

Unlocking the potential of
advanced therapies
for hearing loss



May 2023



1

SENSORION

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



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 2022 Annual Financial Report published on March 30, 2023, and available on our website (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: Overview

- Sensorion currently develops two **Gene Therapy** (GT) programs in the ear, targeting monogenic forms of deafness with **pediatric** and **adult** onset:
 - **OTOF-GT** caused by mutations of the gene encoding for **otoferlin**, EU & US **ODD**, US **RPDD**
 - **GJB2-GT** related to mutations in **GJB2 gene (candidate selected)**
 - Prospective natural history studies ongoing, strong European eco-system in place
- **Oral small molecule asset SENS-401**, for the prevention and treatment of hearing loss:
 - **Sensorion and Cochlear Ltd collaboration** (ongoing clinical Proof-of-Concept study)
 - **Cisplatin-Induced Ototoxicity** (ongoing clinical Proof-of-Concept study)
 - **Sudden Sensorineural Hearing Loss** (completed Phase 2 study)
- **Exclusive relationship with Institut Pasteur** in the field of hearing genetics, several GT programs initiated under strategic collaboration
- Strong partnerships with key players in hearing care and devices, including **Necker Hospital (Paris, FR)**, **Cochlear Ltd. (ASX listed)** and **Sonova (global hearing aid market leader)**
- Strong shareholder base including **leading blue-chip investors; listed on Euronext Growth**

We Want People With Inner Ear Hearing Disorders To Live Life With Unlimited Connections



1. Make OTOF-GT the Standard of Care

- Replacing cochlear implantation
- Transforming lives for babies

2. Develop GJB2-GT and Other GT Products

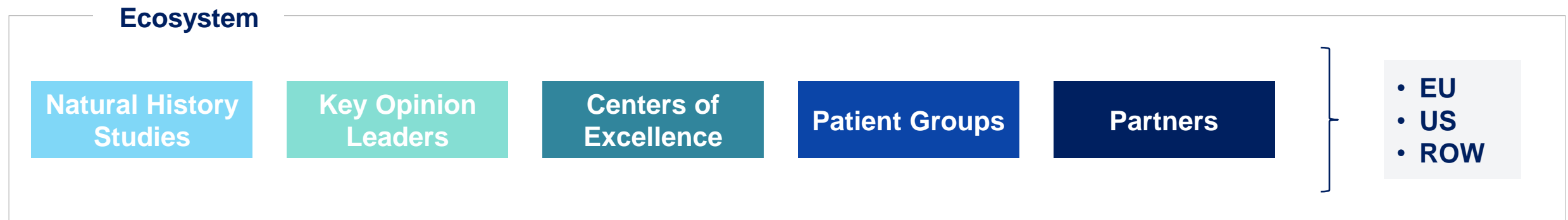
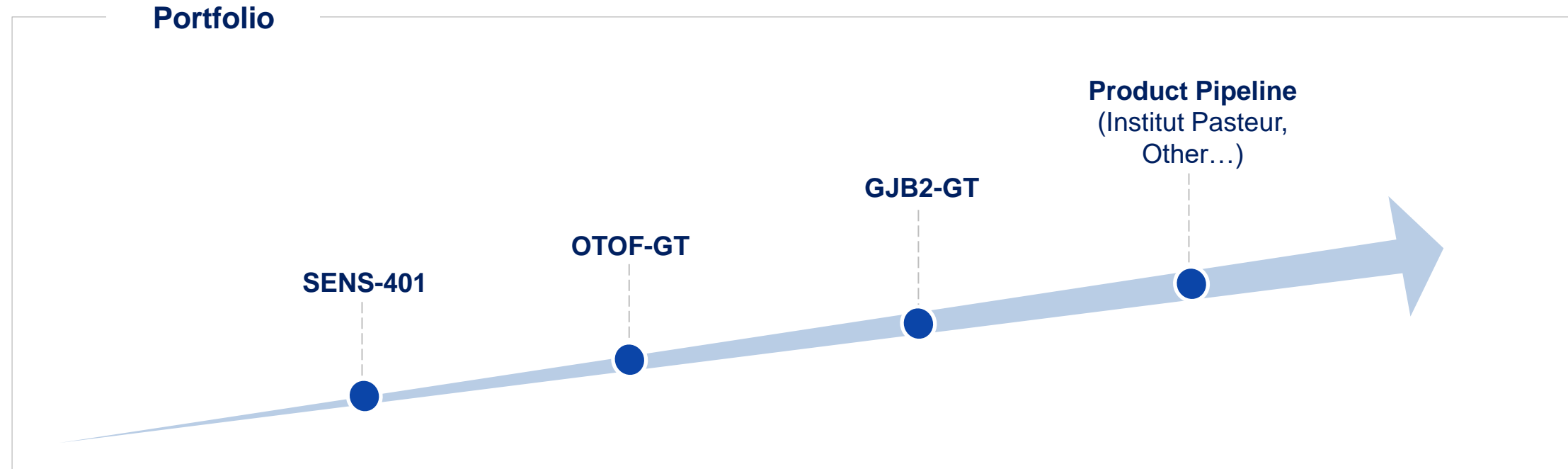
- Addressing adolescent and adult populations

3. Enjoy Life to the max with 24/7 Access to Sound

- Kids navigating with ease in school
- Adults effortlessly adjusting to the different voices of multiple talkers in workplace, social spaces
- Reducing cognitive effort and mental workload

Our Vision: A Global Franchise

Establishing Leadership In The Hearing Space



Together With Best-In-Class Partners We Can Transform the Current Standard of Care



- Interdisciplinary approach to the mechanisms of hearing and its damage
- Research in deafness therapies and preclinical studies

TRANSLATIONAL
RESEARCH

CLINICAL
RESEARCH

SENSORION

DIAGNOSIS
&
PATIENT
JOURNEY



- EU reference center for monogenic forms of deafness
- Natural History Study currently running for all monogenic forms of deafness; extension in EU clinical sites in preparation (OTOCONEX study)



**French Military Biomedical
Research Institute**

- Access to a military population at risk of noise-induced hearing loss
- Strong medical network, strict monitoring and precise, regular, well-documented explorations
- Partnership to identify biomarkers for noise-induced hearing loss



- Global leader in implantable hearing solutions
- Currently developing a drug/ device combination to maintain residual hearing after CI surgery



- Biggest retail chains in the world
- A significant shareholder in Sensorion
- Collaboration to initiate Natural History in presbycusis



- Functional exploration in the field of otolaryngology and neurosciences (combining biological and audiological data)

Sensorion is Well Positioned to Transform the Hearing Landscape

- Institut Pasteur Partnership Provides GT Pipeline

GENE THERAPY

Otoferlin deficiency (OTOF-GT)

CTA enabling studies

- Hearing restoration in DFNB9 pediatric patients

Connexin 26 deficiency (GJB2-GT)

Candidate selected

- Hearing restoration in DFNB1 **pediatric patients**
- Hearing restoration in **childhood onset** of hearing loss linked to GJB2 mutations
- Hearing restoration in early onset severe **presbycusis** linked to GJB2 mutations

SMALL MOLECULE: SENS-401

Sudden Sensorineural Hearing Loss (SSNHL)

AUDIBLE-S Ph2 study completed

- Meaningful and statistically significant effect on PTA change over time in a large idiopathic population
- Complete PTA recovery in 50% of treated patients

Cisplatin-Induced Ototoxicity (CIO)

NOTOXIS Ph2 study ongoing


- Assess prevention of the ototoxicity induced by Cisplatin in patients with neoplastic disease

Cochlear Implantation (CI)

Ph2 study ongoing

- Assess preservation of the residual hearing after cochlear implantation
- Evaluate the presence of SENS-401 in the perilymph

Sensorion's Portfolio Of Advanced Hearing Loss Therapies

	Product	Indication	Discovery	In-vivo POC	Preclinical	Phase 1	Phase 2	Phase 3	Upcoming Milestones (estimated)
RESTORE	OTOF-GT*	Otoferlin Deficiency							Clinical Trial Application Q2 2023
	GJB2-GT*	Adult onset (presbycusis)							Candidate Selected
	GJB2-GT*	Pediatric progressive							Candidate Selected
	GJB2-GT*	Congenital onset							Candidate Selected
PREVENT	SENS-401	Hearing preservation after CI						 Cochlear™	Preliminary Results mid 2023
	SENS-401	Cisplatin-Induced Ototoxicity							Preliminary Results mid 2023
TREAT	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 OTOF-GT

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

An Experienced Leadership Team and SAB



NAWAL OUZREN
Chief Executive Officer

SENSORION
(Since 2017)
SHIRE
(2016-2017)
Head of the Global Genetic
Diseases Franchise
BAXALTA
(2014-2016)
Vice President
of the Global Hemophilia Franchise



GÉRALDINE HONNET
Chief Medical Officer

SENSORION
(Since 2020)
GENETHON
(2011-2020)
Director of Development
TRANSGENE
(2007-2011)
Responsible of development
of infectious diseases programs



DAVID LAWRENCE
Chief Financial Officer

SENSORION
(Since 2023)
VALNEVA
(2017-2021)
Chief Financial Officer
SYNPROMICS
(2011-2019)
Co-Founder & Board member
GSK/CHIRON/ACAMBIS
(1988-2006)



STEPHANIE FILIPE
Head of PMO

SENSORION
(Since 2020)
CELLECTIS
(2016-2020)
Program Leader &
Preclinical Manager
OTR3
(2008-2015)
R&D Director & Clinical Project
Manager



LAURENT DESIRE
Head of Preclinical Development

SENSORION
(Since 2020)
YPOSKESI
(2017-2020)
Head of Cellular &
Molecular Biology Unit
DIAXONHIT
(2012-2017)
R&D Executive Director



CHRISTINE LE BEC
Head of CMC Gene Therapy

SENSORION
(Since 2020)
GENETHON
(1996-2020)
Head of CMC
Analytical Department

Scientific Advisory Board

- **Pr Christine Petit**, France, Chair SAB, Professor, Institut Pasteur
- **Pr Alain Fischer**, France, Professor, Collège de France
- **Dr. Robert Dow**, UK, Chief Medical Officer, Scendea
- **Dr. Paul Avan**, France, Head of the Center for Research, Hearing Institute (Paris)
- **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)

We Have Established Strong Internal Capabilities To Ensure Successful Execution



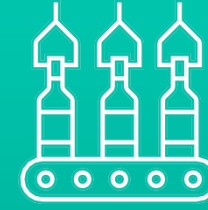
PRECLINICAL CAPABILITIES FOR SMALL MOLECULES & GT PROGRAMS

- **Cell Model Platform:** assays development, target & drug discovery, biomarkers
- **Animal Pharmacology platform:** from the POC to the dose-finding studies in disease-relevant rodent models, surgery
- **Technology & Innovation platform:** design and select the best drug candidate (capsid & promoter selection)



CLINICAL EXPERIENCE

- 400 people enrolled in Sensorion led clinical trials
- Set-up audio tests in different countries, languages
- Central reading of audiometry testing
- In-house audiology expertise of more than 20 years for the pediatric and adult populations and cochlear implants



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 Agency interaction (EU/US)
- Shape the treatment guidelines and standardize clinical endpoints

Our Team has Significant Experience in Gene Therapy Clinical Development

The team has been involved in 15+ programs from preclinical to BLA filing...

10

Preclinical

4

Clinical

1

BLA filing

... using different technologies...

15

Gene therapy
(AAVs / LVs)

1

Cell
therapy

1

Gene editing

... across different organs and indications...



... with multiple organizations



AUDENTES
THERAPEUTICS

GENETHON
CURE THROUGH INNOVATION

rocket
pharma

SOLID
BIOSCIENCES

cellectis

ESTEVE
Advancing health together

GenSight
BIOLOGICS

Necker
ENFANTS MALADES
HÔPITAL UNIVERSITAIRE

SAREPTA
THERAPEUTICS

Orchard
therapeutics



2

GENE THERAPY PROGRAMS

Sensorion's Gene Therapy Programs Target Rare Auditory Diseases

FIRST PROGRAMS RESULTING FROM THE INSTITUT PASTEUR COLLABORATION

OTOFERLIN DEFICIENCY

- 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 ODD
- US FDA has granted RPDD

GJB2-RELATED HEARING LOSS

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

- Early onset of severe presbycusis
- Childhood onset
- Congenital onset
- ~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

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](#))

DELAYED DIAGNOSIS – NOT SUSPECTED AT FIRST SIGHT

GENE THERAPY HAS A LIFE-CHANGING POTENTIAL FOR THESE AUDITORY DISEASES

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

CRITERIA	SENSORION
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	✓
Natural History Study preparing execution of the clinical trial	✓
Regular engagement with regulatory agencies	✓

Gene Therapy Pediatric Indications Have Blockbuster Sales Potential

OTOF-GT is the perfect pilot program

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



- OTOF-GT will be the pilot program demonstrating that GT is a relevant medical approach for the inner ear
- OTOF-GT 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 :
 - ✓ Orphan Drug Designation in the US and EU
 - ✓ Rare Pediatric Disease Designation with eligibility for voucher in the US

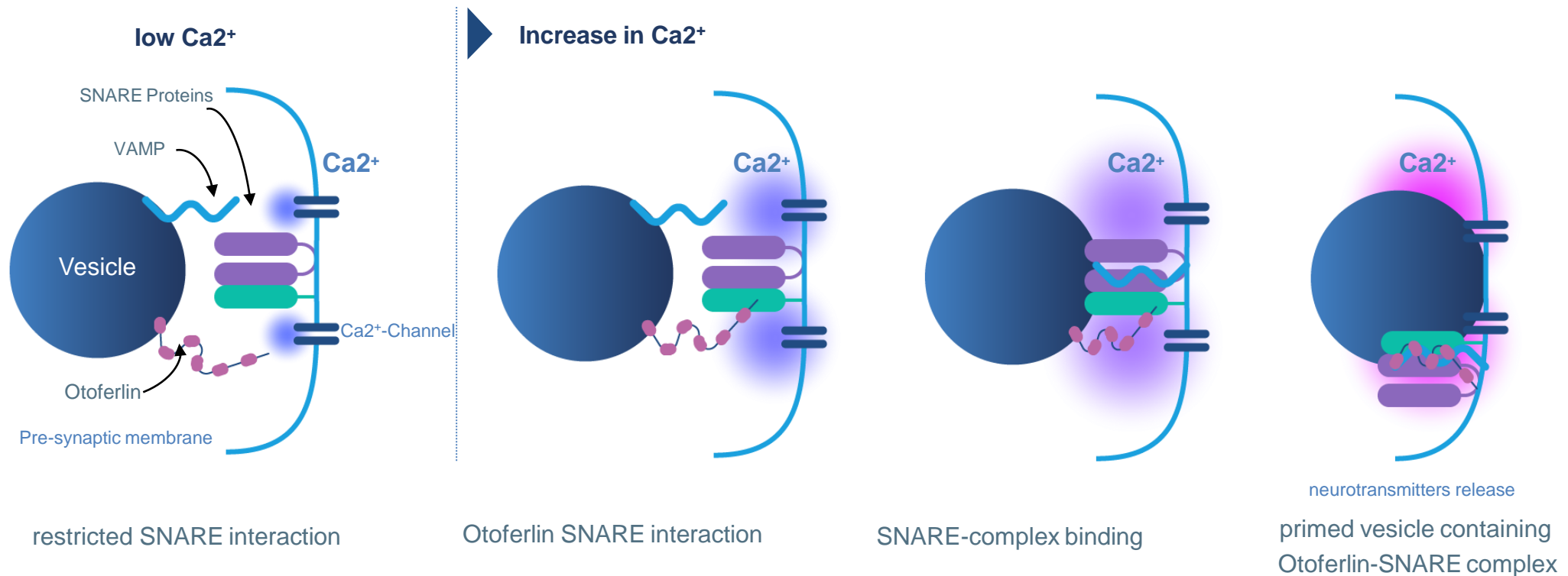
Sales potential illustration

OTOF-GT

GJB2-GT

Sources: Sensorion, AT Kearney market research

OTOF Gene Encodes Otoferlin, A Key Ca^{2+} Sensor Protein

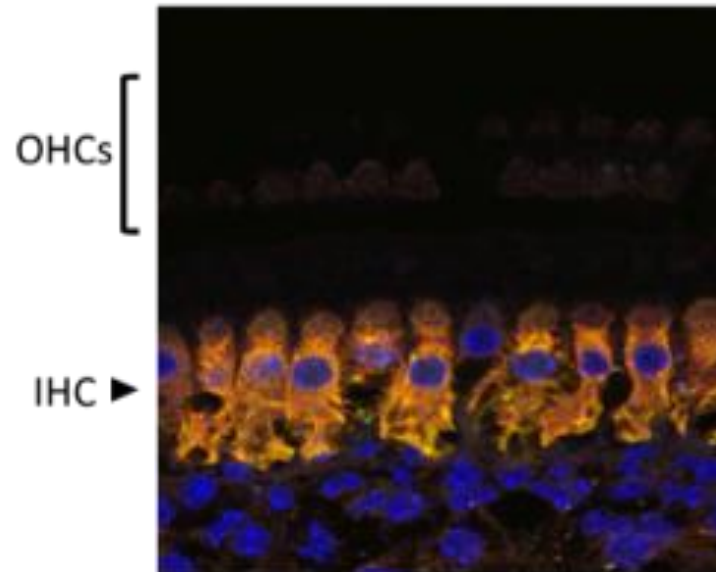


Model illustrating calcium regulation of otoferlin/SNARE interaction in the hair cell – Adapted from Ramakrishnan *et al.* 2014

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

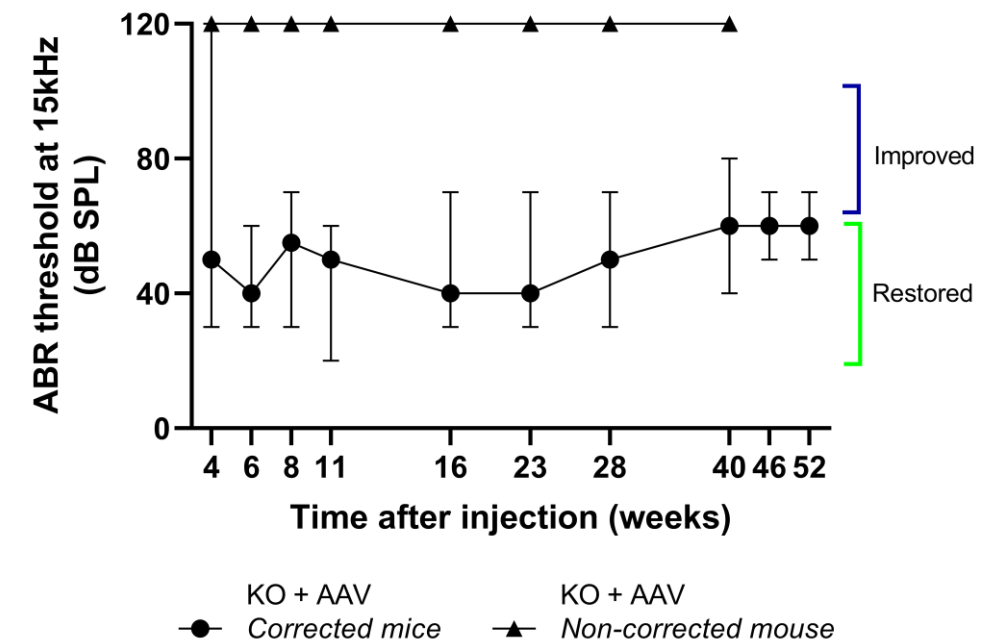
Dual AAV-OTOF Resulted In IHCs Specific Expression And Hearing Restoration In DFNB9 Mice

Target cell specific protein expression



- Dual AAV-OTOF injection into the cochlea leads to **IHC specific de novo otoferlin protein expression**

Hearing restoration in DFNB9 mice



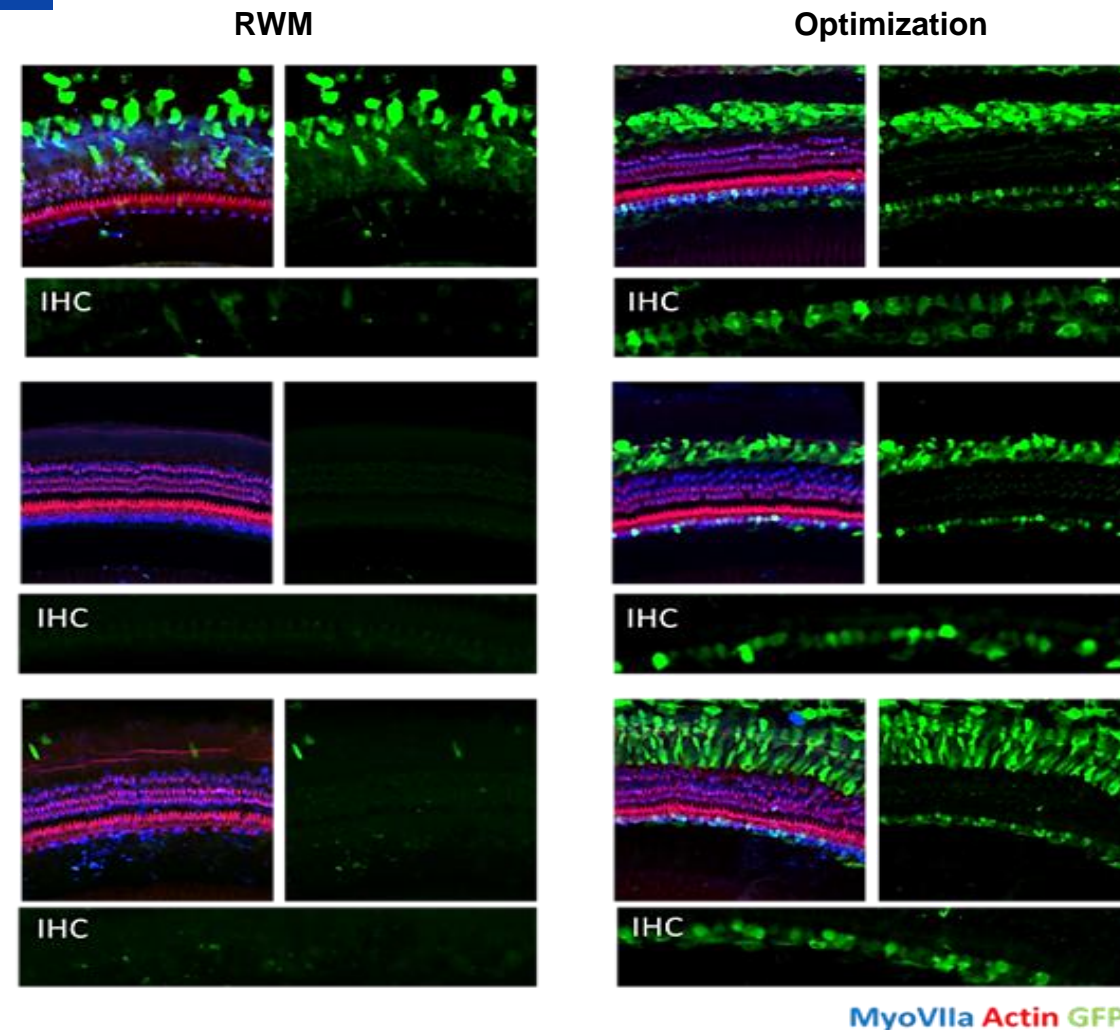
- **Durable hearing restoration** in *Otof*^{-/-} mice by dual AAV-OTOF directly delivered to the inner ear up to one year post-injection

Lahlou et al. ARO 2022 [link](#)

Optimized Surgical Procedure Leads To IHC Specific AAV-delivered Transgene Transduction In Mature NHP Cochlea

AAV vector distribution in cochlea of NHP

- Delivery of the AAV transgenes to **IHCs and not OHCs** in NHP
- **High transduction efficiency** with more than 50% IHCs along the tonotopic axis in mature NHP cochlea
- **No correlation** between anti-AAV neutralizing antibodies (measured in blood before injection) and the average of GFP⁺ cells



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
- **New injection system** device under development

Lahlou et al. ARO 2022 [link](#)

Otoferlin “Audinnove” Consortium Provides Privileged Access To Patients And Surgeons

Audinnove consortium received Hospital-University Research (RHU) prize:

- The consortium is eligible to receive up to €9.7m to develop a Gene Therapy program addressing otoferlin deficiency
- Audioferlin: Natural History Study: clinical evaluation and selection of patients
- Database compilation with genotypic and phenotypic characterization of children with congenital hearing loss
- Phase 1/2 Gene Therapy study (financing up to 1st patient in the clinical study)

Audinnove consortium is key to the understanding of the epidemiology and to build awareness of the emerging gene therapies

Necker-Enfants Malades Hospital

- The first dedicated pediatric hospital in the world

The Reference Center for Genetic Deafness at Necker coordinates the French and European genetic deafness networks



Audinnove is financed by the French State, via the National Research Agency through the “Investing for the future” program (ref: ANR-18-RHUS-0007)

OTOCONEX: expanding the Natural History Study across Europe

AUDINNOVE CONSORTIUM MEMBERS



OTOF Gene Therapy Program Status – Progressing On Track

POC data in mouse & POC
preliminary data in NHPs



Submission of European Natural
History Study OTOCONEX



Product development and
manufacturing agreement



Delivery of batches for toxicology
study mid-2022



Advice from regulatory
authorities



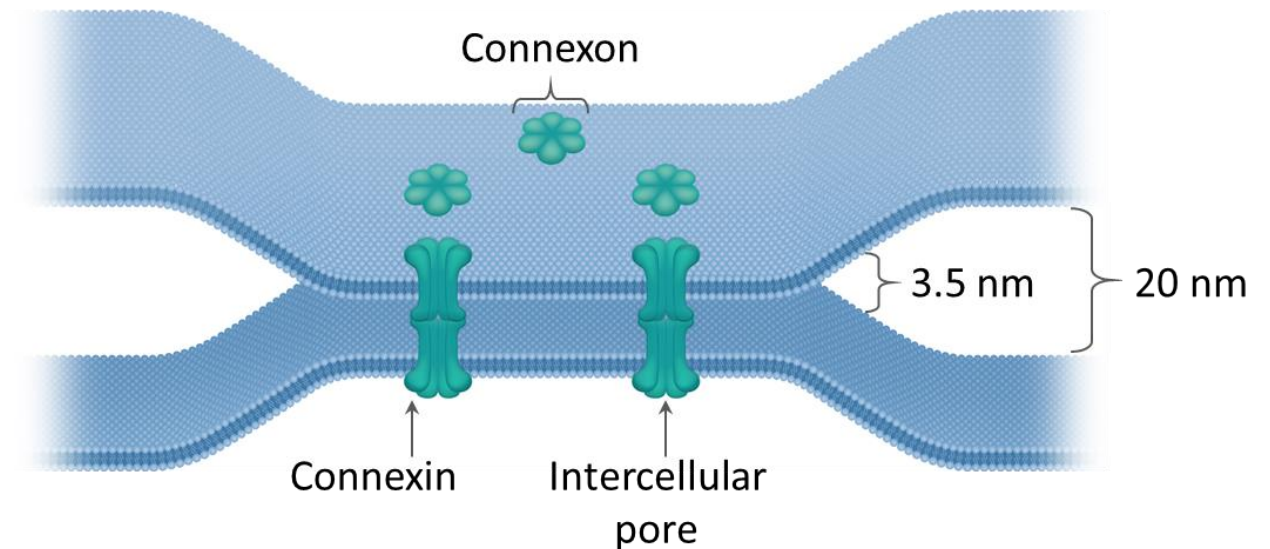
Clinical Trial Application Q2 2023



Connexin 26: A Gap-junction Protein Encoded By *GJB2* Gene and Responsible for Tissue Homeostasis

Mutations in the Gene Lead to Deafness

- ***GJB2*** is the gene encoding for the **Connexin 26** protein; one of 20 known connexins in humans and almost endemic to the cochlea (together with Cx30); **a hexamer of 6 proteins forms Gap Junctions**
- Gap Junctions are **key for the intercellular exchange of molecules** (miRNA, glucose, ions, etc.) hence responsible for **tissue homeostasis**
- *GJB2* cDNA = 681 bp compatible with the use of a **single AAV**
- More than 100 recessive mutations origin Cx26 truncation / deletion leading to non-syndromic hearing loss and deafness
- *GJB2* mutations are the **most prevalent form of congenital deafness** (DFNB1)
- Children are usually **diagnosed during routine newborn screening** and current SoC is cochlear implantation prior to language acquisition
- Prof. Christine Petit observed in an epidemiology study that some patients demonstrating early onset of **severe presbycusis** carried *GJB2* mutations^[1]



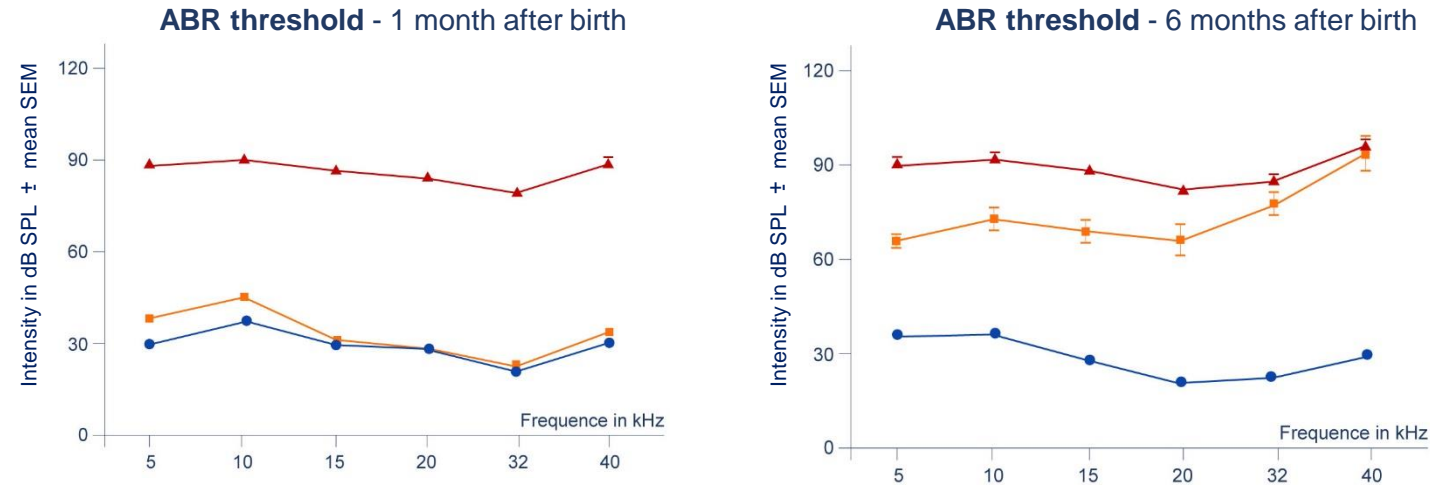
Schematic representation of a gap junction – adapted from Kemperman, Hoefsloot and Cremers J R Soc Med 2002;95; 171-177

[1]: Boucher et al. 2020

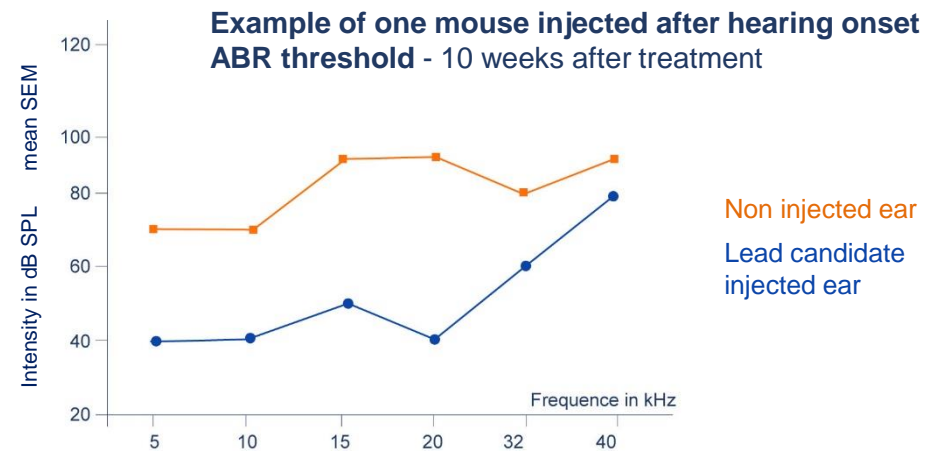
Candidate Selected Prevents Hearing Loss in Relevant Mouse Model

PROOF OF CONCEPT IN PROGRESSIVE MOUSE MODEL

Conditional knock-out mouse model leading to 2 phenotypes



Control mice Congenital-like Profound Cx26 ↓ ↓ ↓ Progressive Cx26 ↓

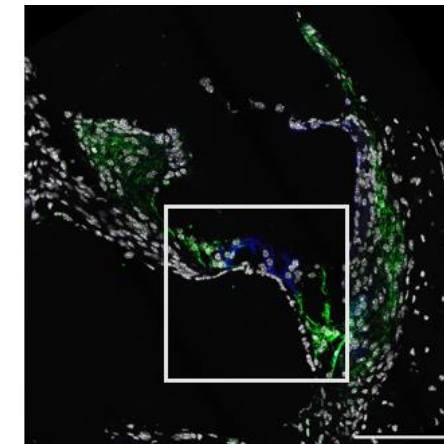


Non injected ear
Lead candidate injected ear

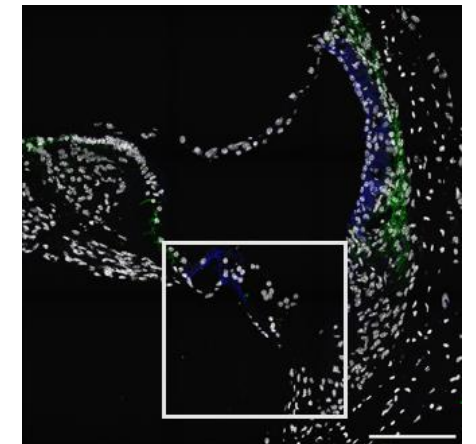
HEARING LOSS PREVENTION CORRELATES WITH CONNEXIN 26 EXPRESSION

Example of one mouse injected after hearing onset
Connexin 26 expression in the cochlea
- 10 weeks after treatment

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

GJB2 Gene Therapy Program Next Steps

Submission of European Natural
History Study OTOCONEX



Submission of Natural History Study
in collaboration with Sonova



Candidate selection Q2 2023



Preclinical IND enabling studies









3

SMALL MOLECULE PROGRAMS

SENS-401: Multiple Indications To Treat And Prevent Hearing Loss

	Product	Indication	Discovery	<i>In vivo</i> POC	Preclinical	Phase 1	Phase 2	Phase 3
PREVENT	SENS-401	Hearing preservation after cochlear implantation						
	SENS-401	Cisplatin Induced Ototoxicity						
TREAT	SENS-401	Sudden Sensorineural Hearing Loss*						

**"Patriot" Consortium (IRBA, Sensorion, Echodia, Institut Pasteur) awarded up to €10.8m non dilutive financing by French government, staged over the duration of the project. Sensorion will receive up to €5.6m to further develop SENS-401 in SSNHL French army*

SENS-401 - A Portfolio With Potential Blockbuster Value



SENS-401 SSNHL clinical data and insight **derisk** further development of SENS-401 in other indications

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).

>70% of cases are idiopathic, known causes include noise/head trauma, ischemia, infection.

>50% of patients suffer from permanent disabling hearing loss, mostly those with initial severe/profound hearing loss.

Complications significantly impact quality of life due to:

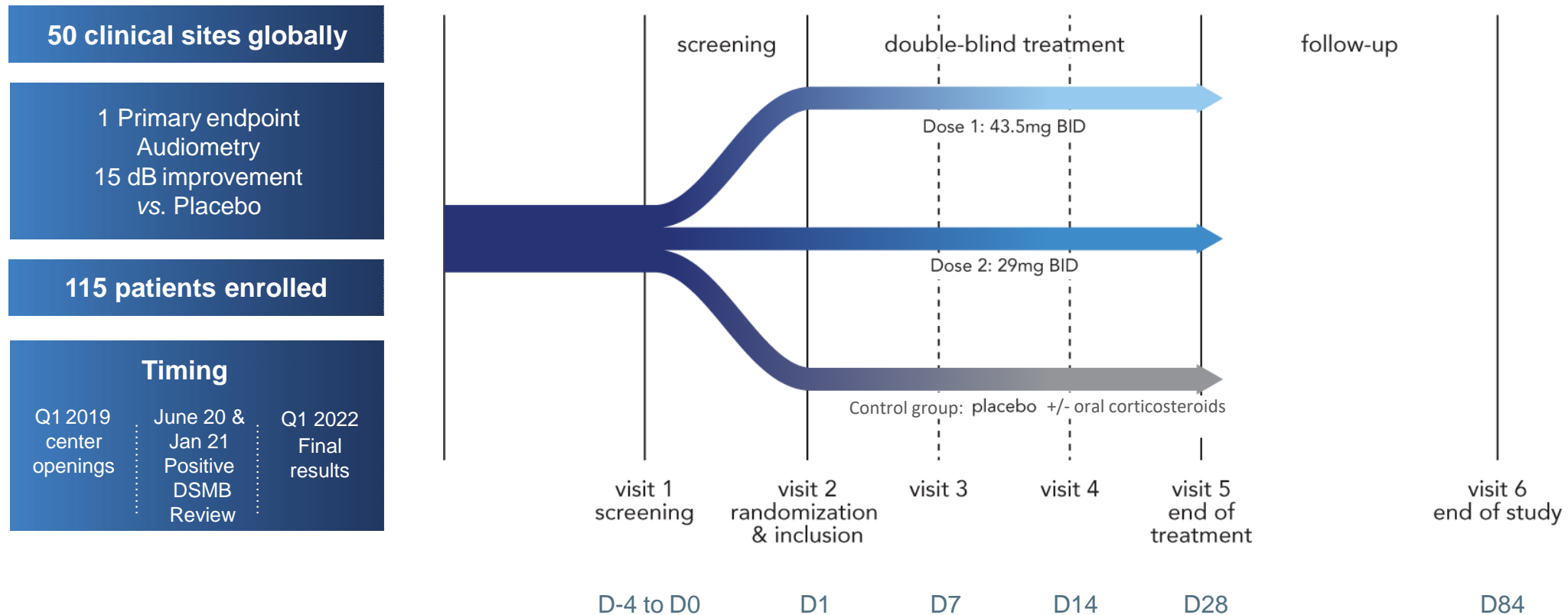
- Difficulties in communicating, social isolation, cognitive decline
- Accompanying tinnitus

Incidence: 27-35 per 100,000 (218,000 patients in 2017 in G7 countries)¹

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

SENS-401 SSNHL Program: Phase 2 Design

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

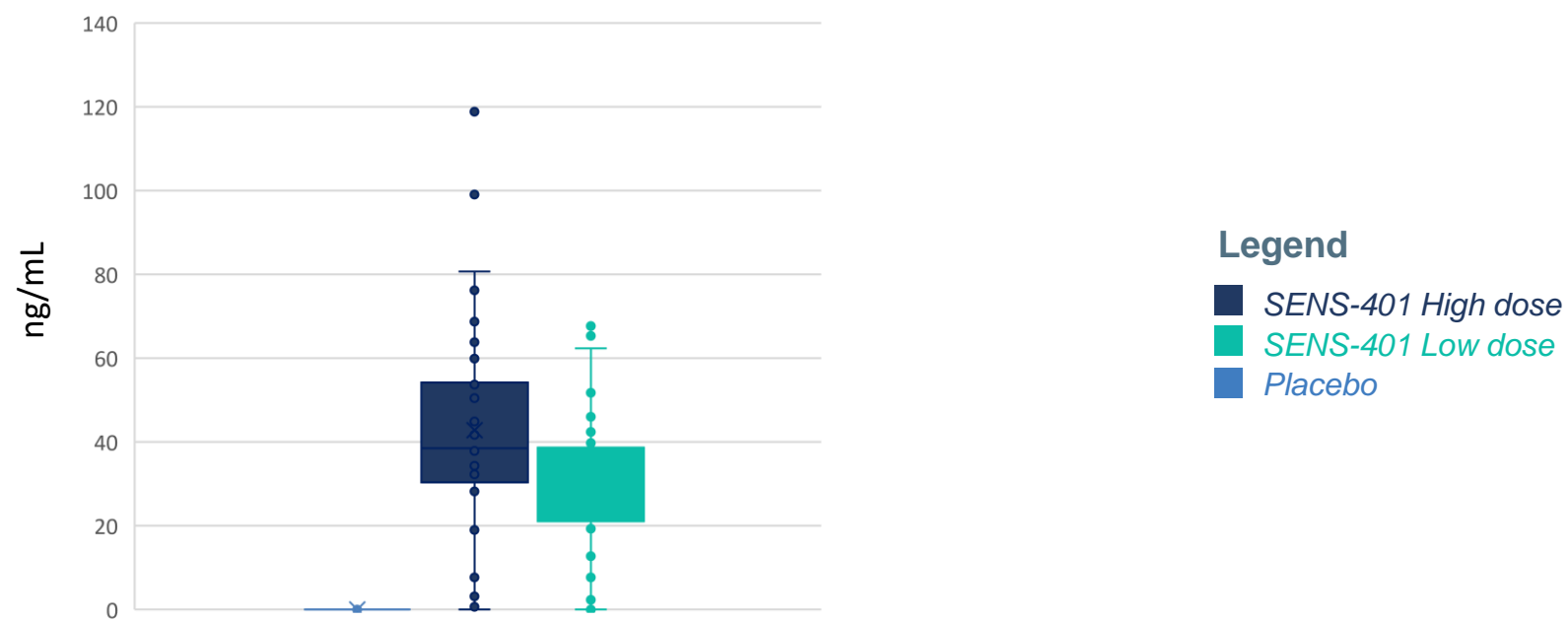


Primary endpoint definition:

“...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)”

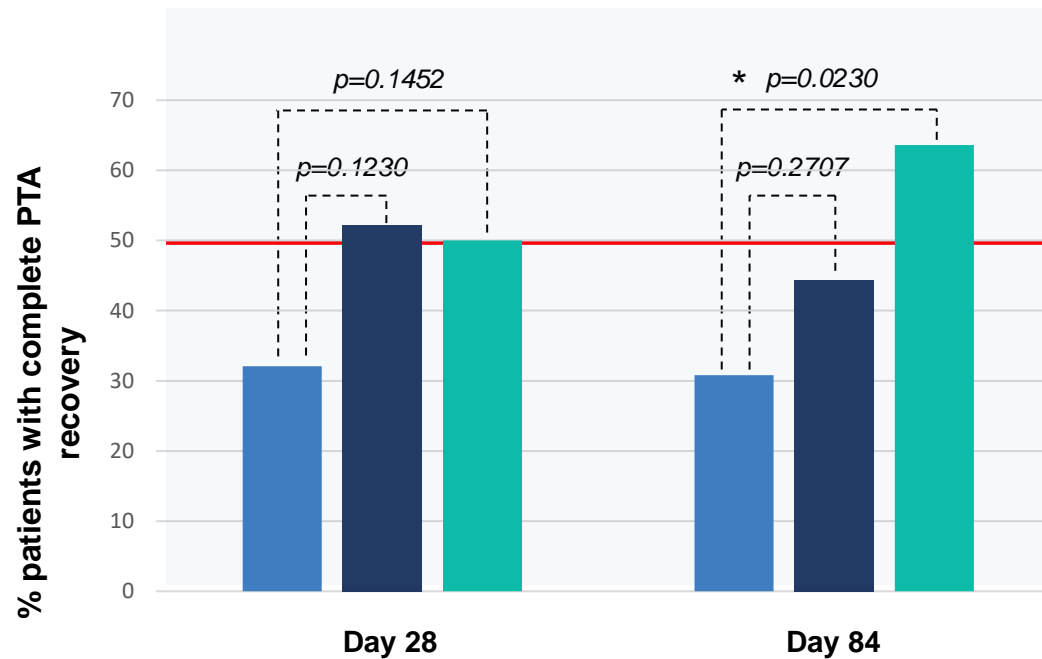
SENS-401 Plasmatic Exposure

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

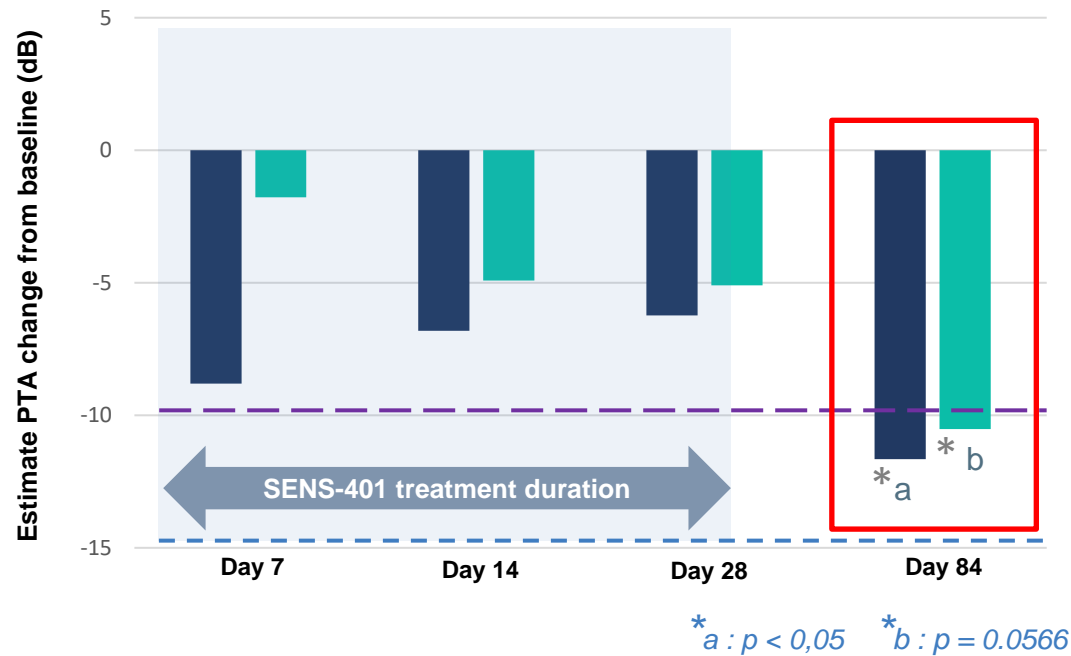
Legend

- 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.

Although Primary Endpoint Not Met, Data Supports And Informs Further Clinical Development

PTA improvement from baseline compared to placebo on per protocol idiopathic SSNHL



Legend

- SENS-401 High dose vs Placebo
- SENS-401 Low dose vs Placebo

- **Statistically significant effect** on PTA change with more than 10 dB change from baseline vs placebo observed over time in homogeneous idiopathic population of patients treated with corticosteroids.

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

Primary analysis

Comparing SENS-401 treatment groups to Placebo at **Day 28** with a **target of an improvement of 15 dB**.

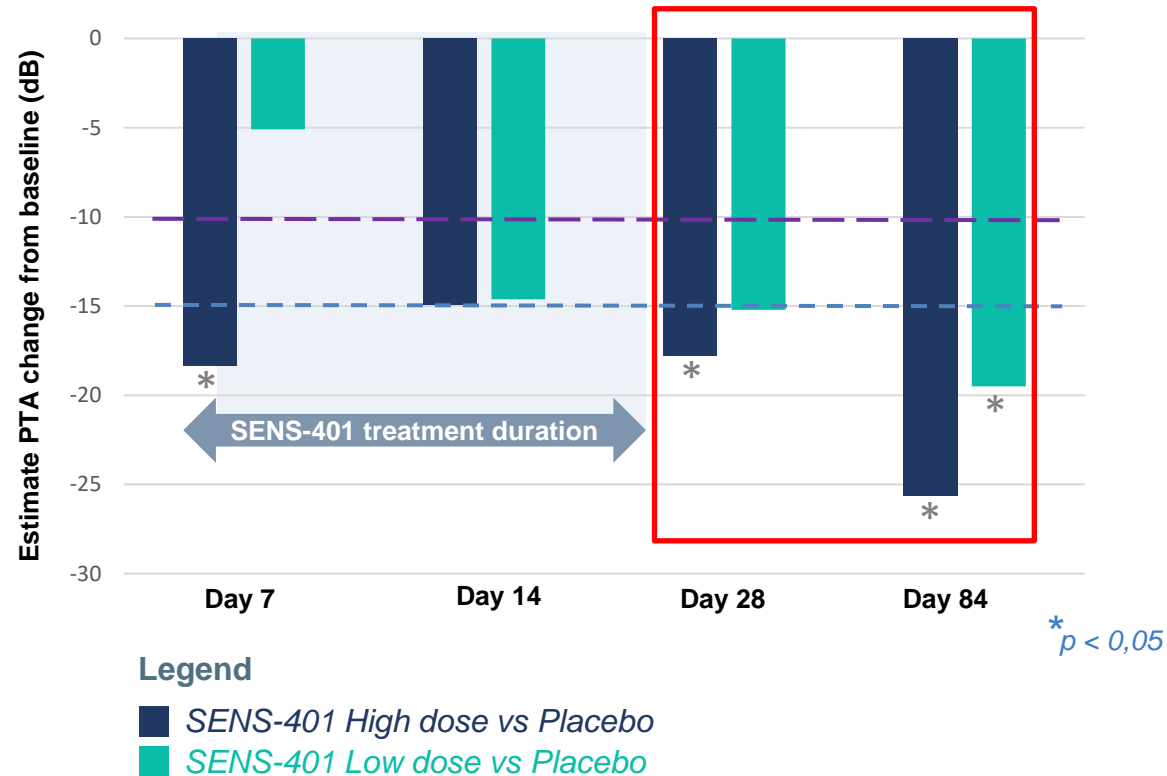
10 dB change from baseline considered as clinically meaningful.

Sub-population

Homogeneous idiopathic population of patients treated with corticosteroids.

SENS-401 Effect Is More Pronounced In A Profound Hearing Loss Sub-group (PTA \geq 80 Db)

PTA improvement from baseline compared to placebo



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

Primary analysis

Comparing SENS-401 treatment groups to Placebo at Day 28 with a **target of an improvement of 15 dB**.

10 dB change from baseline considered as clinically meaningful.

Sub-population

Homogeneous idiopathic population of patients with profound hearing loss (PTA \geq 80 dB) 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 hearing loss**.
- A better response was observed in both treatment groups with a **continuous improvement between Day 28 and Day 84**.

SENS-401 SSNHL Phase 2 Results Summary

Seeking Partners For Late-Stage Development And Commercialization

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 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**
- The change in PTA translates into functional improvement evidenced with speech audiometry tests
- Safe and well tolerated in 115-patient SSNHL study; primary endpoint not met
- **Responder rate is always better in the treated group** compared to Placebo and difference with Placebo increases over time

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 50-60% of adult cases and in 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: 500,000 patients in 2025 in G7 countries¹



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

First Data Expected Mid-2023

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

SCREENING PERIOD (between -28 and -2 days)

Subjects suffering from a neoplastic disease for which the treatment protocol includes a chemotherapy with cisplatin and having a higher risk of ototoxicity induced by the cisplatin treatment

(about 58 subjects)

RANDOMIZATION

Arm A - Up to 29 subjects

Arm B - Up to 29 subjects

Objectives:

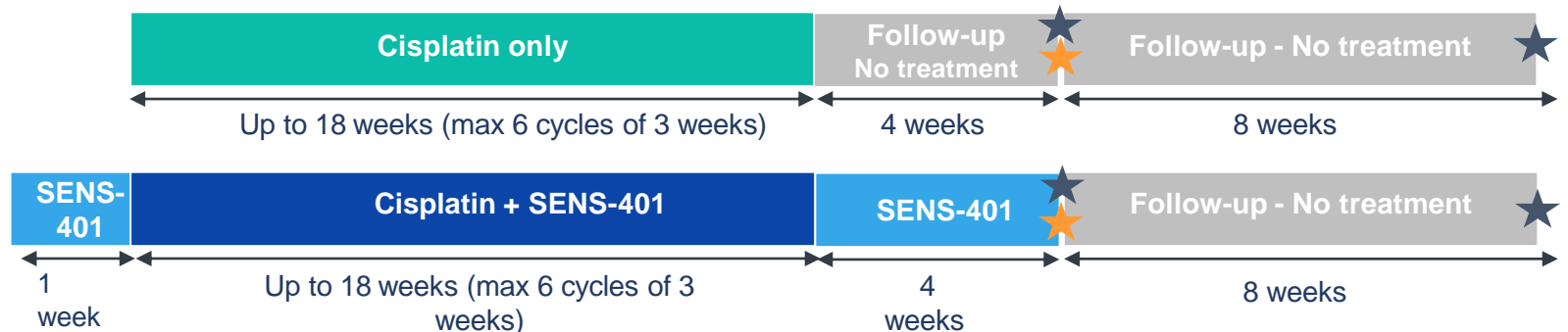
Efficacy

- Rate of ototoxicity
- High Frequency PTA
- Speech in Noise and quiet
- THI questionnaire

Safety

- AEs & SAEs incidence

STUDY DURATION (max 31 weeks)



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

36,450

Implants sold by Cochlear® globally in 2021¹
(representing ~60% of global market share)

\$1.5bn

Cochlear implant market in 2020²

80%

Market penetration in children in developed
markets¹
and 3% in adults¹

¹Cochlear® FY21 Result Presentation ([link](#))

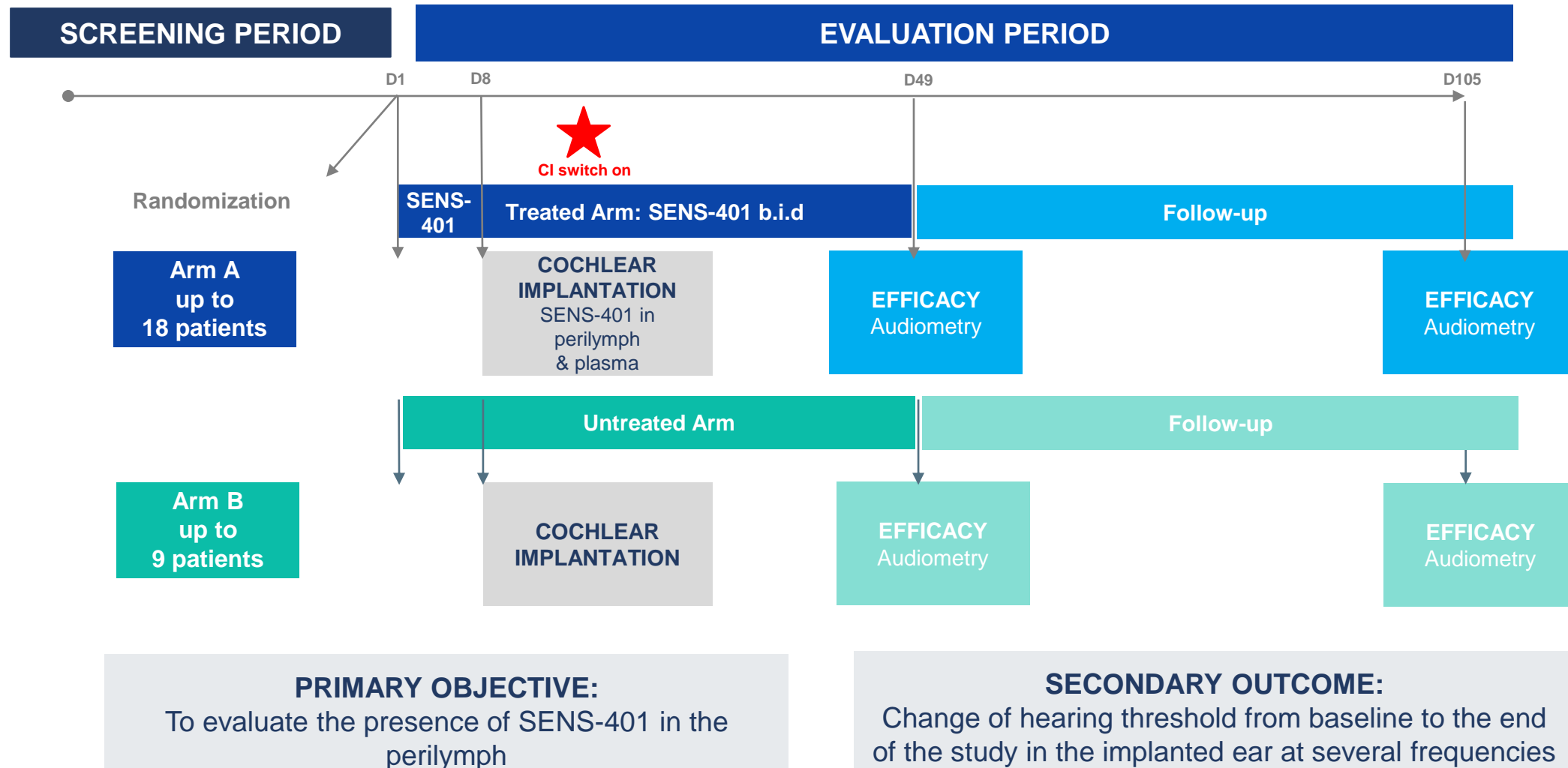
²Market estimates ([link](#))

SENS-401 Study Commenced In Sept. 2022

First Data Expected Mid-2023



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



SENS-401 Program Key Milestones, Data Readouts Mid 2023

SENS-401 CIO NOTOXIS CTA
amendment approved Oct 2022



First patient enrolled in SENS-401
CIO NOTOXIS Dec 2022



SENS-401 combo with cochlear implants
- preliminary results mid 2023



SENS-401 CIO NOTOXIS
- preliminary results mid 2023



Sensorion Newsflow [estimated timelines]

- Mid-2022 – OTOF-GT: delivery of batches for toxicology study ✓
- H2 2022 – OTOF-GT: EMA's positive opinion for ODD ✓
- H2 2022 – SENS-401 CIO: NOTOXIS CTA study amendment approval ✓
- H2 2022 – OTOF-GT: FDA approval for RPDD ✓
- H2 2022 – OTOF-GT: FDA approval for US ODD ✓
- April 6, 2023 – Sensorion to host a Gene Therapy R&D day ✓
- Q2 2023 – GJB2-GT: candidate selection ✓
- Q2 2023 – OTOF-GT: submission of the Clinical Trial Application (CTA)
- Mid-2023 – SENS-401 in combination with cochlear implantation: preliminary results
- Mid-2023 – SENS-401 CIO: NOTOXIS preliminary results

THANK YOU



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

