

Corporate Presentation

Unlocking The Potential Of Advanced Therapies
For Hearing Loss

January 2026

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1

SENSORION

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

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Head of Preclinical
Development

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(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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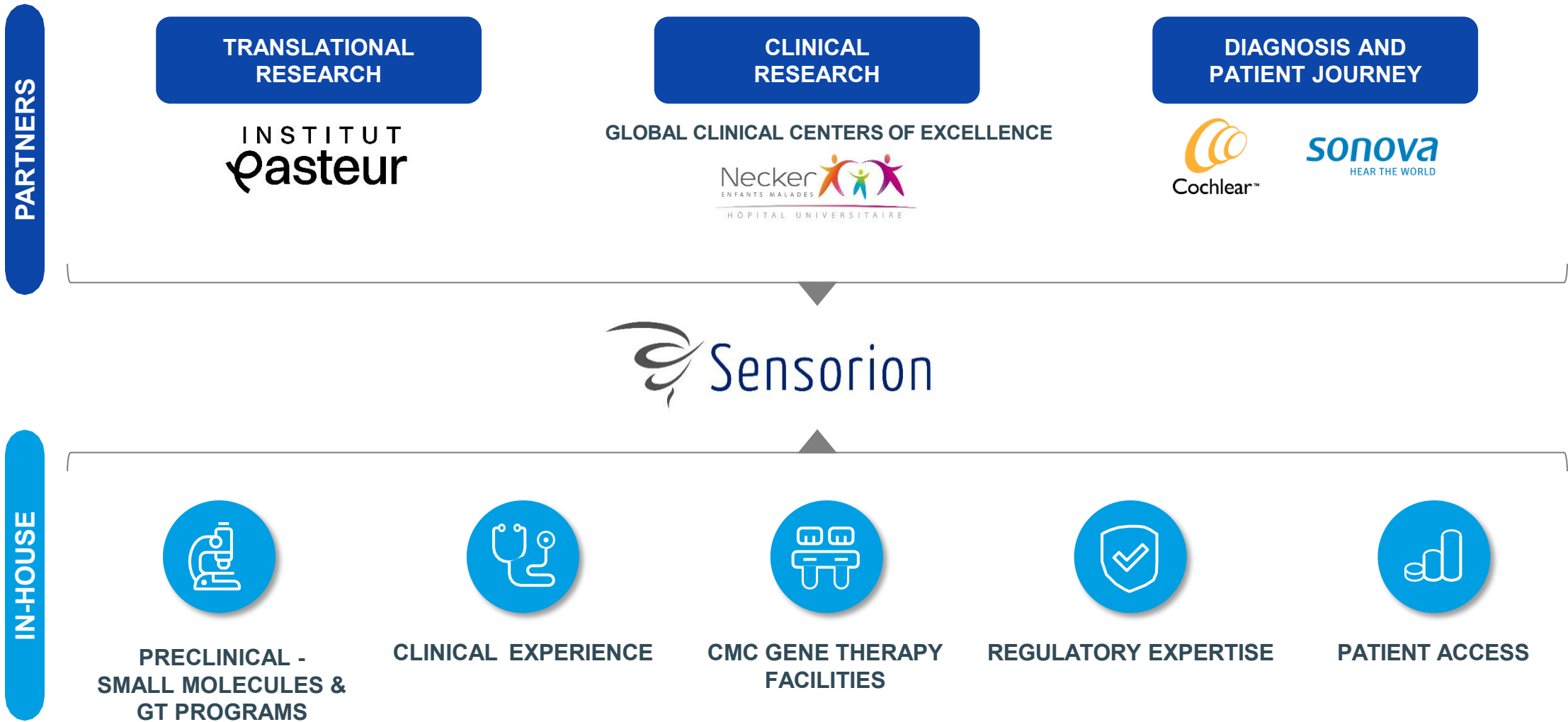
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Sensorion

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



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						6-months follow-up data in Q1 2026 for C2
	SENS-601* (GJBE-GT)	HL related to <i>GJB2</i> mutations Adult Onset (presbycusis)							CTA/IND Enabling Activities
	SENS-601* (GJBE-GT)	HL related to <i>GJB2</i> mutations Pediatric Progressive							CTA/IND Enabling Activities
	SENS-601* (GJBE-GT)	HL related to <i>GJB2</i> mutations Congenital Onset							CTA/IND Enabling Activities
SMALL MOLECULE TREAT & PREVENT	SENS-401	Hearing Preservation after CI							Exploring Partnering Opportunities
	SENS-401	Cisplatin-Induced Ototoxicity							Upcoming Topline Data
	SENS-401	SSNHL							Exploring Partnering Opportunities

HL: Hearing Loss
 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)



2

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* 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

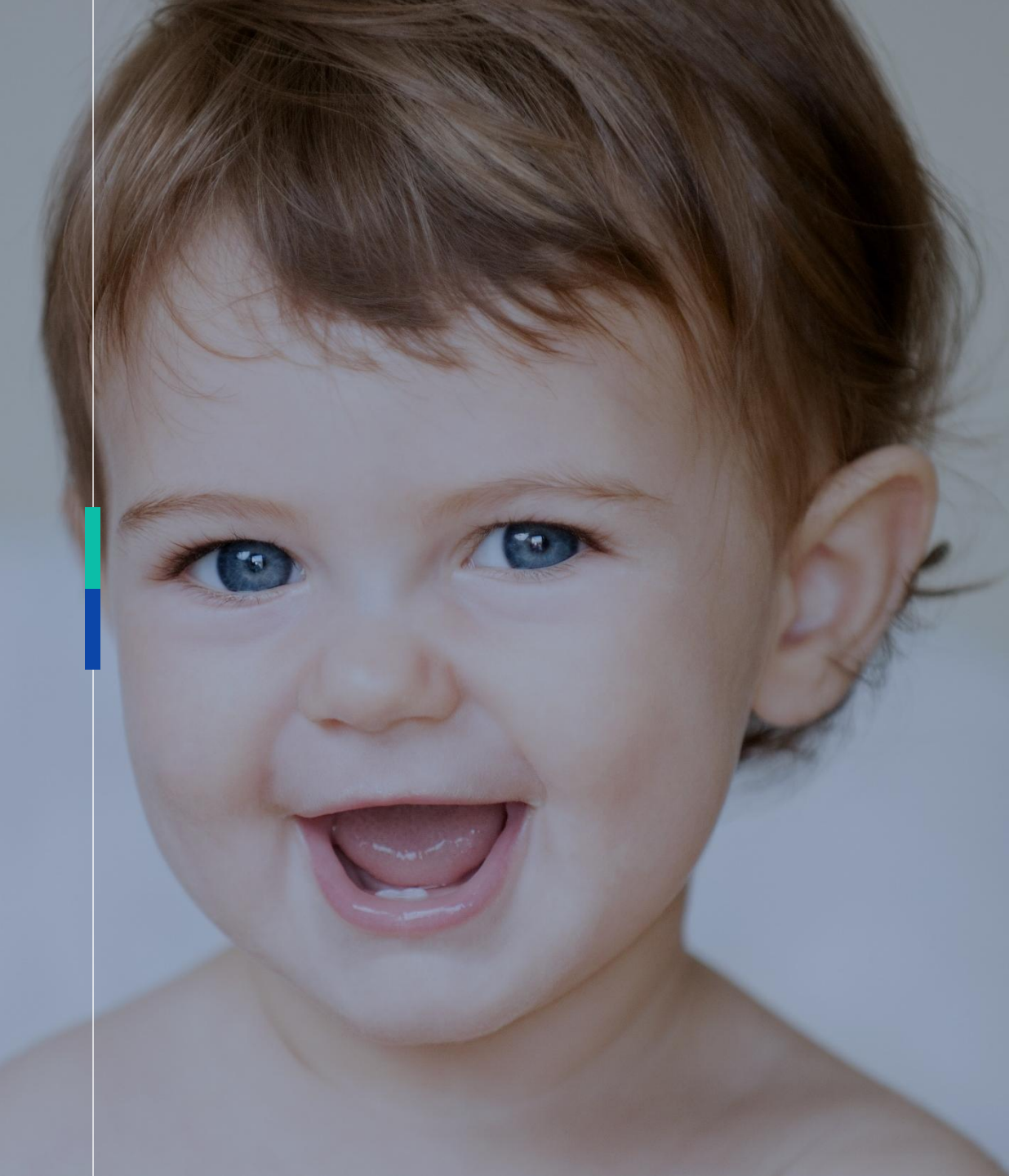


Current Standard Of Care Is Cochlear Implantation

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

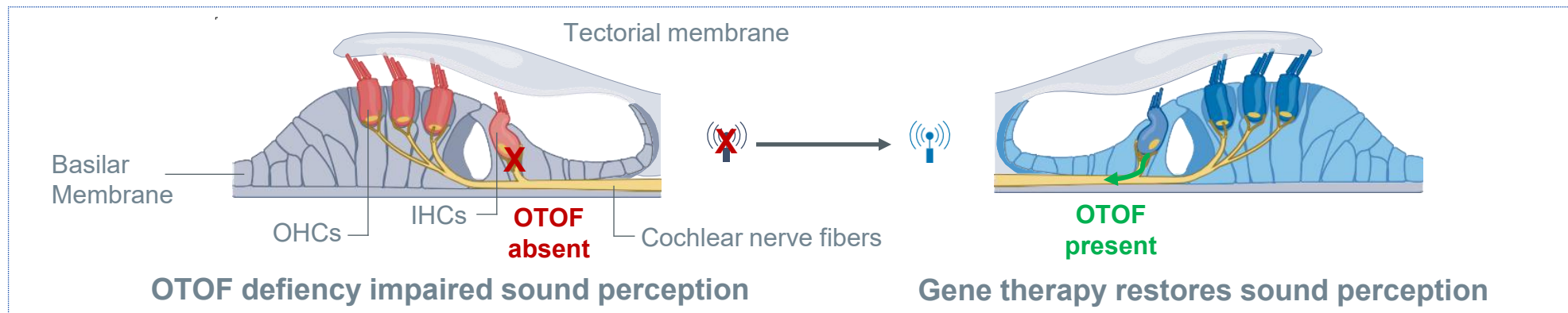
SENS-501

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

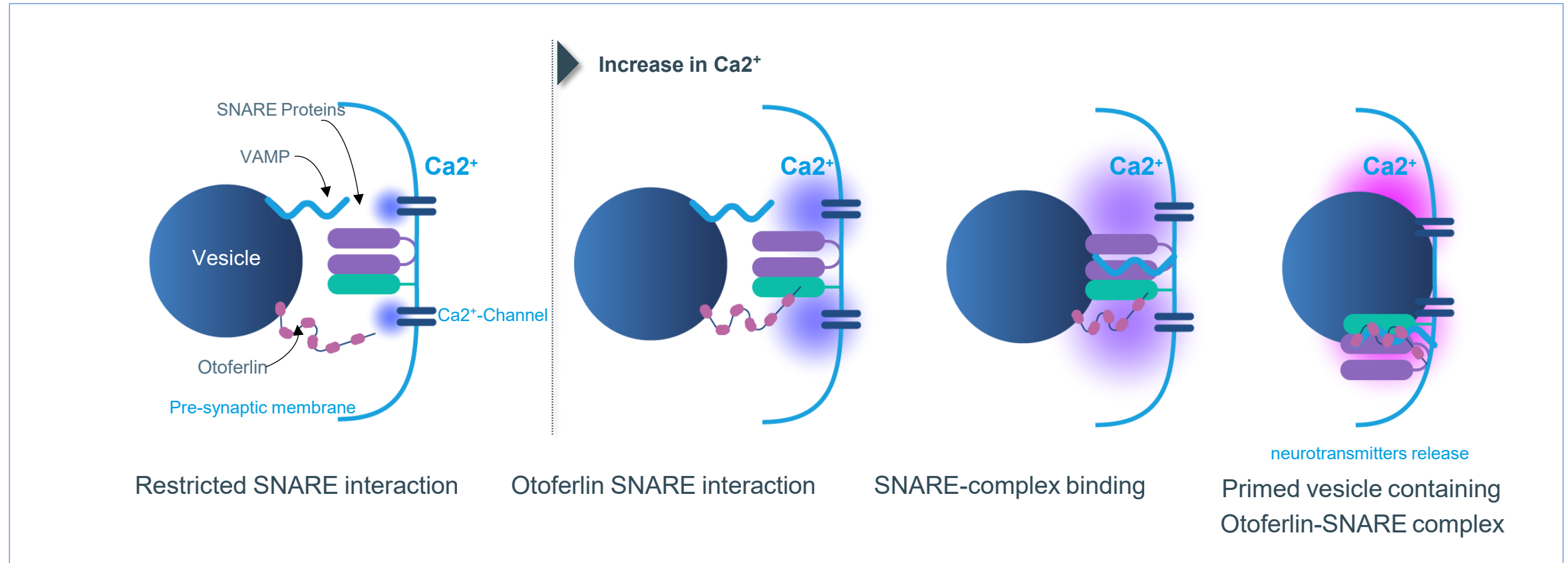


- SENS-501 is the pilot program that has the potential to demonstrate that GT is a relevant medical approach for the inner ear
- SENS-501 will establish understanding of GT in the inner ear by the Regulators and the Payers for future GT programs
- Medical plausibility and target population have been 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 Ca^{2+} Sensor Protein



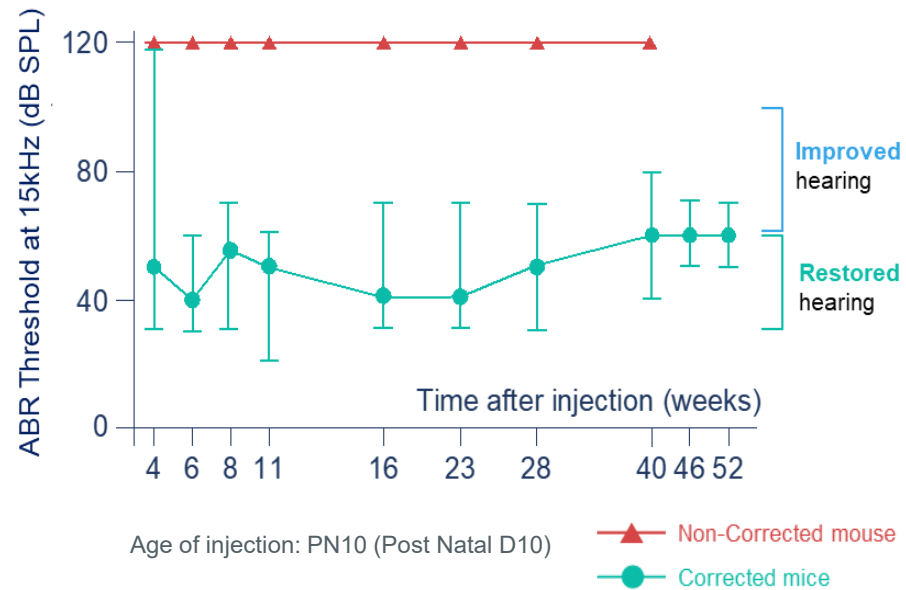
***OTOF* is the gene coding for the otoferlin protein, a Ca^{2+} sensor key for vesicle fusion and vesicle pool replenishment at auditory hair cell ribbon synapses**

SENS-501

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

Long-Term Hearing Restoration

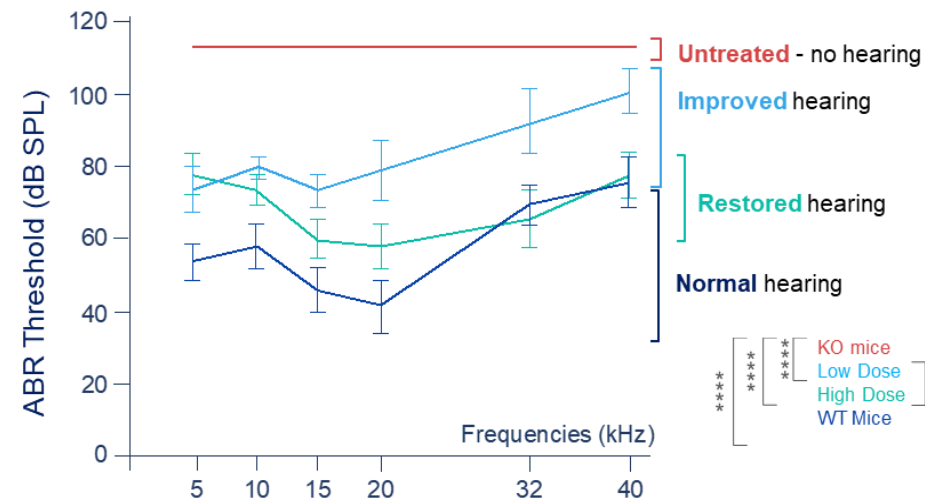
AAV-mOTOF injected in mice before hearing onset



- **Durable hearing restoration** in *Otof*^{-/-} 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

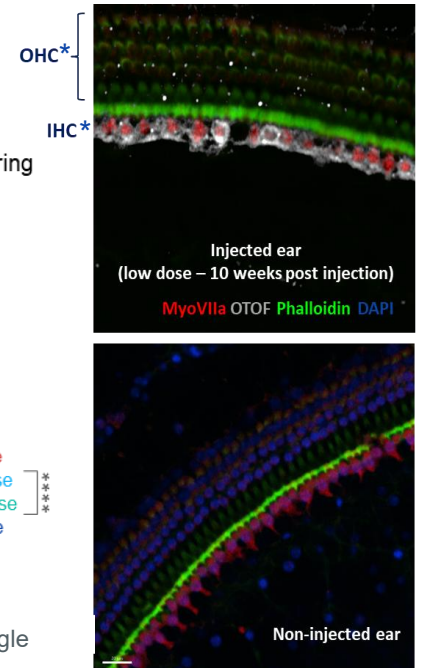
SENS-501 injected in mice after hearing onset
10 months after injection



****: $p < 0.0001$; two-way ANOVA, Dunnett's Multiple comparison test with a single pooled variance

Age of injection: PN17-25

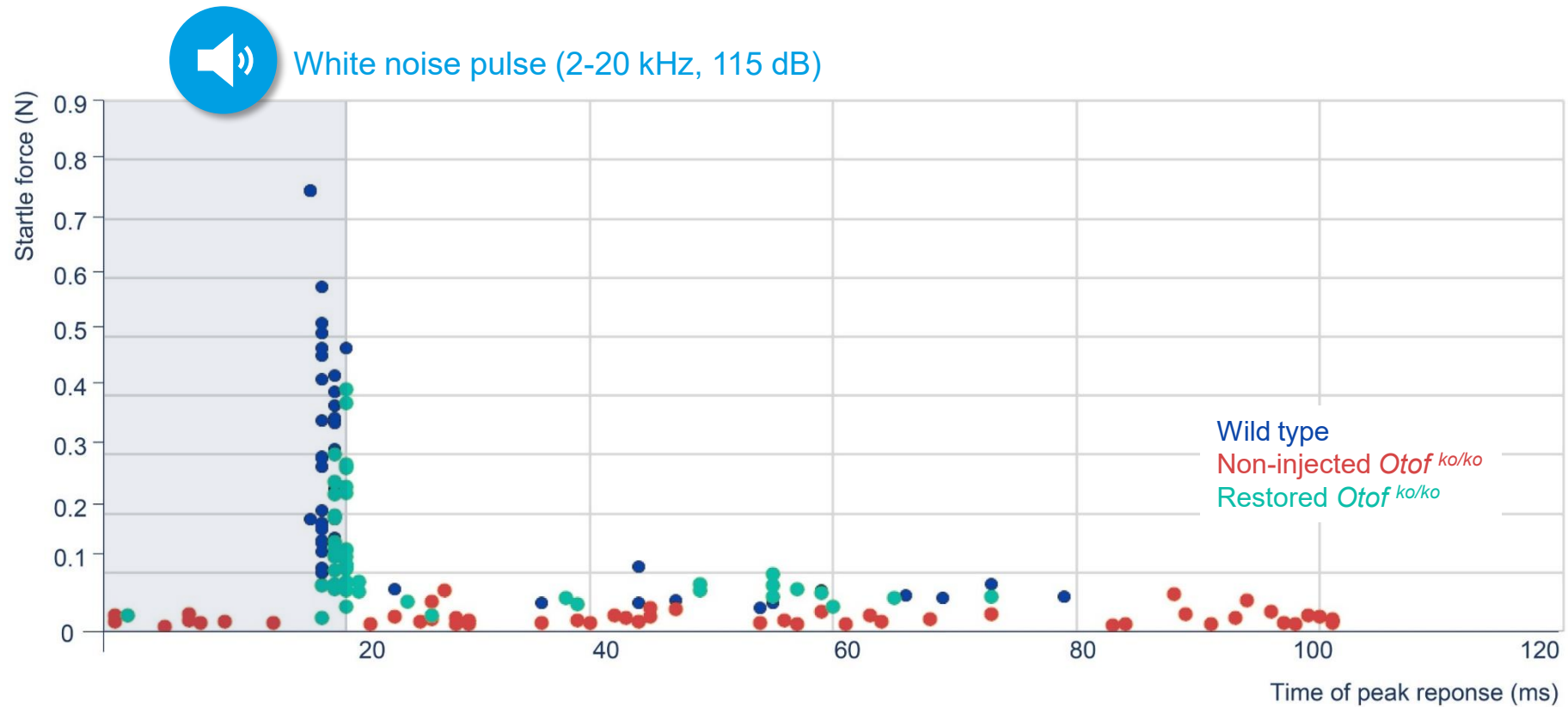
- Both doses of SENS-501 demonstrated efficacy in **improving hearing in KO mice**
- SENS-501 leads to **otoferlin expression in Inner Hair Cells**



*O/IHC: Outer/Inner Hair Cells

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

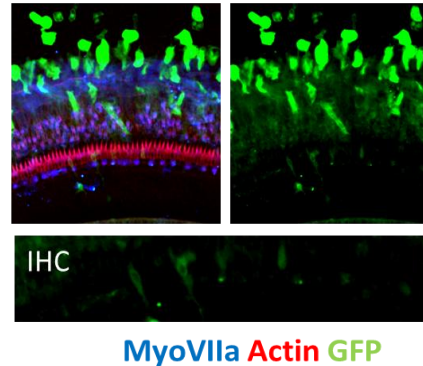
Non-Human Primates injected through the round window membrane with or without stapedotomy

1 Fenestration

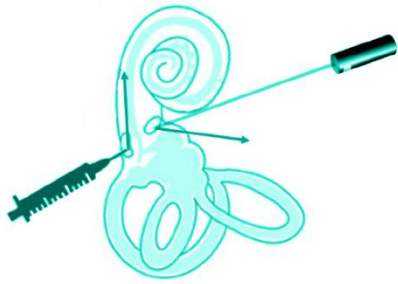


Used for cochlear implant

- Overpressure
- Limited volume
- Backflow
- Irregular transduction rate

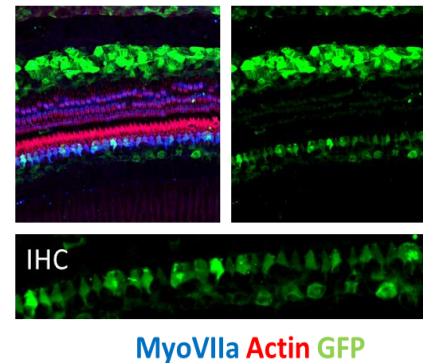


2 Fenestrations



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:

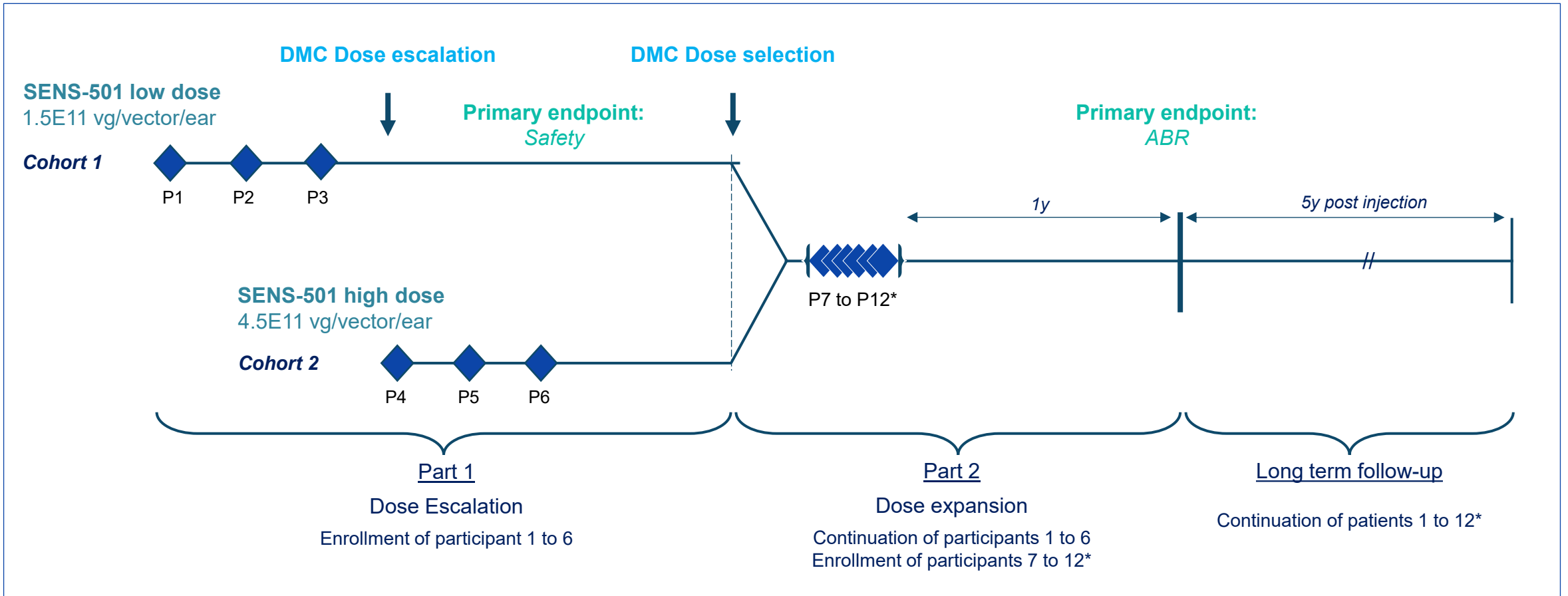
- A **homogeneous** clinical study population in the right target age for **speech acquisition** (ie: below 3 years old)
- **No concomitant or previous cochlear implantation at the time of the injection**, to be able to document the contribution of the GT in speech development
- Global clinical study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



- **Successful completion of recruitment for the first two cohorts (n=6) in H2 2025**
- **Good safety to date at both doses:**
 - Surgical administration procedure well tolerated
 - No dose-limiting toxicities, no Serious Adverse Events
 - Vestibular function and OAEs remained intact and unchanged from baseline
- In Cohort 2 (high dose), **early promising improvements in two of the three treated patients by Month 3 on Pure Tone Audiometry:**
 - Patient 4: 60 dB HL threshold at best performing frequency
 - Patient 5: 70 dB HL threshold at best performing frequency

STUDY UPDATE



- **In December 2025, the Data Monitoring Committee raised no safety concerns and supported the continuation of the study**
- Upcoming six-months efficacy data to be communicated during Q1 2026
- Continuing Natural History Study Otoconex supporting eligible patients' identification

SENS-501

Program Status





2.2

***GJB2*-RELATED HEARING LOSS**

SENS-601 (GJB2-GT)

Leveraging SENS-501 Program For SENS-601 Program Success

SENS-501 Is Paving The Way For GJB2-GT

SENS-501

SENS-601

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

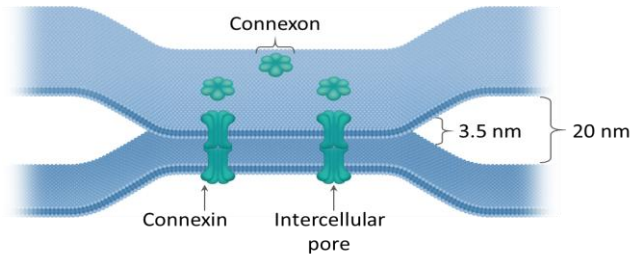
- **AAV capsid selected for high-level of target cells specificity**
- **GT product showing high level of target cells transduction**
- **Limited off-target tissue biodistribution**
- **Surgical approach developed and mastered by ENT surgeons**

SENS-601 (GJB2-GT)

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

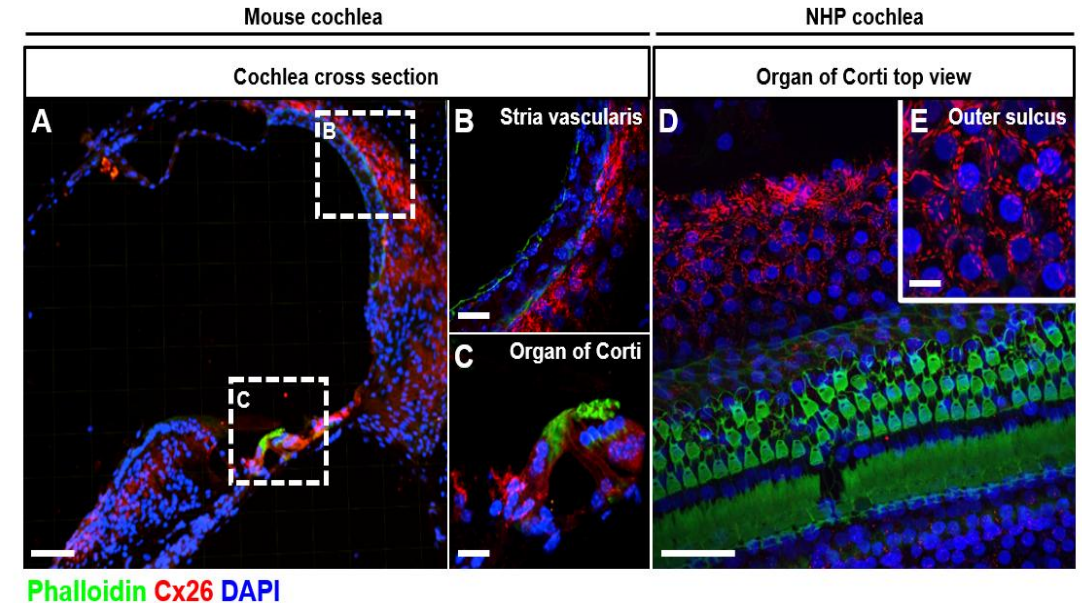
Mutations In The *GJB2* gene Lead To Deafness

- 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

SENS-601 (GJB2-GT)

Lead Candidate Was Selected To Answer Specific Development Criteria

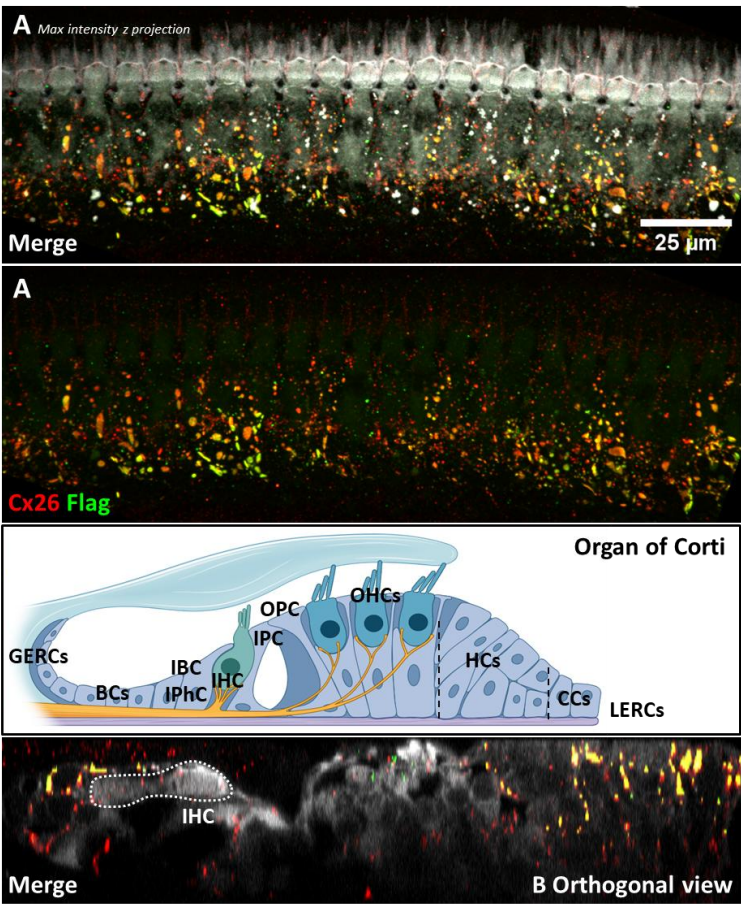
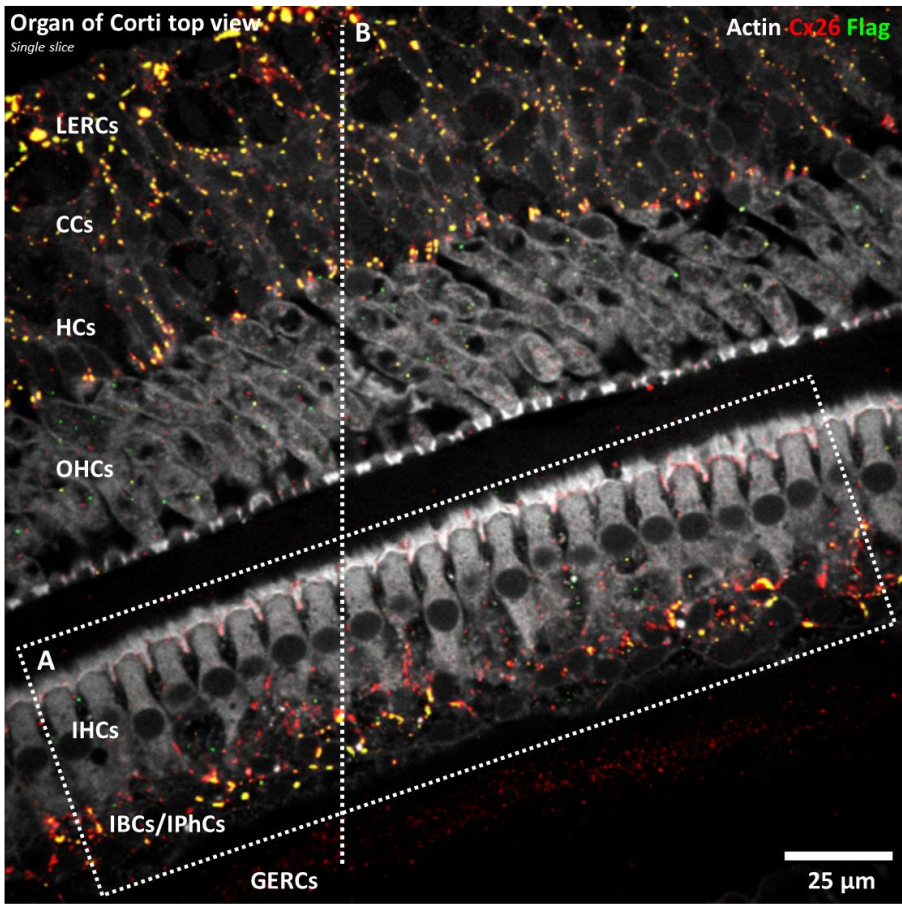
CRITERIA	LEAD CANDIDATE
Natural and synthetic AAV capsid libraries screening for broad coverage of target cells	
Expression cassette design for high-level of target cells transduction, correct cellular localization, active gap-junctions	
Avoiding off-target expression (i.e. hair cells): promoter and 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

SENS-601 (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

- Claudius 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

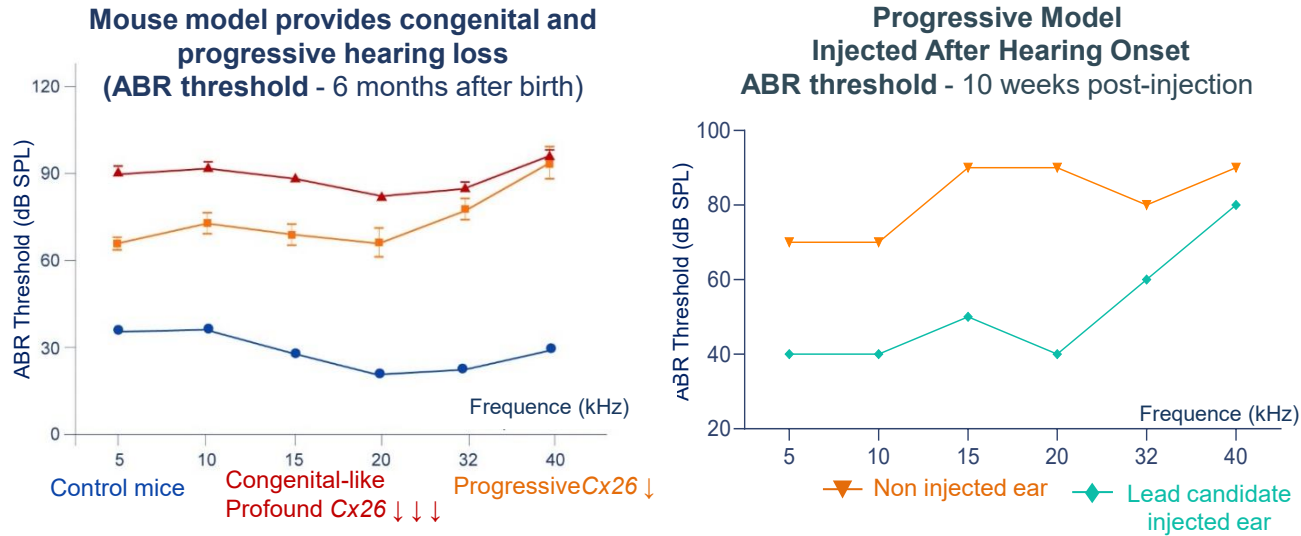


- No expression in Hair Cells confirmed
- No morphological defects observed 3 and 9 weeks after intracochlear administration

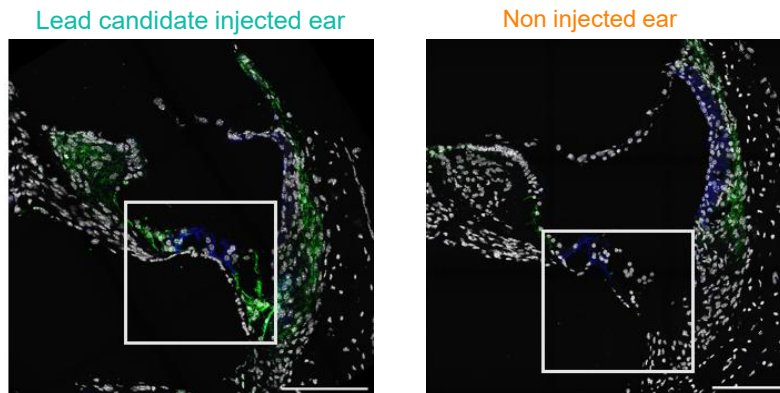
SENS-601 (GJB2-GT)

Lead Candidate Prevents Hearing Loss In Relevant Mouse Model

Proof Of Concept In Mice With Progressive Hearing Loss

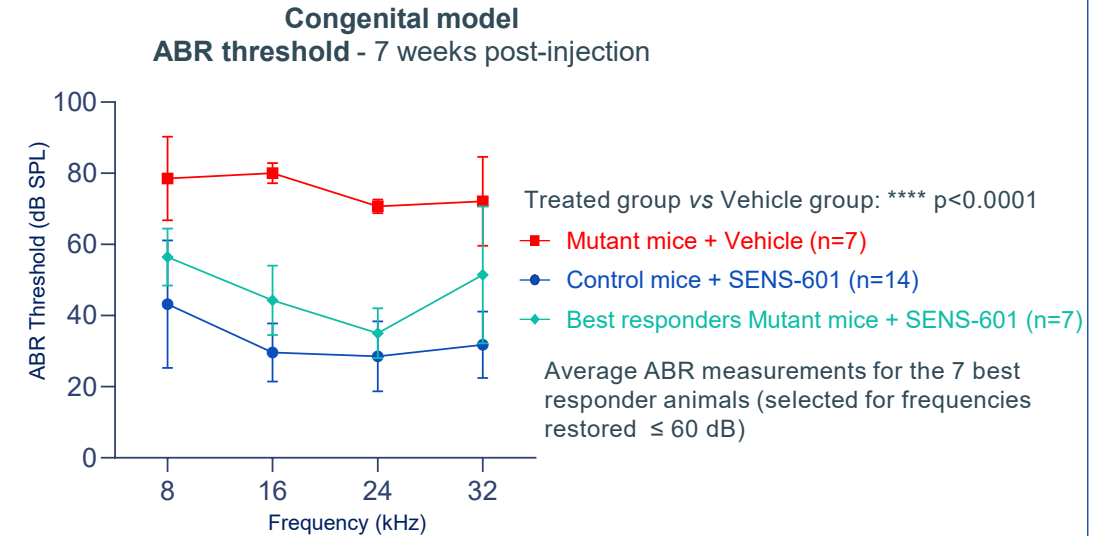


Hearing Loss Prevention Correlates With Connexin 26 Expression



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 SENS-601 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](#))

SENS-601 (GJB2-GT)

Program Status



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 vertical bar on the left side, which is divided into teal and blue segments.

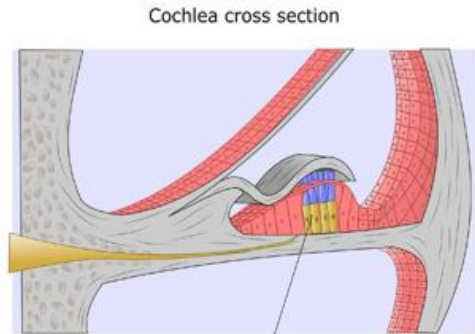
3

SENS-401 PROGRAMS

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**

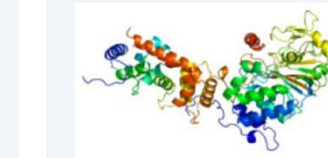
INSULT

Disrupted Ca²⁺ homeostasis
Excitotoxicity
Neuro Inflammation

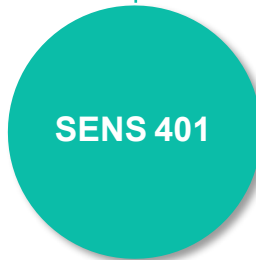
Calcineurin Activation

Neurodegenerative cascades

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

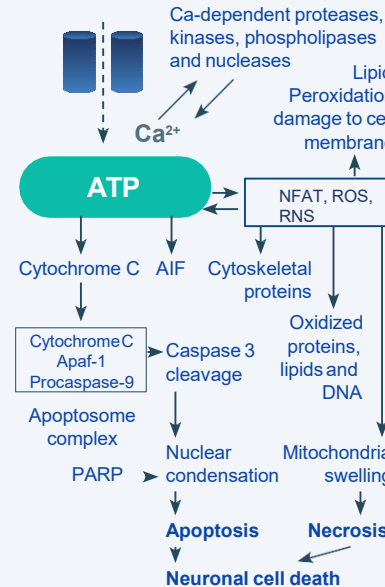


CaN pathway inhibition

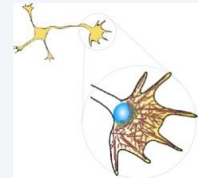


SENS-401 is the **(R)-enantiomer of Azasetron** belonging to the class of selective 5-HT₃ Receptor (5-HT₃R) antagonists with a calcineurin inhibition action

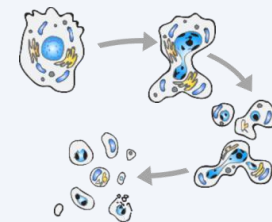
Oxidative Stress



Structural degeneration



Apoptosis





3.1

SENS-401 CI

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

≈ 90,000

Implants sold globally in 2025¹

\$1.8bn

Cochlear implant market in 2020²

3%

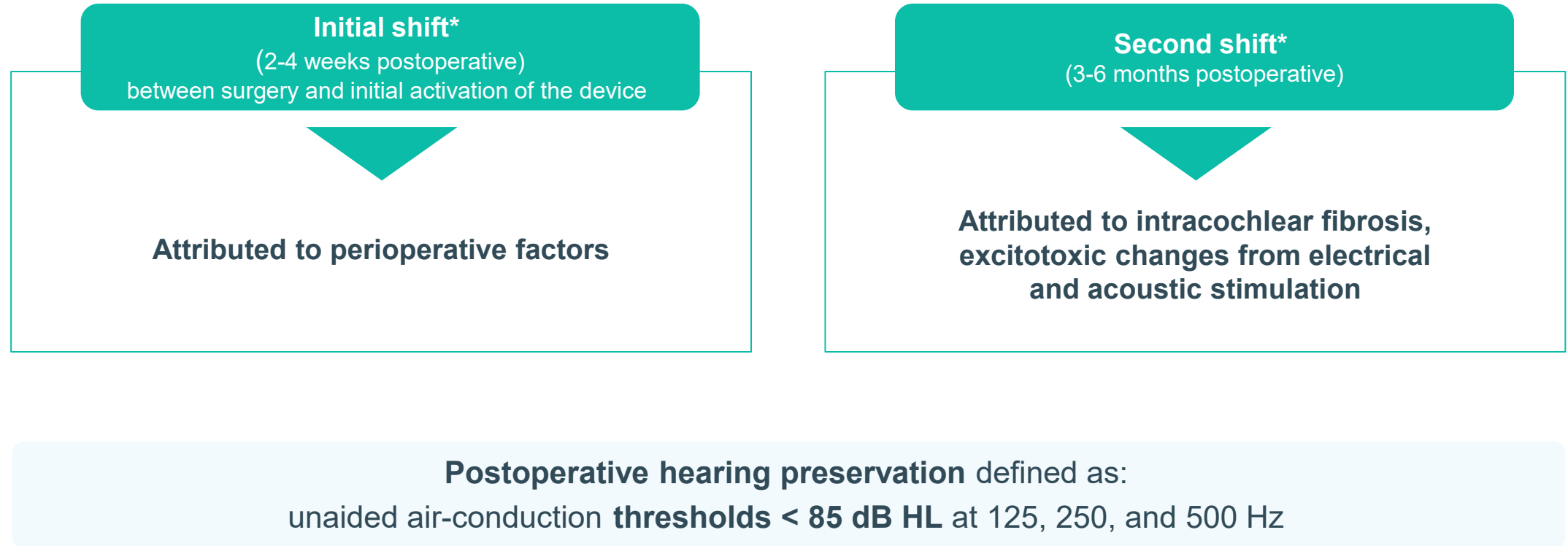
Market penetration in adults eligible to CI
in developed markets¹

1. Cochlear © FY25 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 (n=16) n (%)
SENS-401 levels \leq LLOQ	0
SENS-401 levels $>$ LLOQ	14*(100)

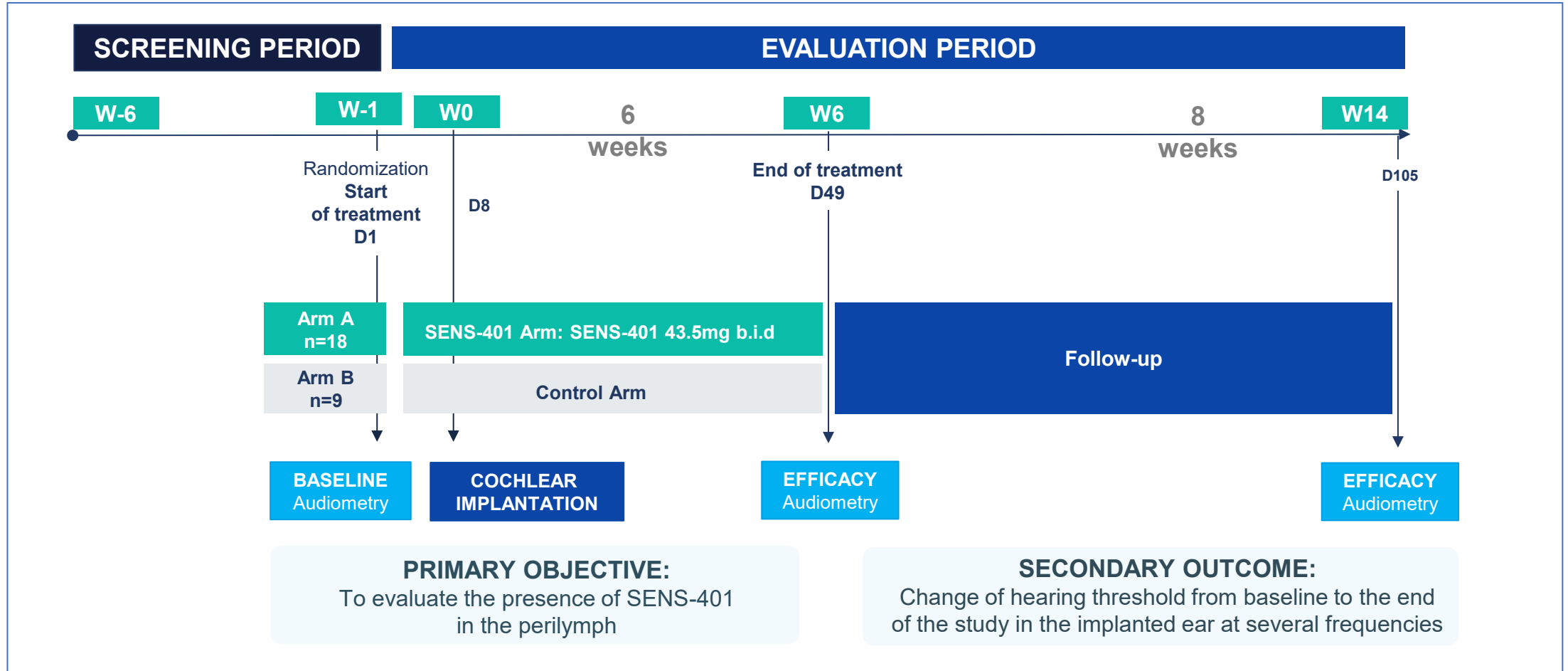
*Among the 16 participants who underwent surgery, 15 have a perilymph samples and 14 samples were analyzable

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

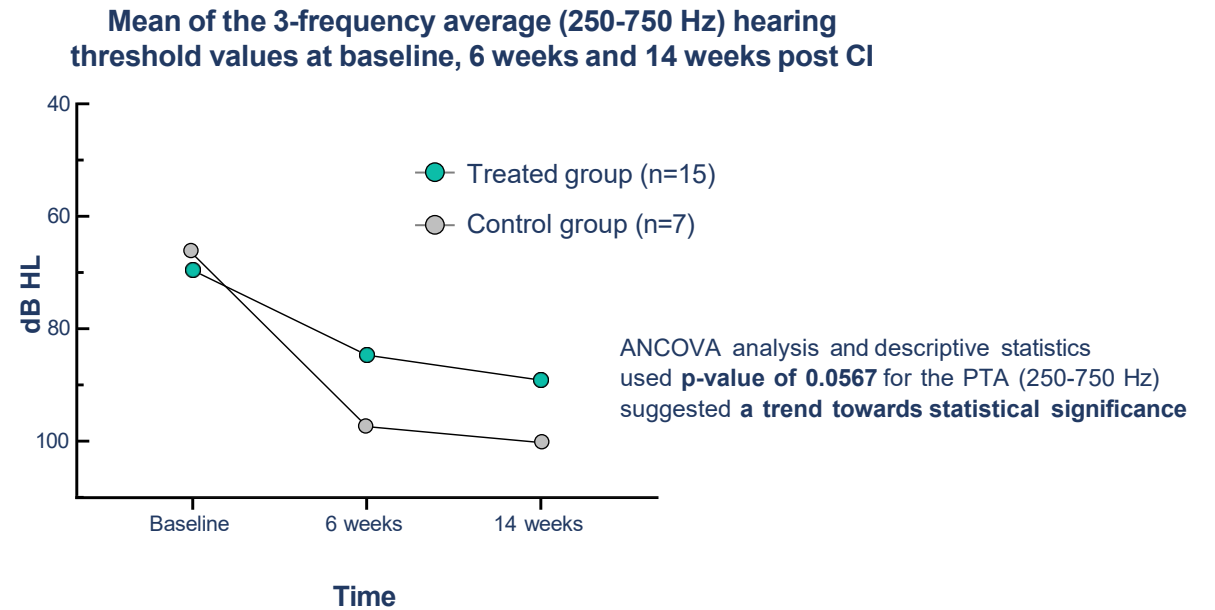
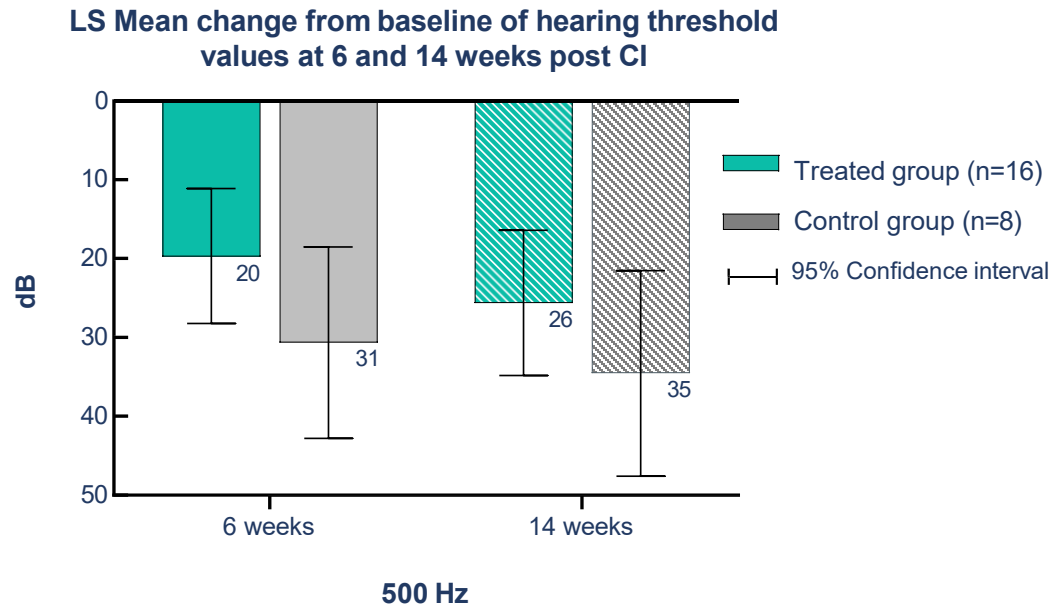
- **Presence of SENS-401 in the perilymph is confirmed in 100% of the patients** sampled following cochlear implantation
- **These results confirm that SENS-401 administered orally crosses the labyrinth barrier**

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



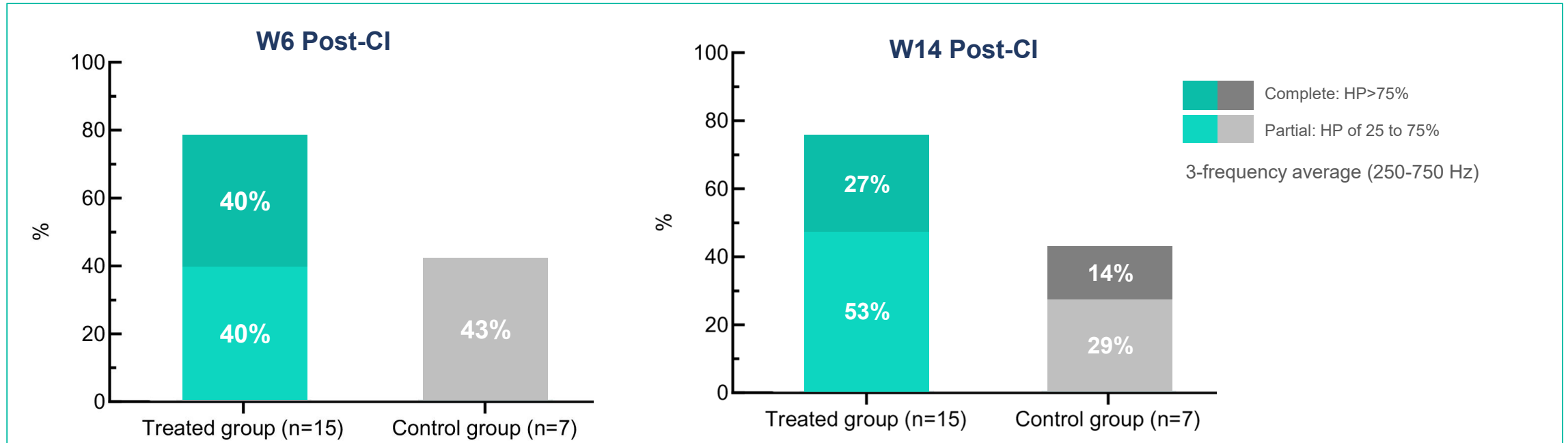
SENS-401 Provides Hearing Protection 6 & 14 Weeks Post-Cochlear Implantation



- 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)

*Skarzyski 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

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%¹ 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 countries²

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

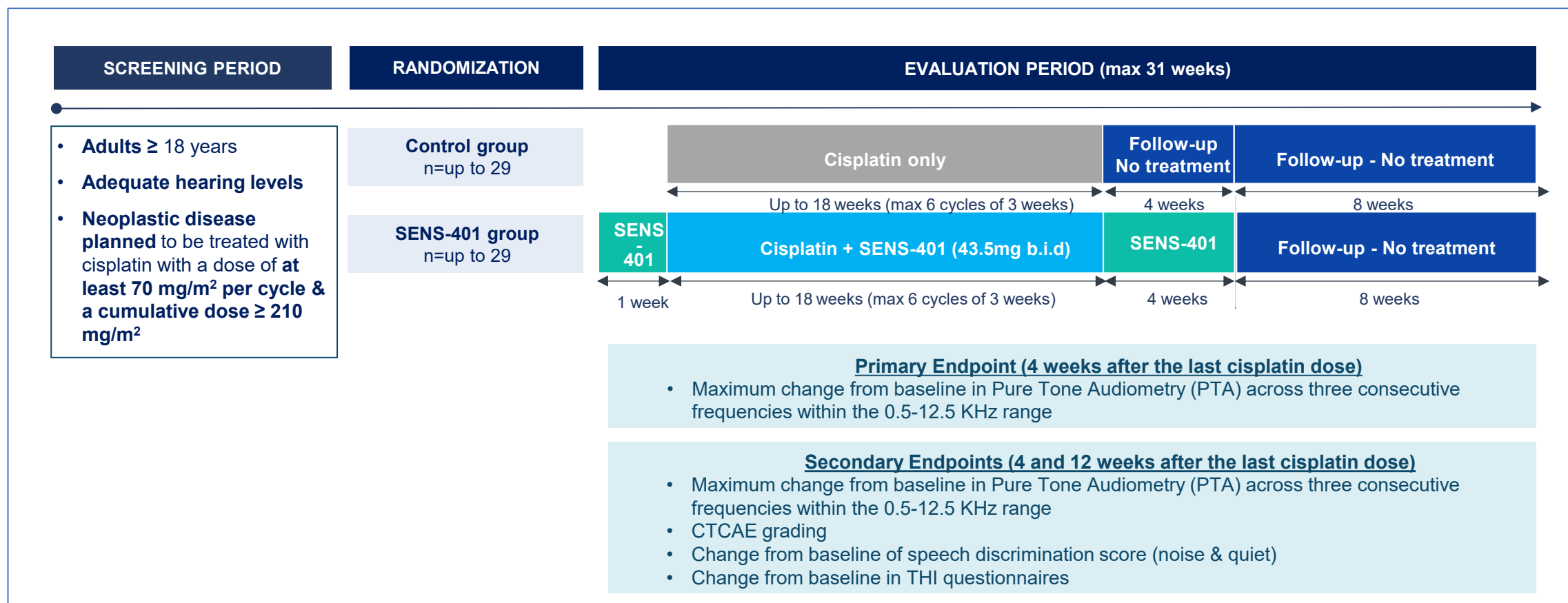
² Globocan 24



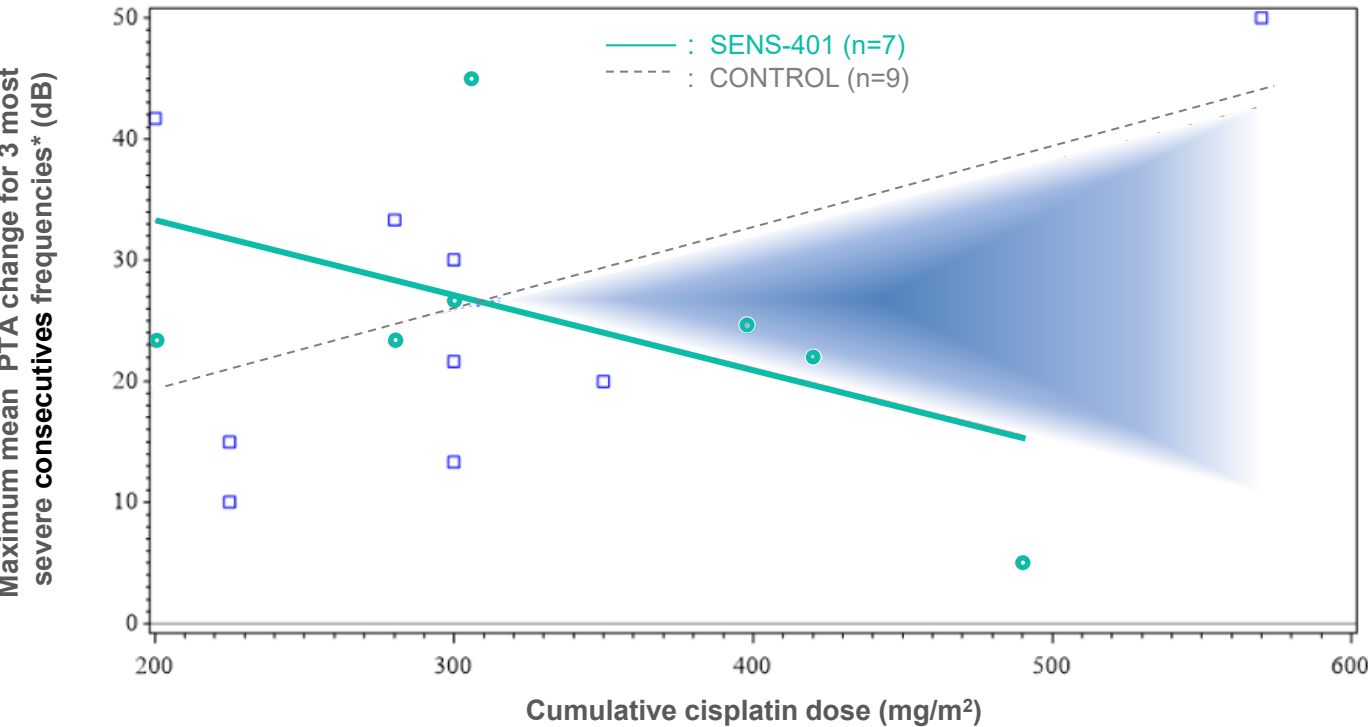
SENS-401 Phase 2a Proof-Of-Concept Study NOTOXIS

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.**

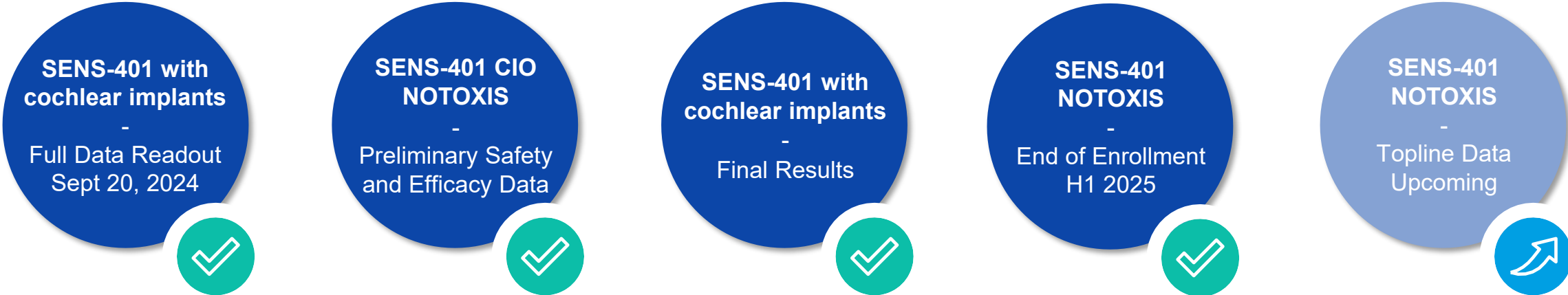


The preliminary results suggest a trend toward an otoprotective effect of **SENS-401** beyond a cisplatin dose of **300 mg/m².**

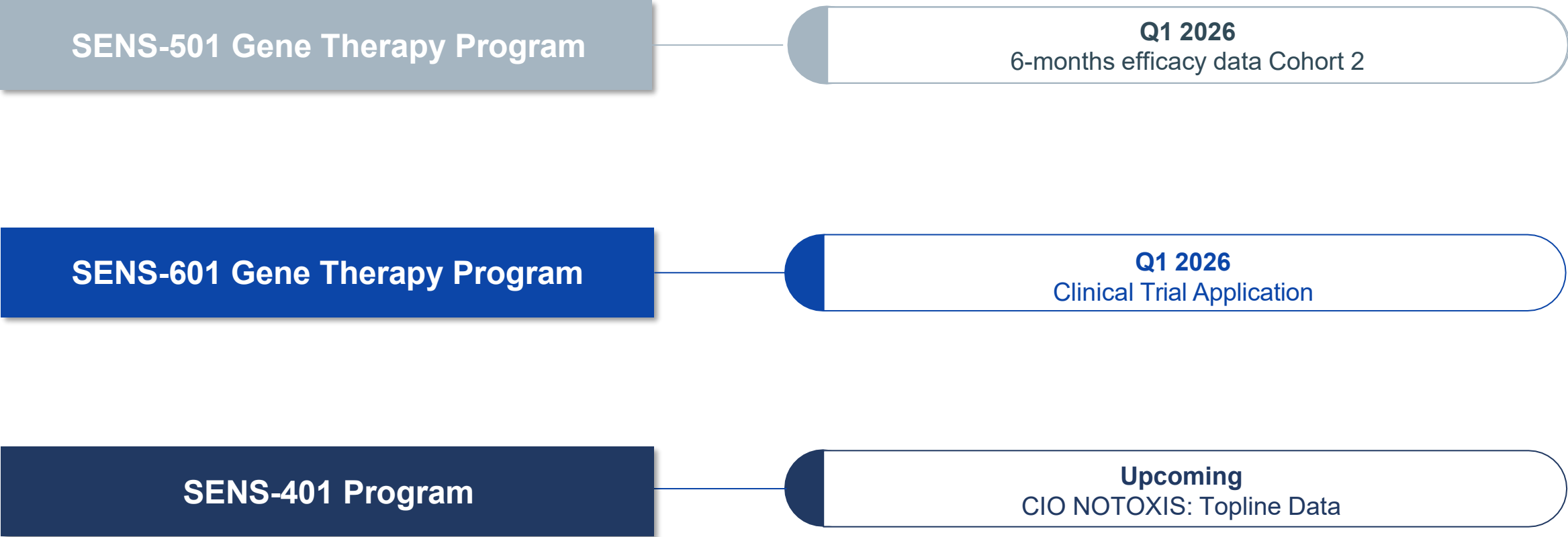


Recruitment completed; 48 patients randomized; follow-up ongoing

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 H1 2026**



- **Upcoming SENS-401 CIO Ph2a topline data**
- **Audiogene 6-months efficacy data for cohort 2 in Q1 2026**
- **Clinical Trial Application for SENS-601 (GJB2-GT) in Q1 2026**

THANK YOU

E:contact@sensorion-pharma.com



HEARING LOSS

Access And Clarity Are Mandatory For Optimal Outcomes

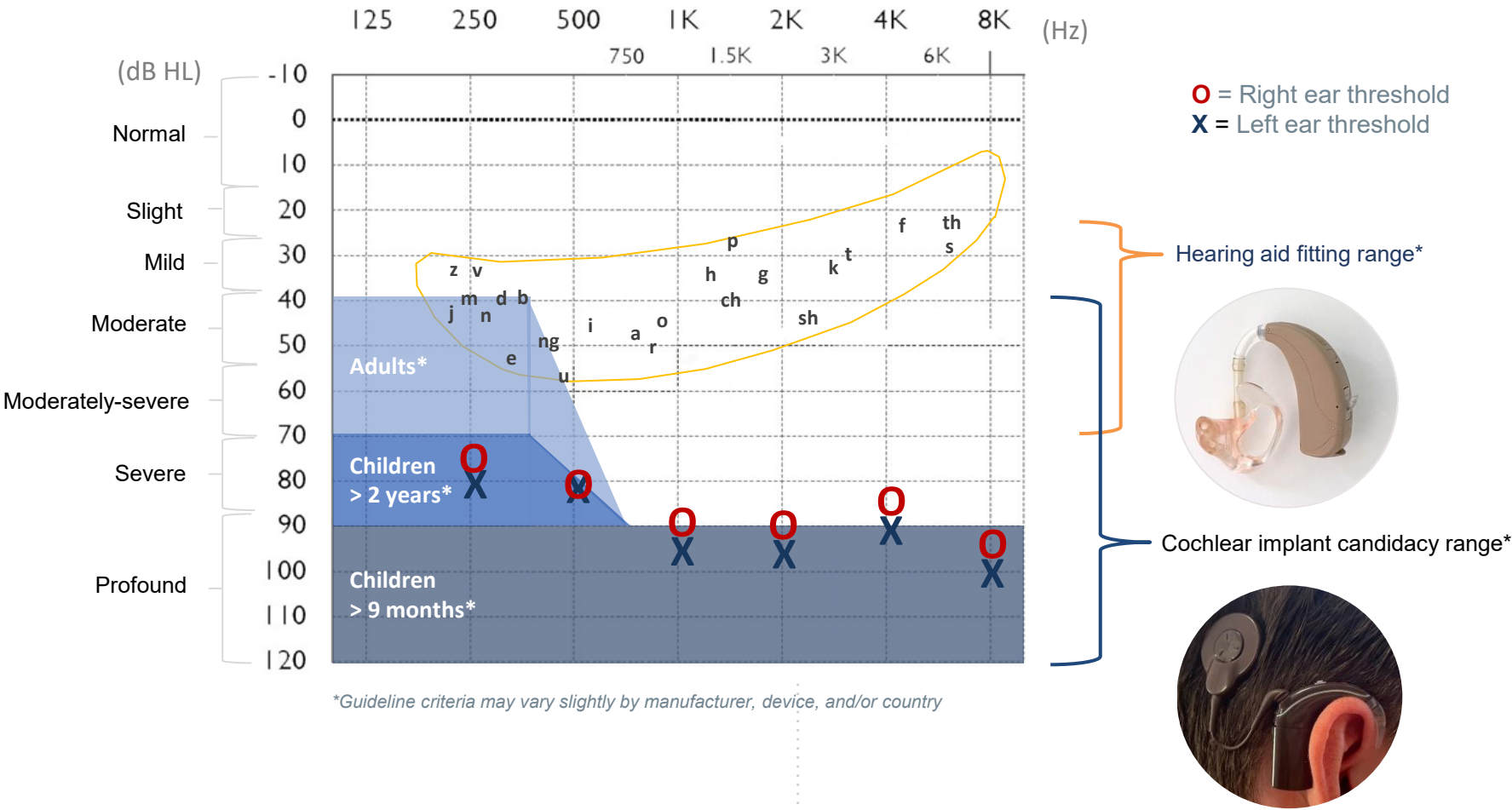


Image of hearing aid: https://commons.wikimedia.org/wiki/File:Unitron_Ziel_photo_2.jpg
Image of cochlear implant sound processor on ear: https://commons.wikimedia.org/wiki/File:Cochlear_Nucleus%C2%AE_7_Sound_Processor.jpg
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Internal Capabilities

We Have Established Internal Capabilities To Ensure Successful Execution



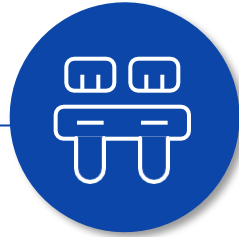
PRECLINICAL - SMALL MOLECULES & GT PROGRAMS

- 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



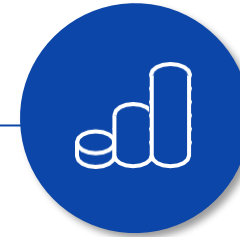
CMC GENE THERAPY FACILITIES

- 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



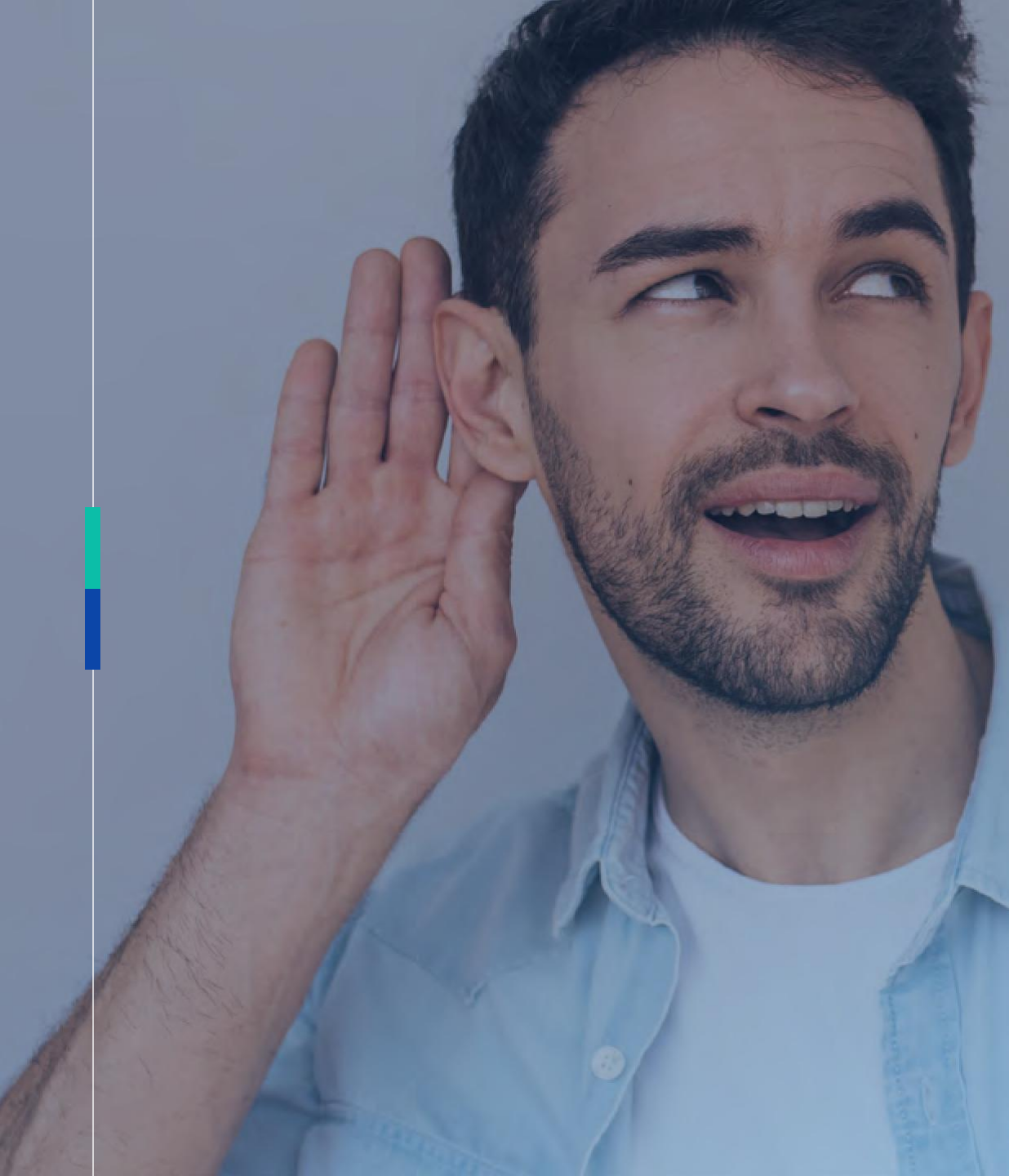
PATIENT ACCESS

- 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

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

>33%² 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 100,000³ to 160⁴ per 100 000 e.g > 200,000 patients in 2017 in G7 countries⁵

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](#)

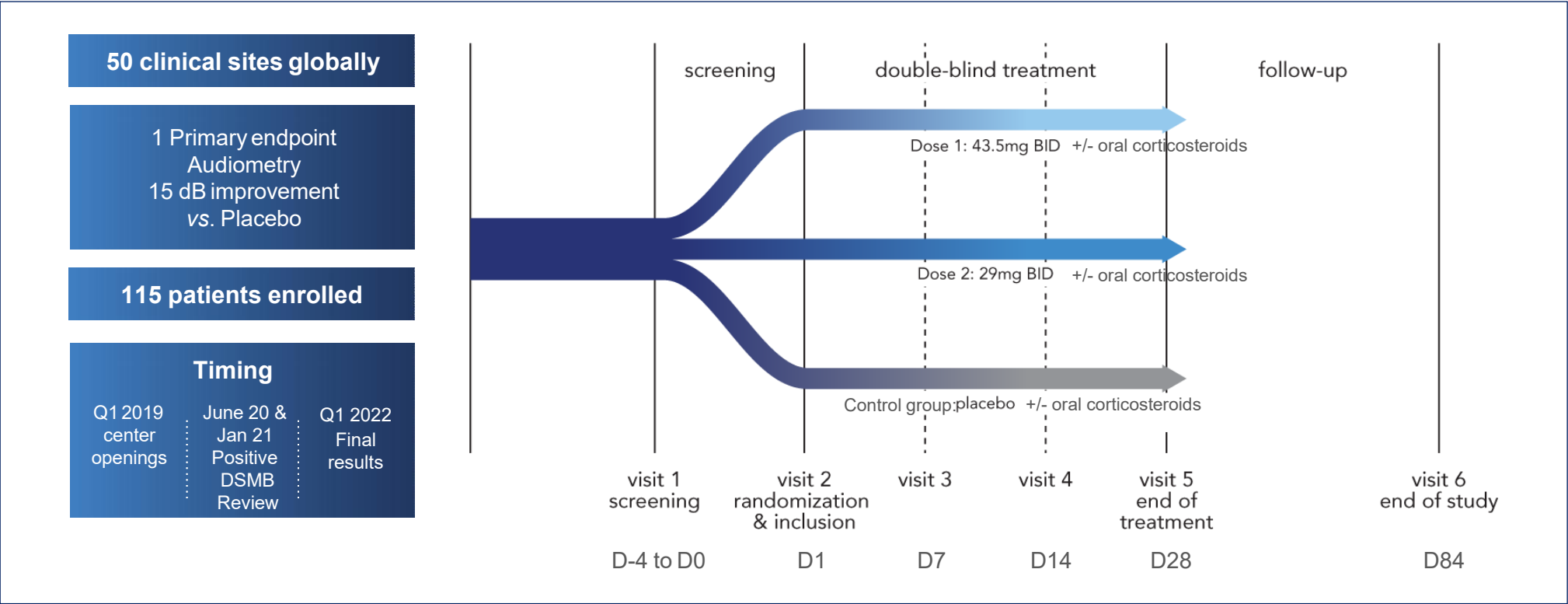
5. Company estimates based on publicly available data (in the US, Japan, Germany, France, the UK, Italy and Spain)

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AUDIBLE-S Phase 2 Design

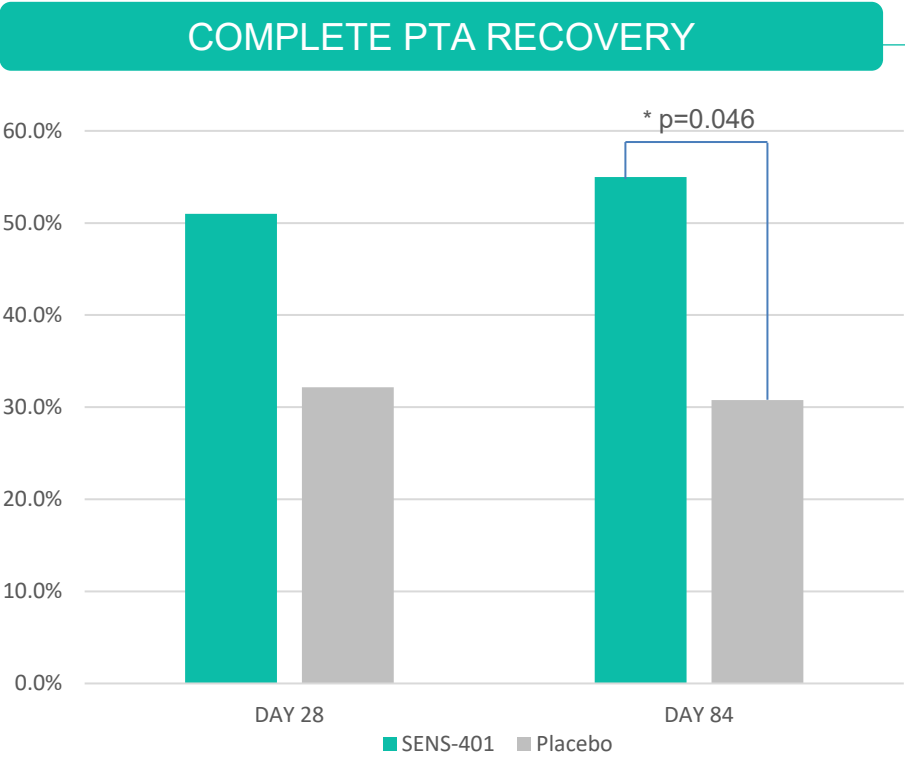
A Phase 2b, Multicenter, Randomized, Controlled, Double-blind Study to Evaluate the Efficacy of SENS-401 to Treat Patients with Severe to Profound Sudden Sensorineural Hearing Loss



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.