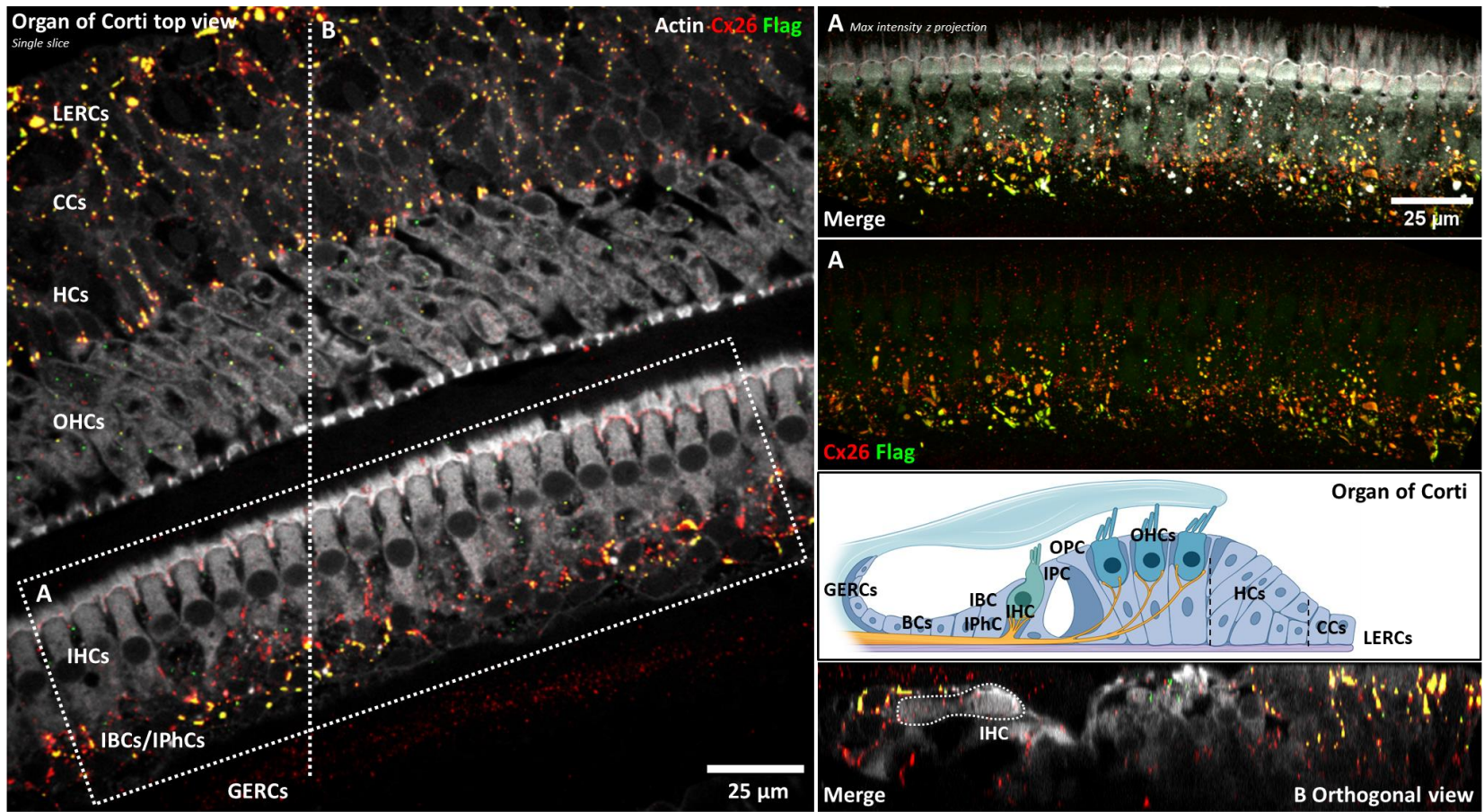
| CRITERIA                                                                                                                    | LEAD CANDIDATE                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| Natural and synthetic AAV capsid libraries screening for broad coverage of target cells                                     |   |
| Expression cassette design for high-level of target cells transduction, correct cellular localization, active gap-junctions |   |
| Avoiding off-target expression (i.e. hair cells): promoter and regulatory sequences design                                  |   |
| Limited off-target tissue biodistribution                                                                                   |   |
| Surgical approach developed and mastered by ENT surgeons                                                                    |  |

**Our Lead Candidate Was Designed to Ensure Broad Coverage of Relevant Cochlear Cells While Detargeting Hair Cells**

# GJB2-GT

## Lead Candidate Can Deliver Connexin 26 In The Appropriate Target Cells

Correct Delivery Of Connexin 26 Using Lead Candidate Flag In Non-Human Primate Cochlea



### Cell Types

- Claudian Cells
- Deiters Cells
- Great Epithelial Ridge Cells
- Hensen Cells
- Inner Border Cells
- Inner Hair Cells
- Inner Phalangeal Cells
- Pilar Cells
- Lateral Epithelial Ridge Cells
- Outer Hair Cells
- Fibrocytes
- Stria Vascularis

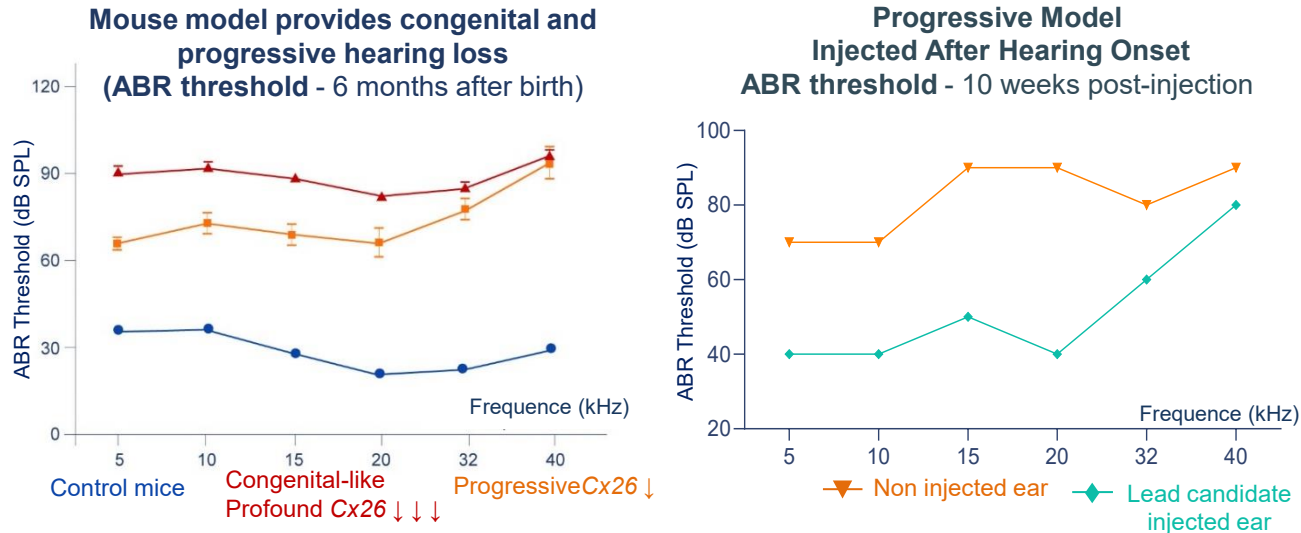


- No expression in Hair Cells confirmed
- No morphological defects observed 3 and 9 weeks after intracochlear administration

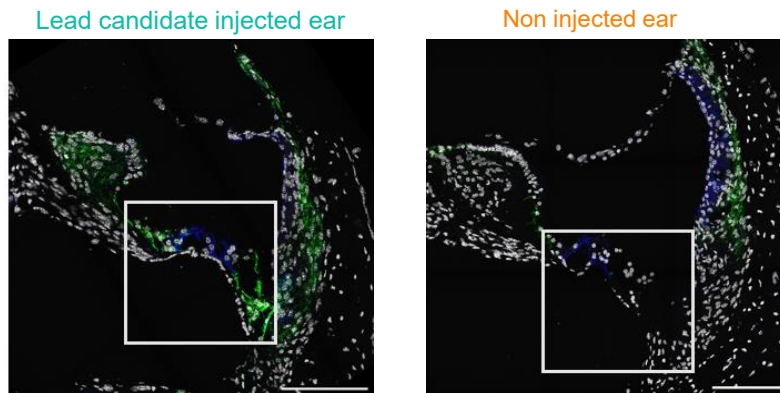
# GJB2-GT

## Lead Candidate Prevents Hearing Loss In Relevant Mouse Model

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

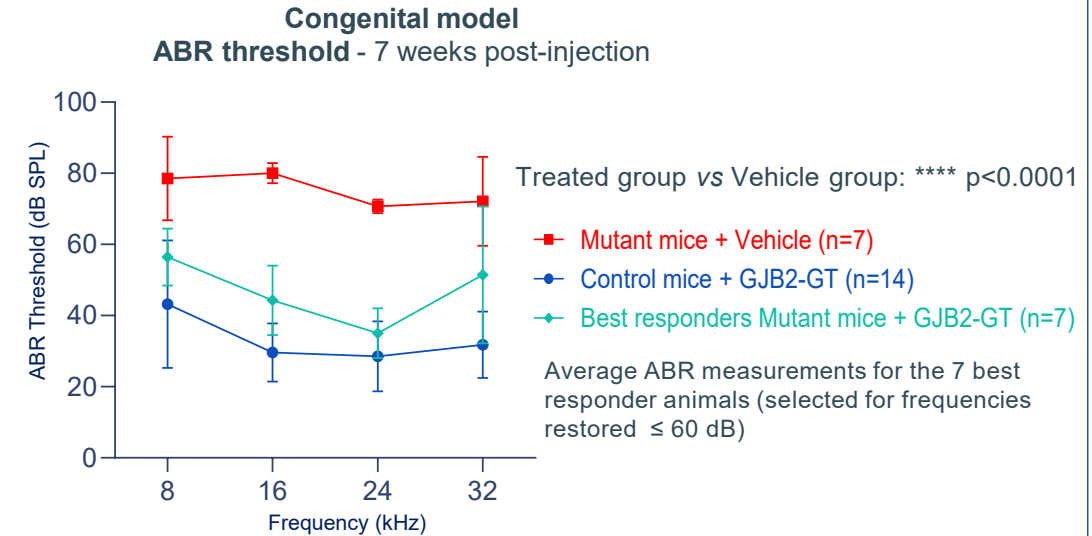


### Hearing Loss Prevention Correlates With Connexin 26 Expression



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



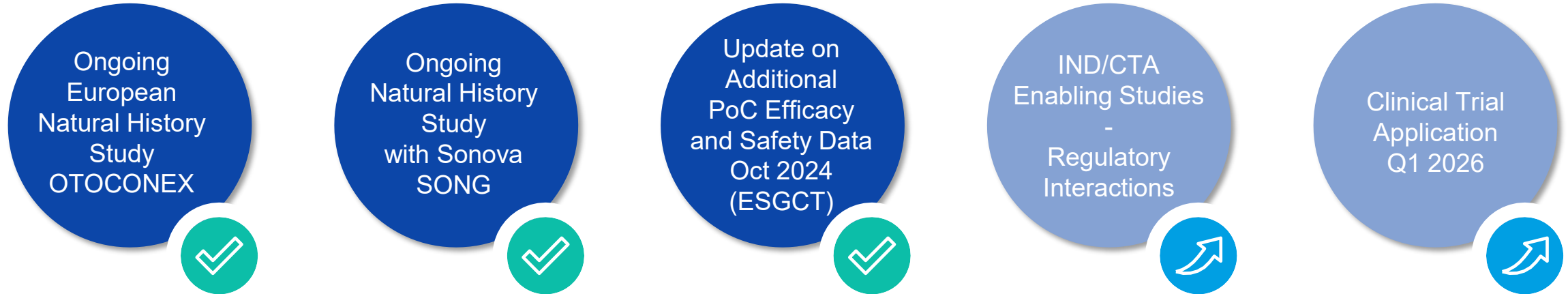
- In **progressive model**: ongoing work indicates that hearing loss prevention correlates with Connexin 26 re-expression in target cells
- In **congenital model**: ongoing studies indicate that lead candidate GJB2-GT induced a statistically significant hearing recovery
  - as early as 3 weeks after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

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

More efficacy data on two additional 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





# 3

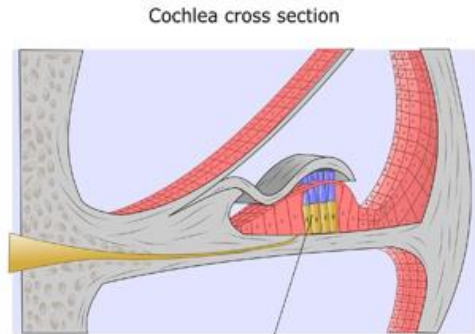
## **SENS-401 PROGRAMS**

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Multiple Indications To Treat  
And Prevent Hearing Loss

# SENS-401

## Mechanism Of Action



Trauma to inner ear can occur after **cochlear implantation**, exposure to **loud noise** or infection, head trauma or administration of **ototoxic drugs**

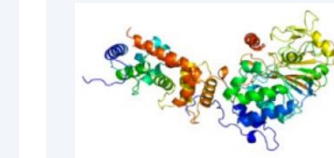
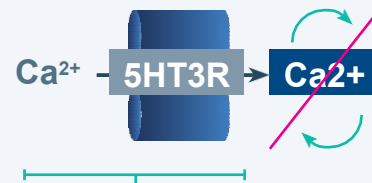
INSULT

**Disrupted Ca<sup>2+</sup> homeostasis**  
**Excitotoxicity**  
**Neuro Inflammation**

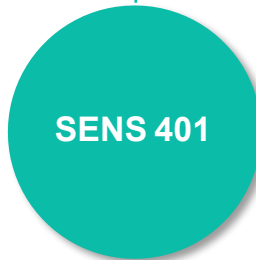
**Calcineurin Activation**

**Neurodegenerative cascades**

- NFAT translocation: oxidative stress, survival, inflammation pathways
- Cell death pathways: BAD, mPTP, AIF, caspases activation
- Structural degeneration, swelling, synaptic uncoupling

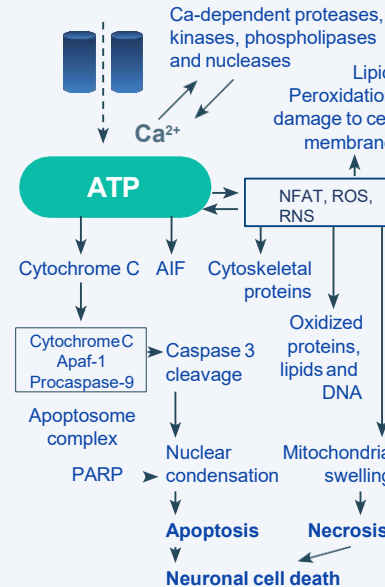


**CaN pathway inhibition**

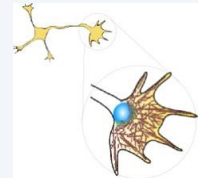


**SENS-401** is the **(R)-enantiomer of Azasetron** belonging to the class of selective 5-HT<sub>3</sub> Receptor (5-HT<sub>3</sub>R) antagonists with a calcineurin inhibition action

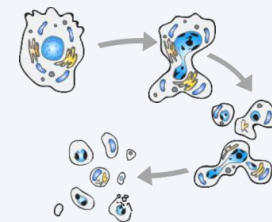
**Oxidative Stress**



**Structural degeneration**



**Apoptosis**





# 3.1

## SENS-401 CI

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Preservation Of Residual Hearing  
Following Cochlear Implantation

# CI

## SENS-401 To Preserve Residual Hearing After Cochlear Implantation

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

#### BURDEN OF DISEASE

Growing understanding of the link between  
healthy hearing and healthy ageing

Depression



Isolation



Cognitive  
decline



Ability  
to work



Falls



Loss of  
independence



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

#### KEY FIGURES

**80, 000**

Implants sold globally in 2024<sup>1</sup>

**\$1.8bn**

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

**3%**

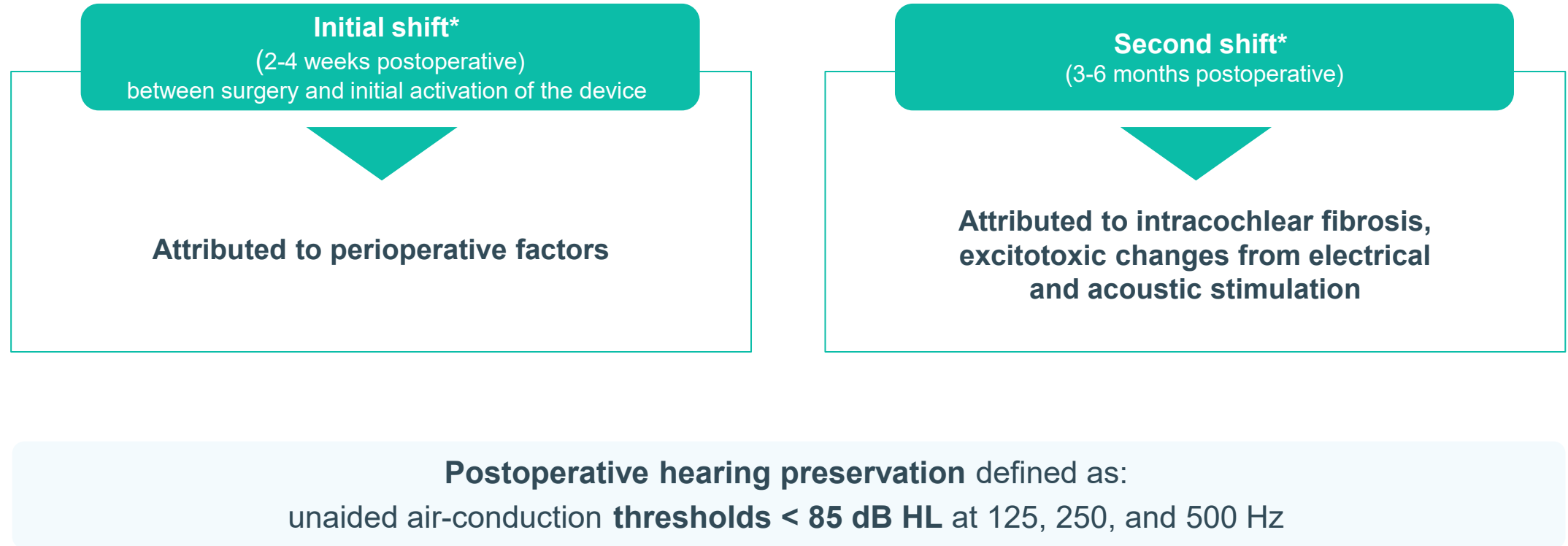
Market penetration in adults eligible to CI  
in developed markets<sup>1</sup>

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



# CI

## Primary Endpoint of The Phase 2a Clinical Study For Residual Hearing Preservation Has Been Met

### Perilymph Concentrations Data

|                             | Treated with SENS-401<br>(n=16)<br>n (%) |
|-----------------------------|------------------------------------------|
| SENS-401 levels $\leq$ LLOQ | 0                                        |
| SENS-401 levels $>$ LLOQ    | 14*(100)                                 |

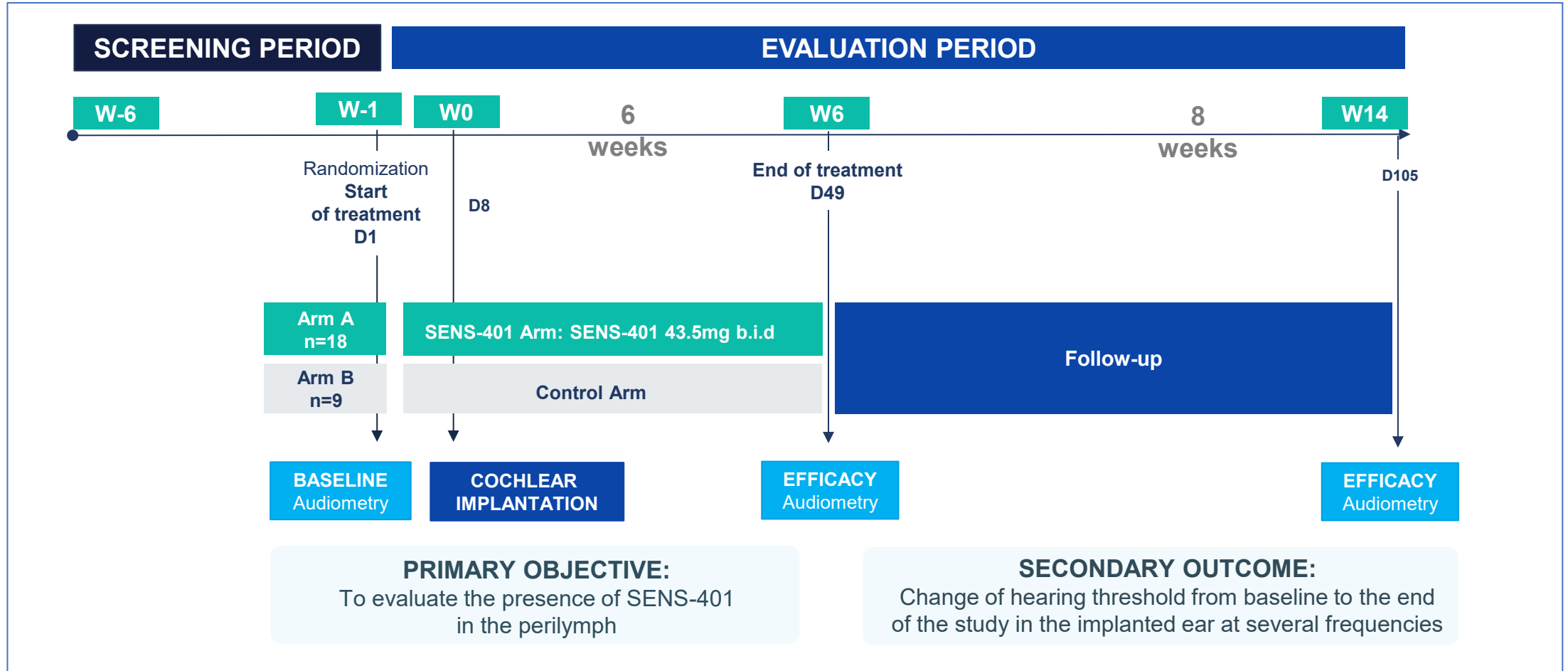
\*Among the 16 participants who underwent surgery, 15 have a perilymph samples and 14 samples were analyzable

\*LLOQ define by a specific method developed for SENS-401

- **Presence of SENS-401 in the perilymph is confirmed in 100% of the patients** sampled following cochlear implantation
- **These results confirm that SENS-401 administered orally crosses the labyrinth barrier**

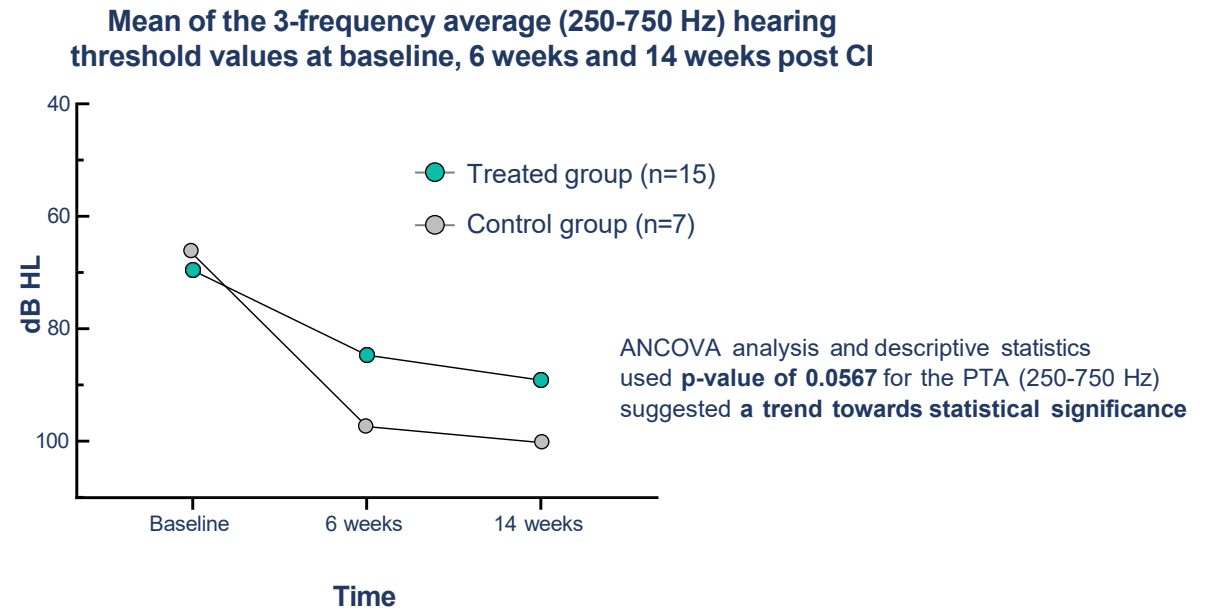
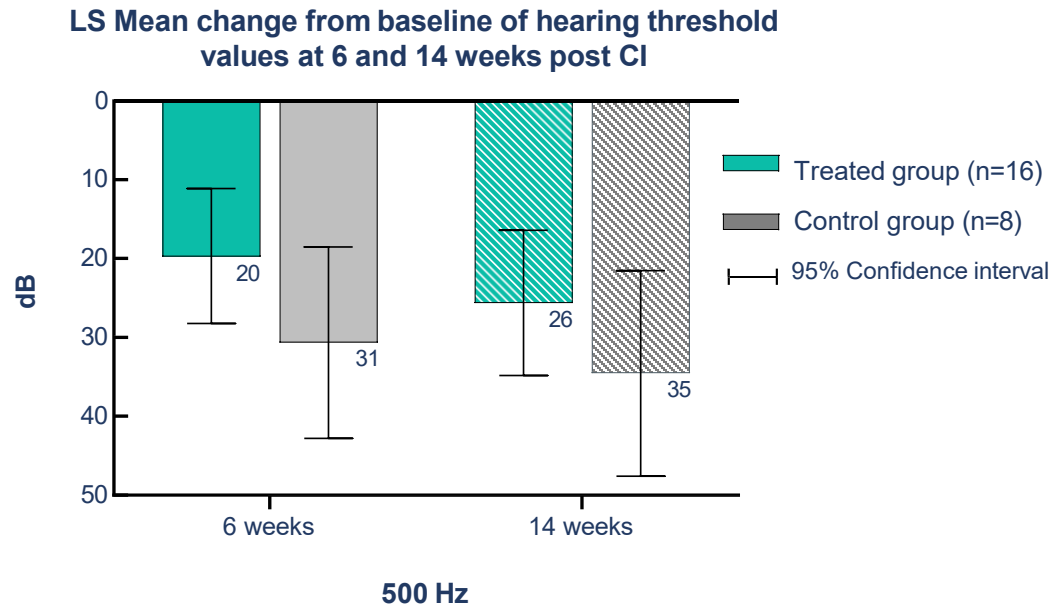
## SENS-401 CI Study Design - Study Completed

**A Phase 2a, Multicenter, Randomized, Controlled, Open-label Study to Evaluate the Presence of SENS-401 in the Perilymph and to Assess Its Efficacy to Prevent Residual Hearing Loss After Cochlear Implantation**



# CI

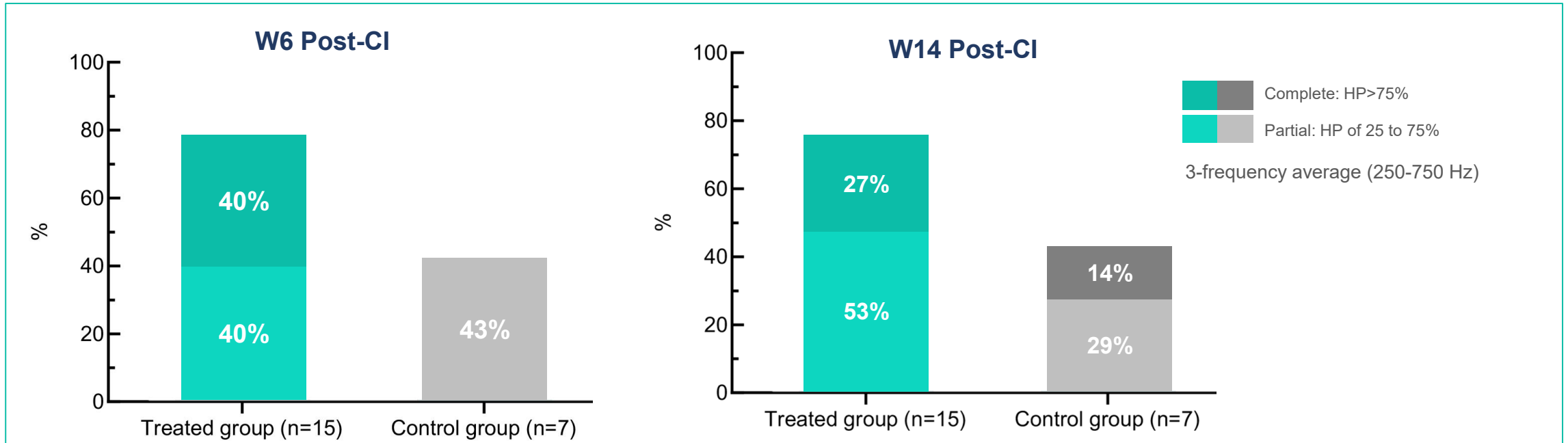
## SENS-401 Provides Hearing Protection 6 & 14 Weeks Post-Cochlear Implantation



- 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.



# 3.2

## **SENS-401 CIO**

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Prevention Of Cisplatin-Induced  
Ototoxicity

# 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%<sup>1</sup> 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.

**Number of total treated patients by Cisplatin per year:** 1 140 000 in G7 countries<sup>2</sup>

<sup>1</sup> JCO Oncology practice, ASCO, volume 19, Issue 5/ CIO: a concise review of the burden, prevention and interception strategies, May 2024 Chattaraj

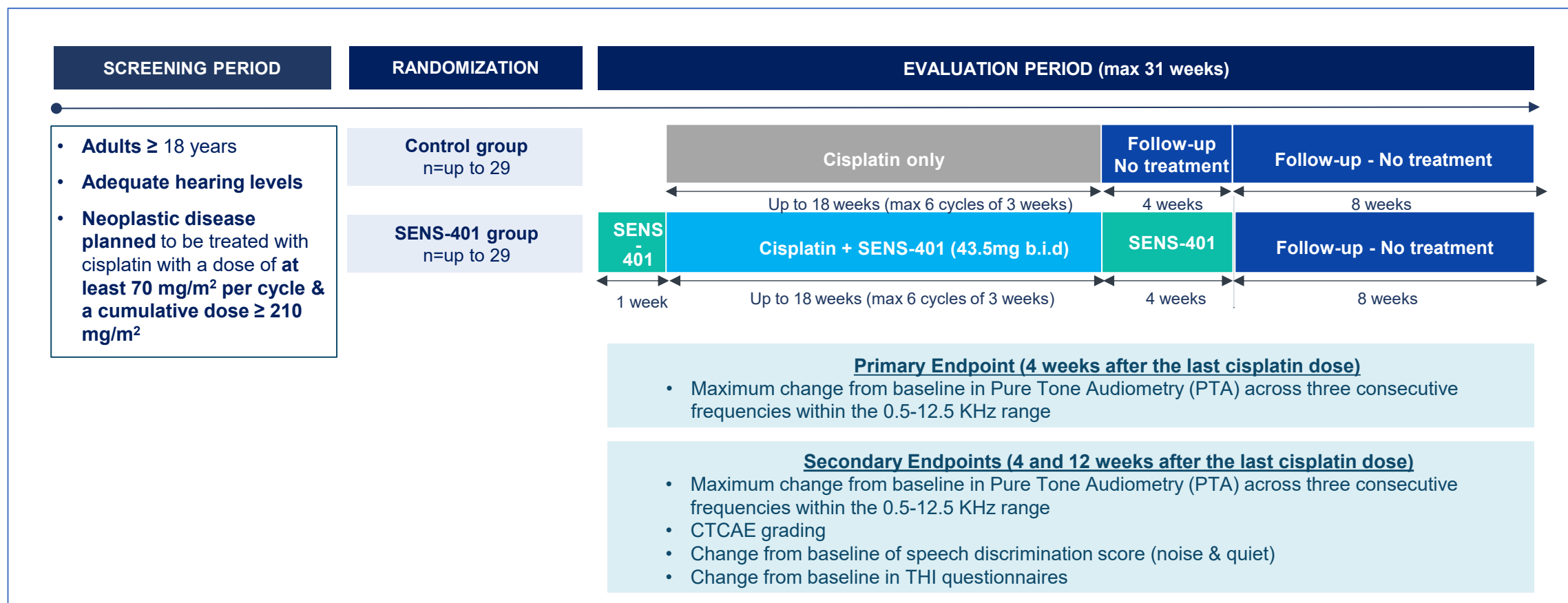
<sup>2</sup> Globocan 24



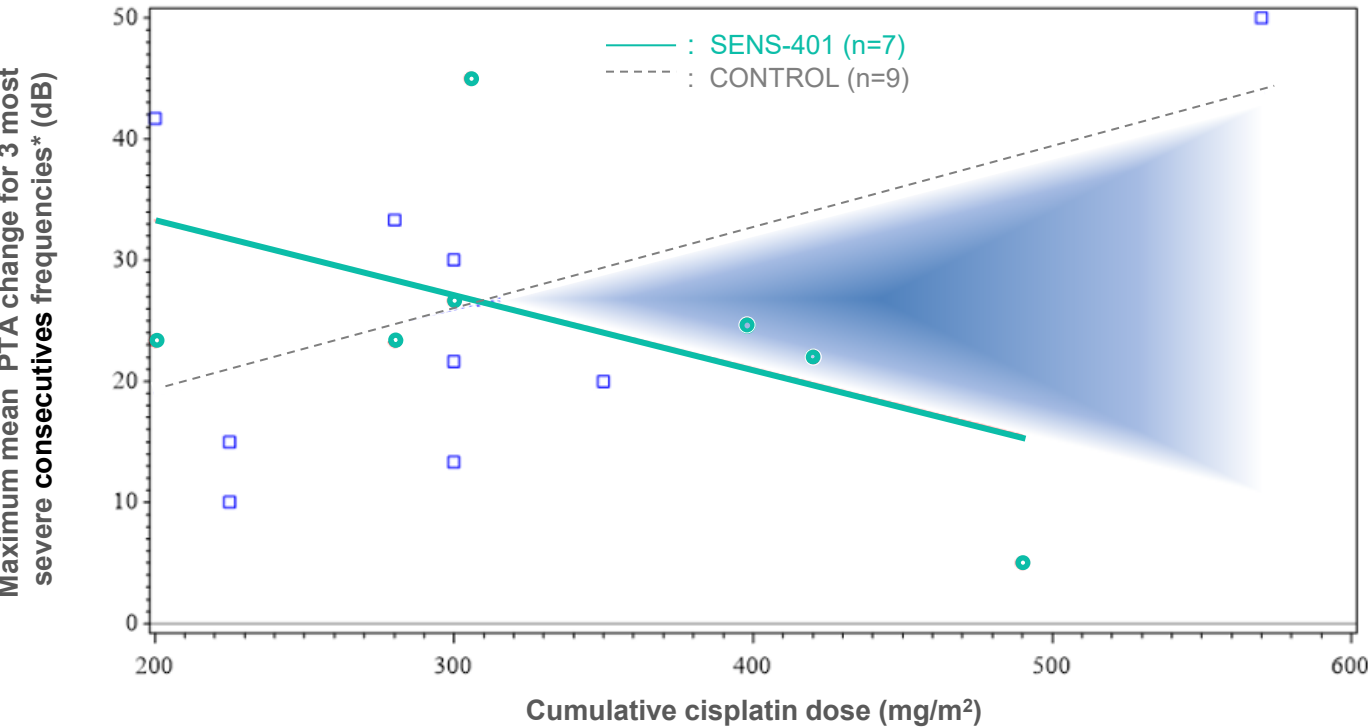
# SENS-401 Phase 2a Proof-Of-Concept Study NOTOXIS

## Recruitment Completed – 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  |

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

- 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/m²**

## 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.



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.**



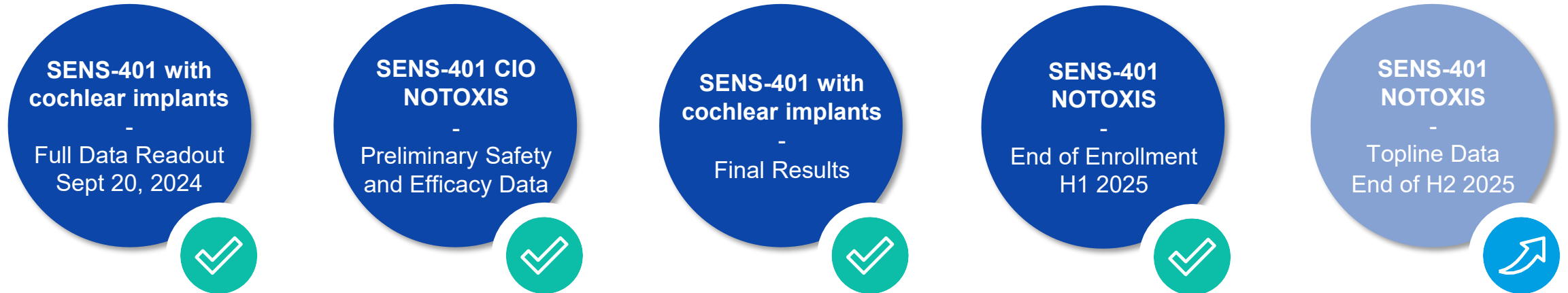
The preliminary results suggest a trend toward an otoprotective effect of **SENS-401** beyond a cisplatin dose of **300 mg/m<sup>2</sup>.**



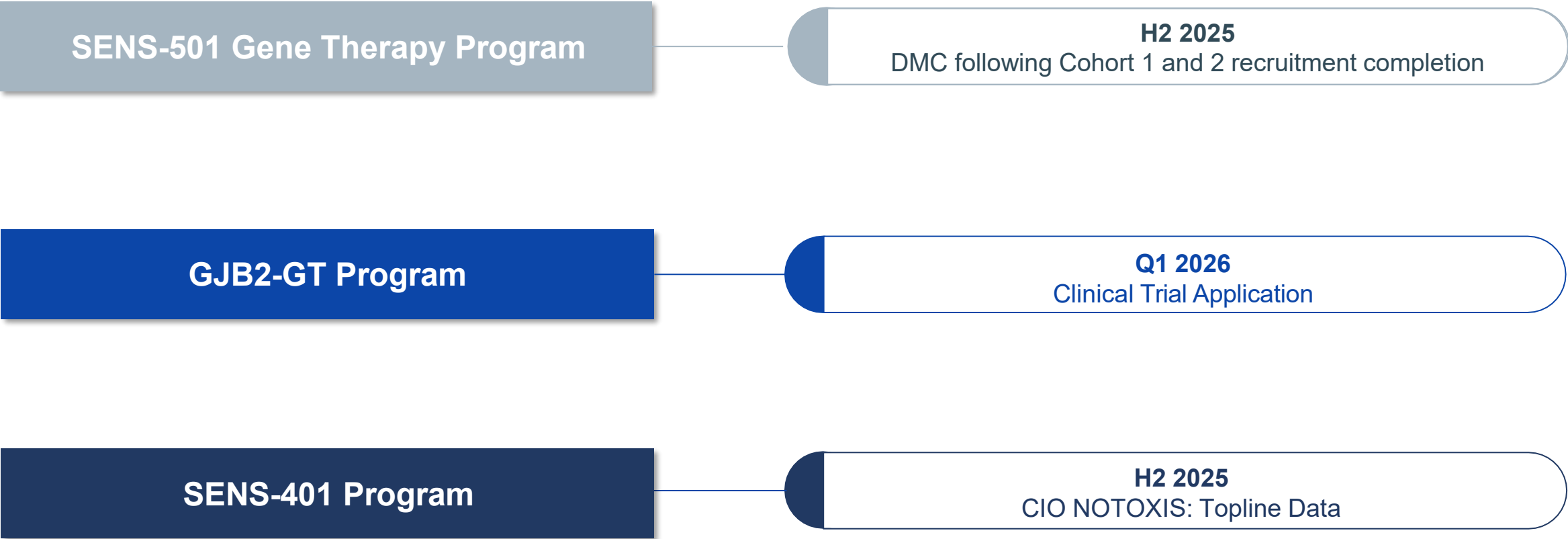
Recruitment completed; 48 patients randomized; follow-up ongoing

## CI & CIO

### SENS-401 Programs Status



# Sensorion Newsflow [Estimated Timelines]





- **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 H2 2025**



- **DMC, following Cohort 1 and 2 recruitment in Audiogene by end of H2 25**
- **SENS-401 CIO Ph2a topline data by end of H2 25**
- **Clinical Trial Application for GJB2-GT in Q1 2026**

# THANK YOU

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E:contact@sensorion-pharma.com



# HEARING LOSS

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# Access And Clarity Are Mandatory For Optimal Outcomes

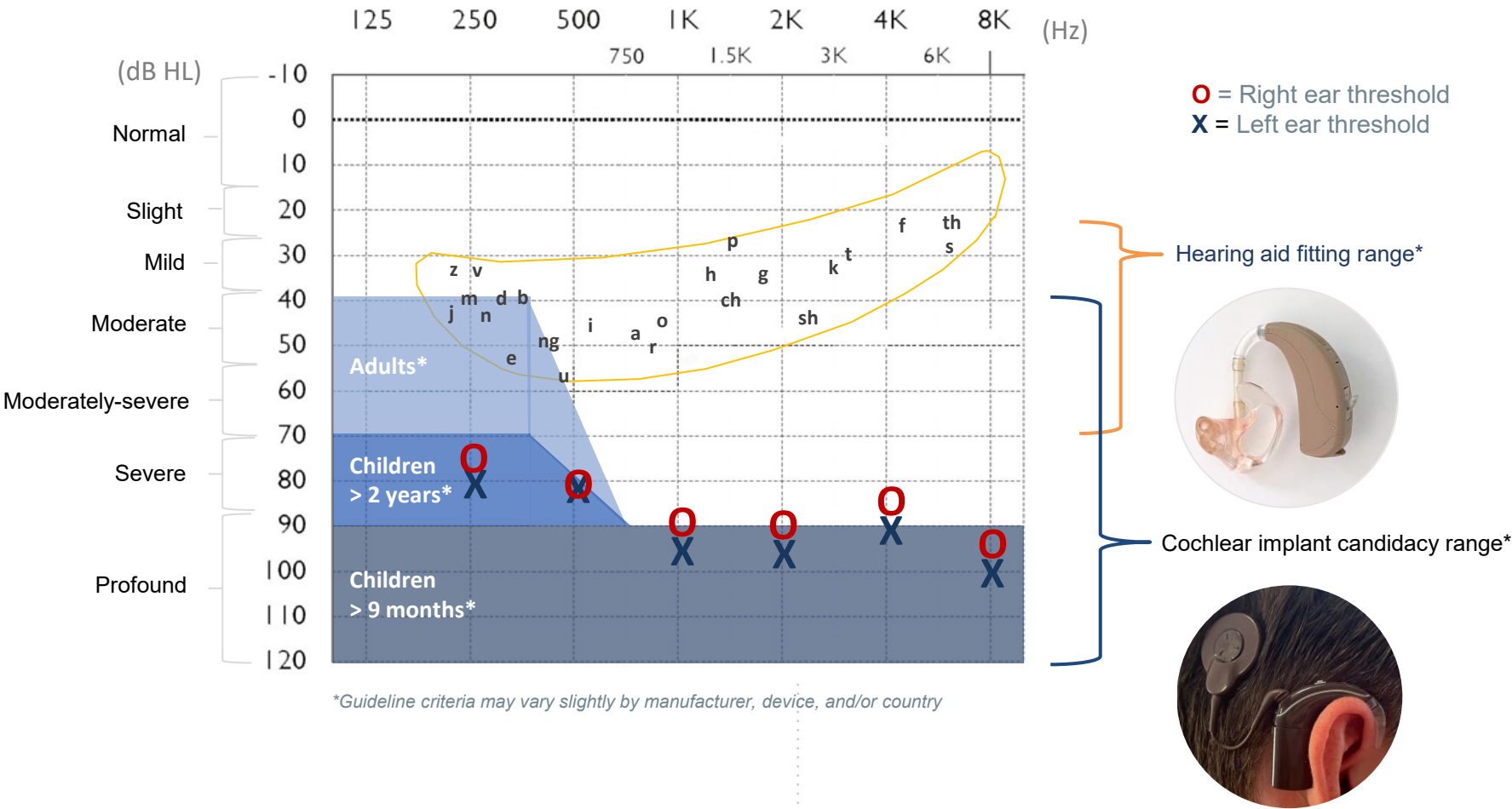


Image of hearing aid: [https://commons.wikimedia.org/wiki/File:Unitron\\_Ziel\\_photo\\_2.jpg](https://commons.wikimedia.org/wiki/File:Unitron_Ziel_photo_2.jpg)  
Image of cochlear implant sound processor on ear: [https://commons.wikimedia.org/wiki/File:Cochlear\\_Nucleus%C2%AE\\_7\\_Sound\\_Processor.jpg](https://commons.wikimedia.org/wiki/File:Cochlear_Nucleus%C2%AE_7_Sound_Processor.jpg)  
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# **Internal Capabilities**

# We Have Established Internal Capabilities To Ensure Successful Execution



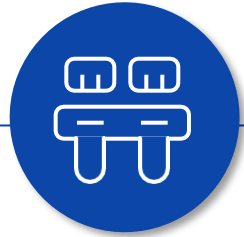
## PRECLINICAL - SMALL MOLECULES & GT PROGRAMS

- Audiology, inner ear surgery and drug administration expertise in preclinical models
- Technology&Innovation Platform: assay development and gene therapy vectors design
- Cell Model and Animal Pharmacology Platforms: from target & drug discovery, to POC/dose-finding studies in disease-relevant models



## CLINICAL EXPERIENCE

- 600 subjects enrolled in Sensorion led clinical trials
- Set-up audio tests in different countries, languages
- In-house audiology expertise of more than 20 years for the pediatric and adult populations and cochlear implants
- Development of gene therapy products in several rare diseases



## CMC GENE THERAPY FACILITIES

- Process development: non-GMP manufacturing from small scale up to 50L in bioreactor
- Analytical development: development of product-specific analytical methods, in-house generic assays to support process development and AAV manufacturing



## REGULATORY EXPERTISE

- Develop regulatory strategies to ensure expedited product development including gene therapy
- Regulatory Agencies interaction (EU/US)
- Shape the treatment guidelines and standardize clinical endpoints



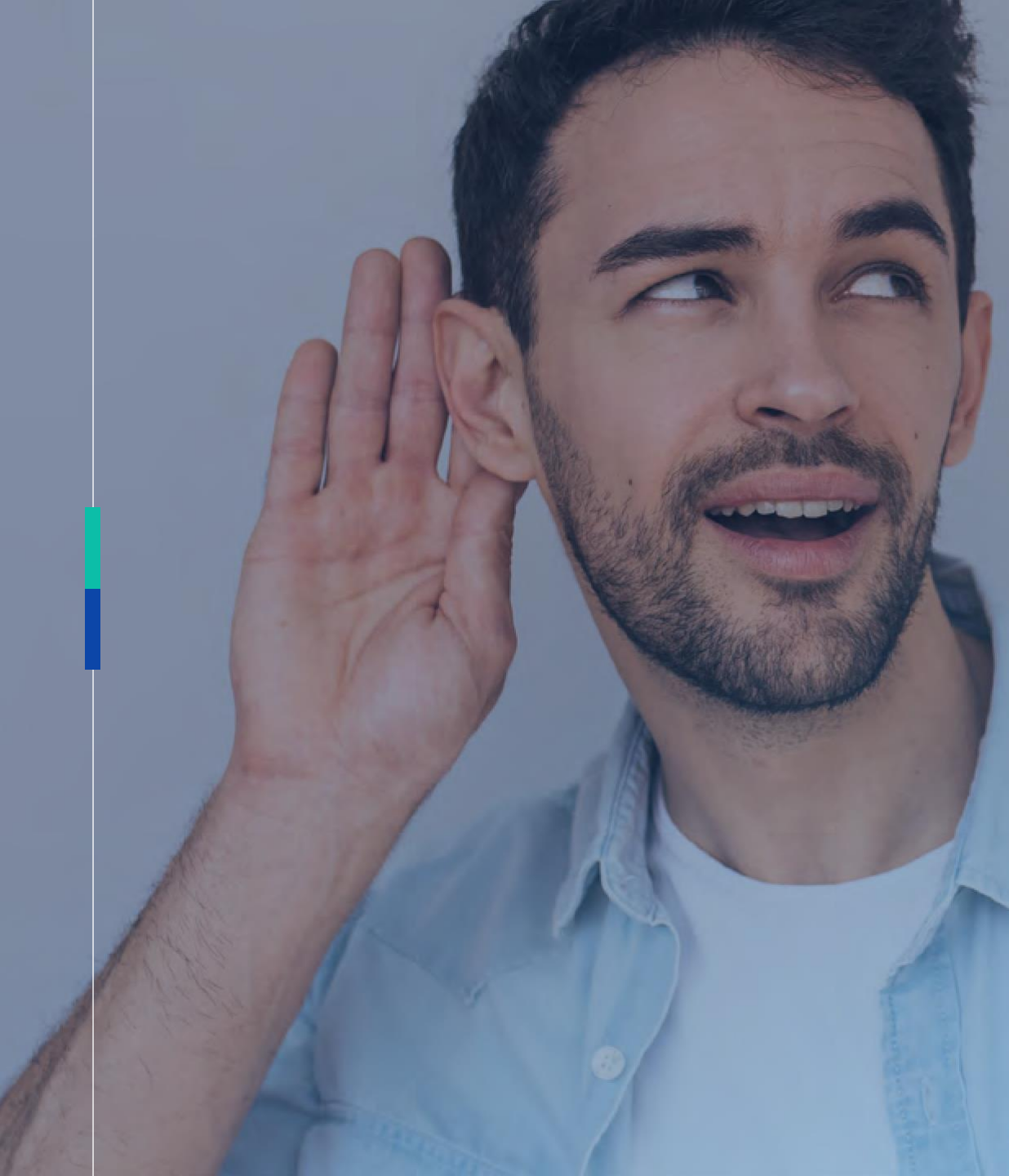
## PATIENT ACCESS

- Working with prominent payers from the EU5
- Obtaining consultation about our early Clinical Development Program within EU and US
- Building capabilities cross-functionally

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 green vertical bar on the left side.

# **SENS-401 PROGRAMS Back-Up**

Multiple Indications To Treat  
And Prevent Hearing Loss



# SSNHL

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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<sup>3</sup> to 160<sup>4</sup> per 100 000 e.g > 200,000 patients in 2017 in G7 countries<sup>5</sup>

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

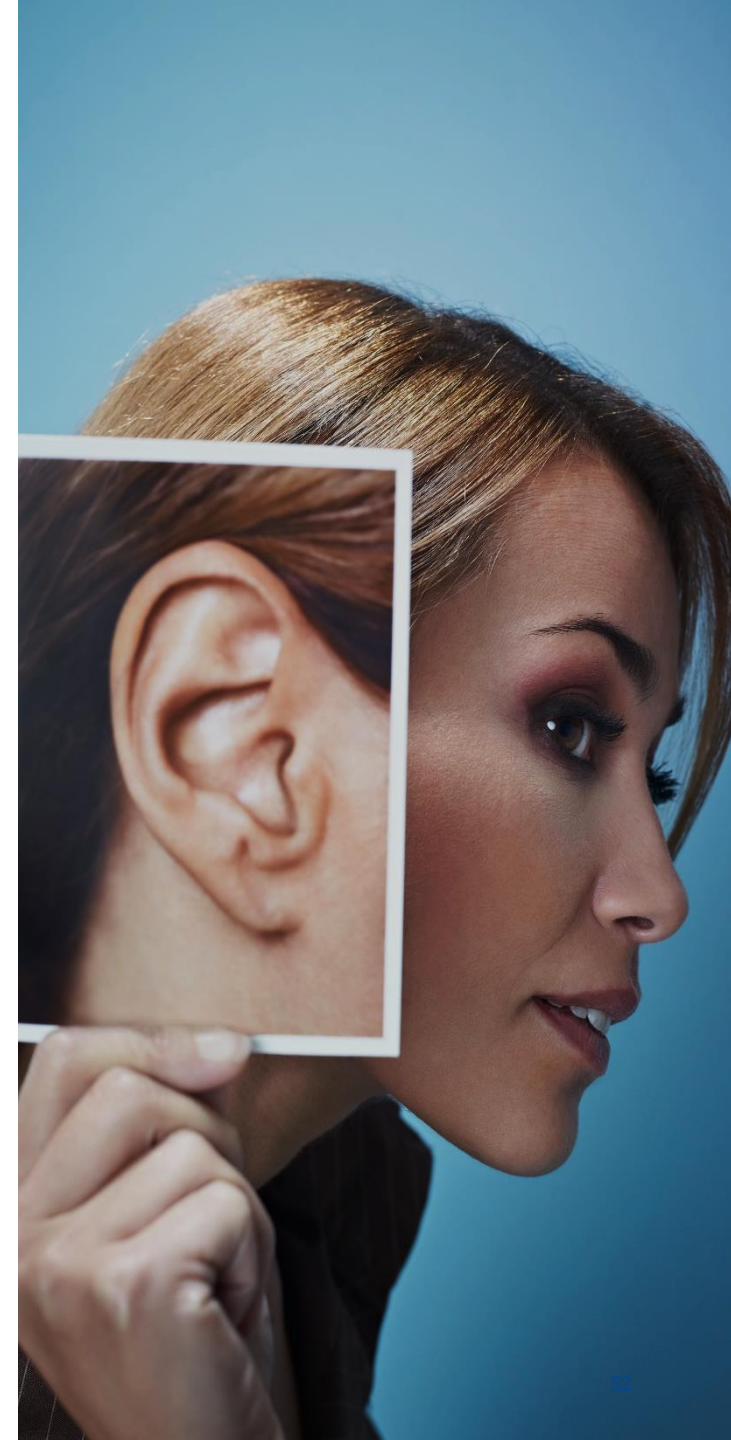
2. Kearney Interviews

3. Incidence of SSNHL - OTOL Neurotol. 2013 Dec, T. Alexander & J. Harris, OTOL Neurotol

4. A present investigation of the epidemiology in idiopathic sudden sensorineural hearing loss] [Article in German] [E Klemm 1](#), [A Deutscher](#), [R Mösges](#)

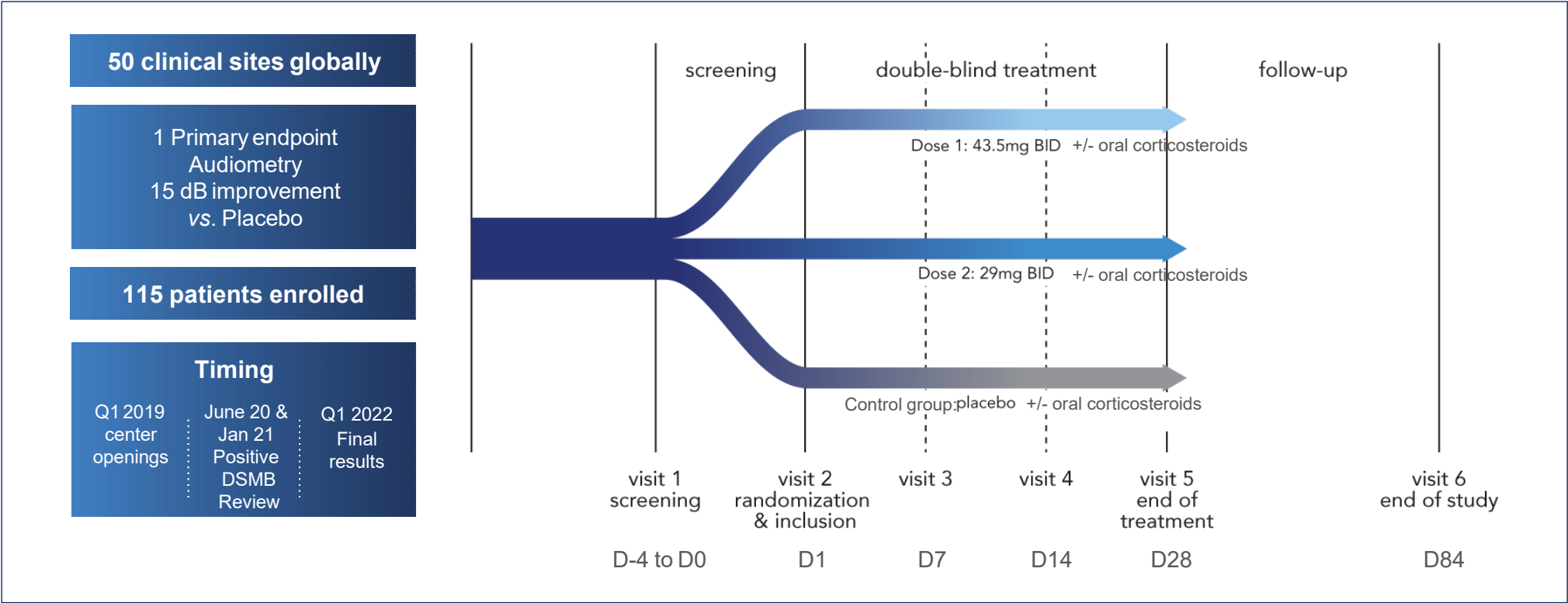
5. Company estimates based on publicly available data (in the US, Japan, Germany, France, the UK, Italy and Spain)

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AUDIBLE-S Phase 2 Design

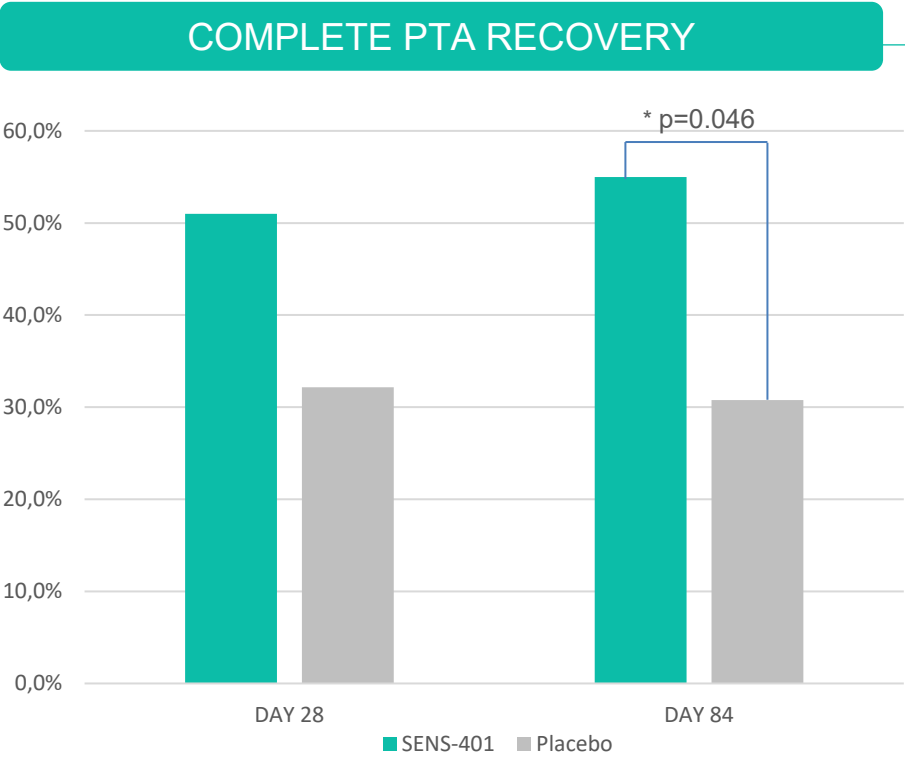
A Phase 2b, Multicenter, Randomized, Controlled, Double-blind Study to Evaluate the Efficacy of SENS-401 to Treat Patients with Severe to Profound Sudden Sensorineural Hearing Loss



**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)”

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



| Complete PTA recovery (n/n total) | Placebo | SENS-401 (2 doses pooled*) |
|-----------------------------------|---------|----------------------------|
| Day 28                            | 9/28    | 25/49                      |
| Day 84                            | 8/26    | 22/40                      |

\*As SENS-401 plasmatic concentration is similar for the two tested doses, the results have been pooled.

- **Complete hearing recovery** is defined as patients with hearing loss at baseline who will **revert to PTA < 20 dB**, considered as “normal” hearing
- SENS-401 is statistically superior to placebo at Day 84 (p<0.05)

# SSNHL

## Phase 2 Results Summary



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.



**Responder rate is always better in the treated group** compared to placebo and difference with placebo increases over time.



Safe and well tolerated in 115-patient SSNHL study; although primary endpoint not met data supports and informs further clinical development.