

November 2022



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**SENSORION**

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# Investments Highlights

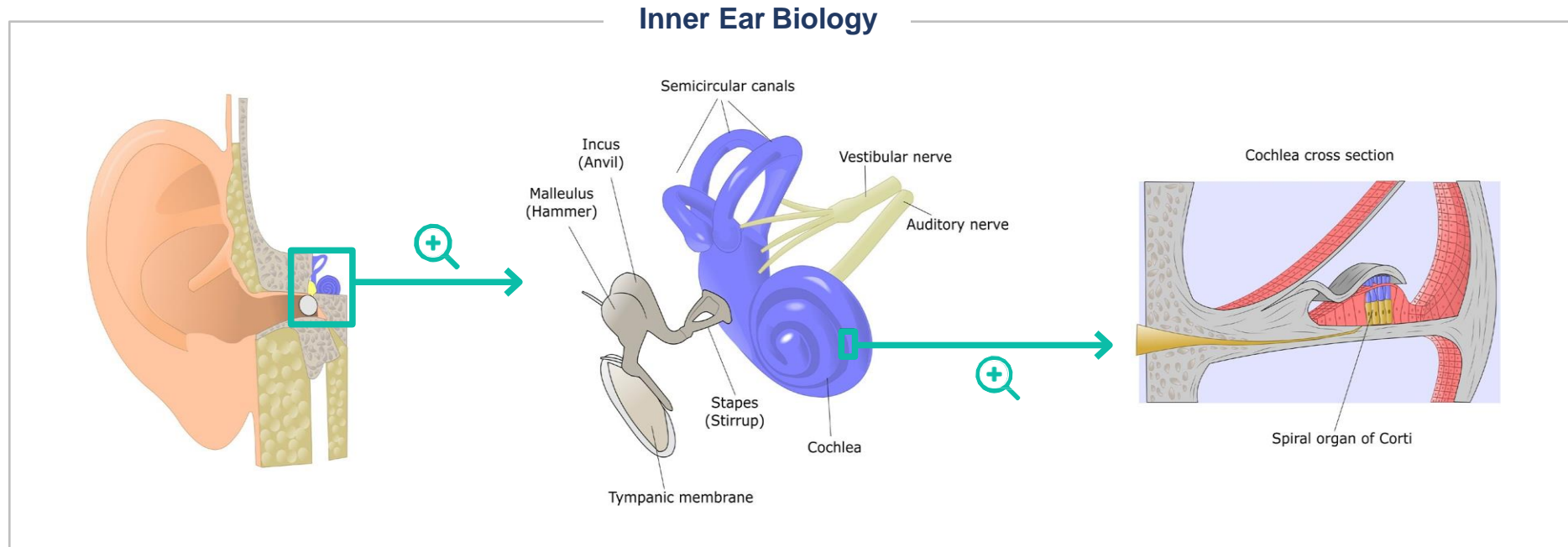
- Sensorion is focused on **innovative treatments** that can **restore, treat and prevent hearing loss**
  - **Its oral small molecule asset SENS-401** currently in clinical development in the following indications:
    - Sensorion and **Cochlear Ltd.** CTA approved for SENS-401 in patients scheduled for cochlear implantation in H1 2022 in France and Australia. First patient enrolled in Sept 2022
    - **Cisplatin-Induced Ototoxicity** clinical POC study continued with CTA amendment approved in H2 2022
    - **Sudden Sensorineural Hearing Loss** indication looking for potential partner
  - **Two gene therapy programs, OTOF-GT and GJB2-GT**, targeting monogenic forms of deafness:
    - caused by a mutation of the gene encoding for **otoferlin**
    - related to mutation in **GJB2 gene**
- **Exclusive relationship with Institut Pasteur** providing exclusive rights of first negotiation for all patents in the field of the genetics of hearing during the timeframe of the agreement
- Strong partnerships with **Necker Hospital, Cochlear Ltd.** and **Sonova**
- Strong shareholders support from **leading blue-chip investors**



## FINANCIAL OVERVIEW

Date Established..... 2009  
IPO..... 2015  
Euronext Paris ..... ALSEN.PA  
Cash (June 30, 2022) ..... ≈€39m  
*Cash runway until end of Q3 2023*

# The inner ear: one of the most delicate organs in the human body



## KEY FACTS

### Limited number of hair cells:

- 3,500 Inner Hair Cells
- 12,000 Outer Hair Cells

Hair cells do not naturally regenerate

### According to the WHO\*:

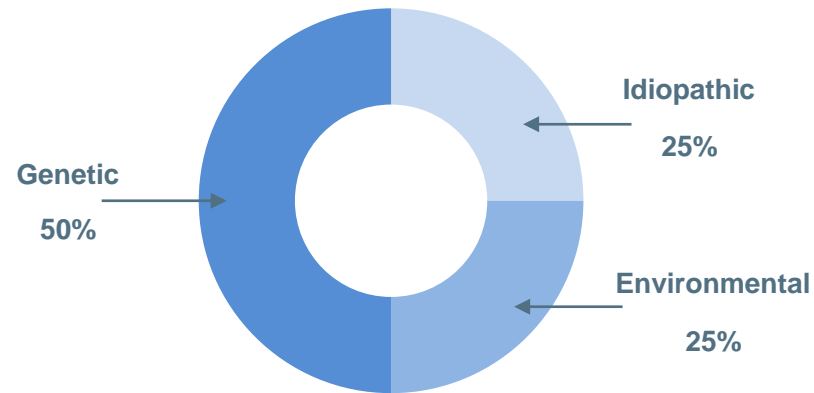
~ 400m people affected by disabling hearing loss worldwide including 34m children

~ 700m people projected to be affected by 2050

*\*World Health Organization, 2021 World report on Hearing*

# Our strategy: **RESTORE**, **TREAT** & **PREVENT** hearing loss

## Causes of hearing loss



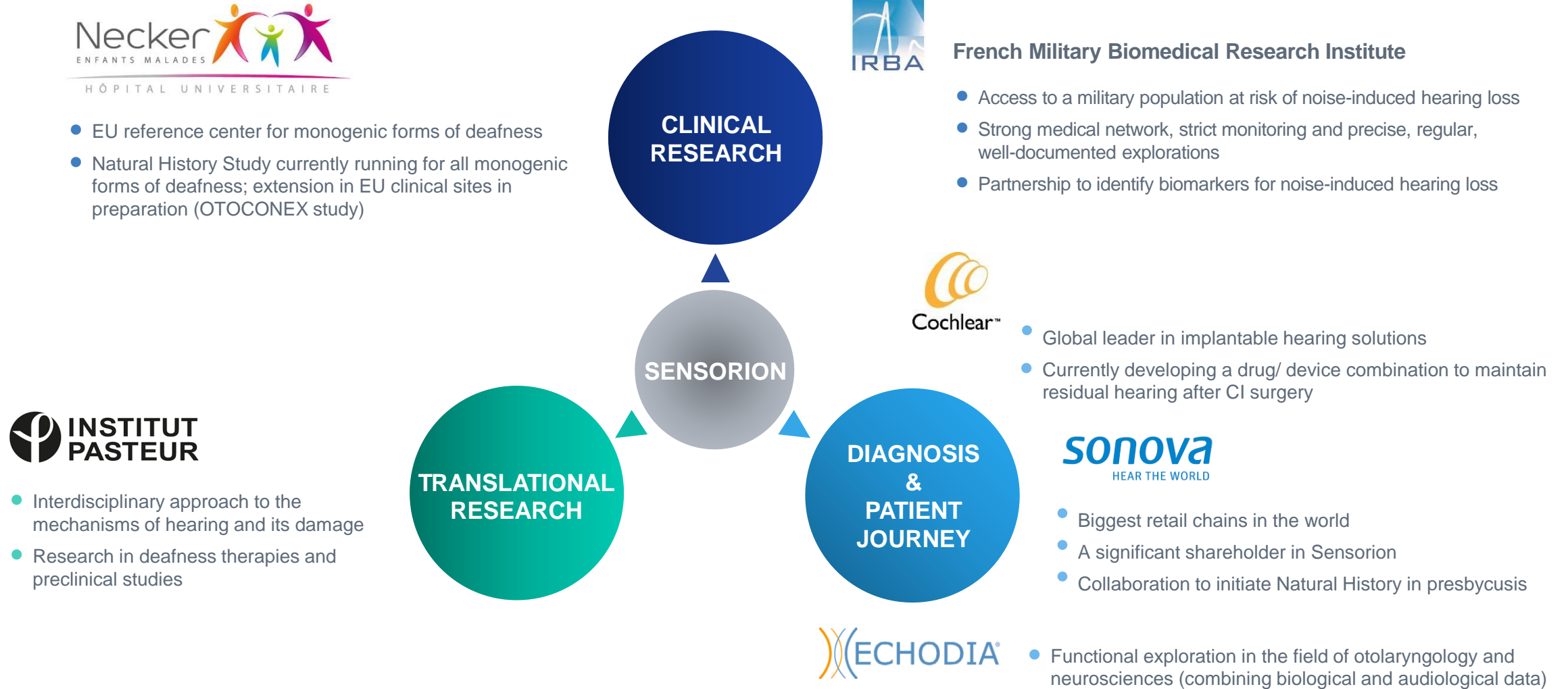
## SMALL MOLECULE APPROACH

- Phase 2 study completed with SENS-401 to **TREAT** Sudden Sensorineural Hearing Loss  
Exploring partnering opportunities
- Phase 2a study with SENS-401 to **PREVENT** residual hearing loss after cochlear implantation
- Phase 2a study with SENS-401 to **PREVENT** hearing loss caused by Cisplatin-Induced Ototoxicity

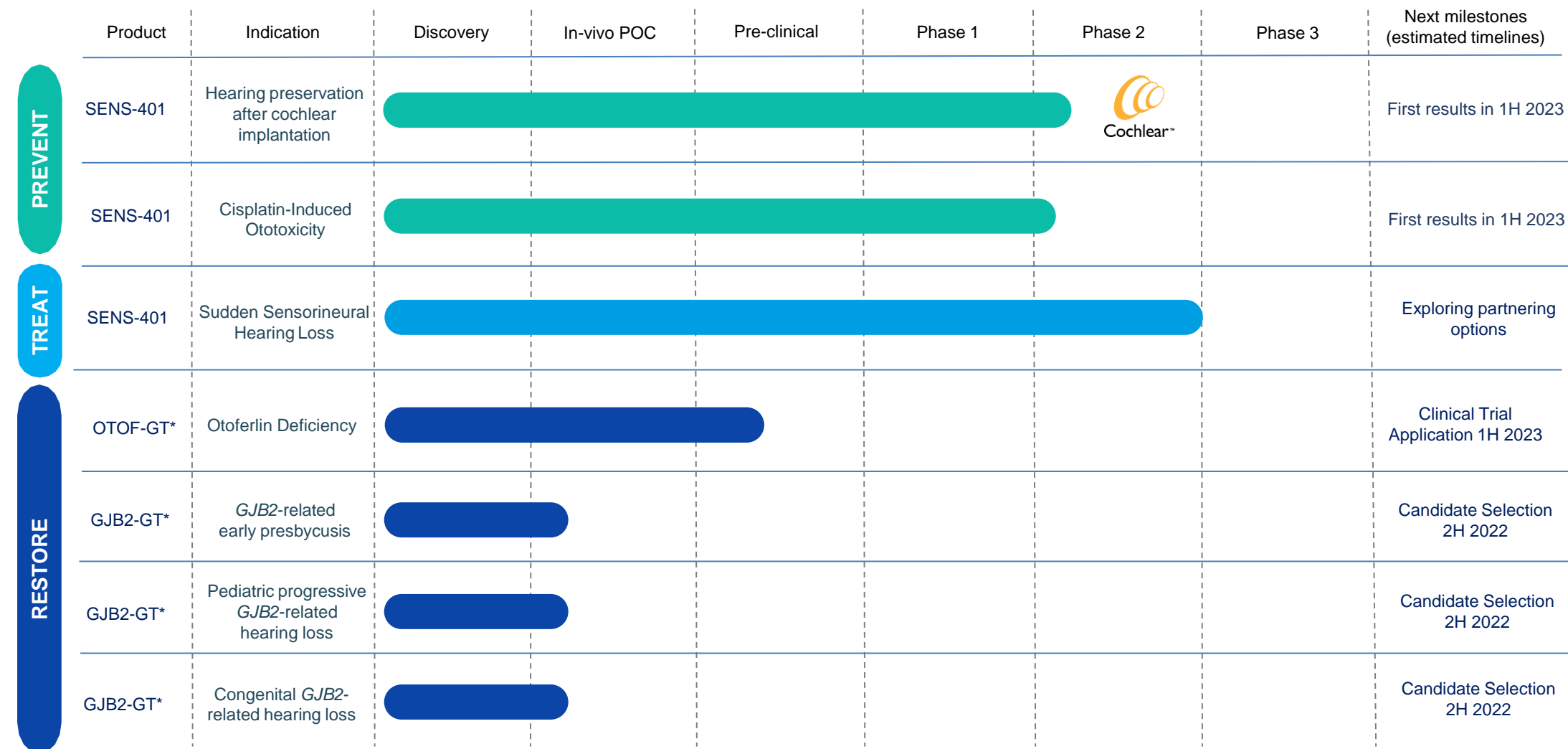
## GENE THERAPY APPROACH

- Exclusive collaboration signed with Institut Pasteur in Gene Therapy to **RESTORE** auditory functions
- Program to **RESTORE** hearing in otoferlin deficiency (DFNB9 deafness), one of the most common forms of congenital deafness
- Program to **RESTORE** hearing in *GJB2*-related hearing loss, the most common form of congenital deafness, also involved in adult early onset forms of severe presbycusis and in childhood onset forms of hearing loss

# Our critical strategic alliances from bench to bedside



# Our pipeline: a comprehensive portfolio to **RESTORE**, **TREAT** & **PREVENT** 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 OTOF-GT*

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



# An experienced team, Board of Directors and SAB



**NAWAL OUZREN**  
Chief Executive Officer



**GÉRALDINE HONNET**  
Chief Medical Officer



**STEPHANIE FILIPE**  
Head of PMO



**LAURENT DESIRE**  
Preclinical Development Director



**CHRISTINE LE BEC**  
Head of CMC Gene Therapy

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

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

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

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

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

## Board of Directors

- **Scott D. Myers**, USA, Chairman, Independent Director
- **Khalil Barrage**, USA, Director representing Invus
- **Julien Miara**, France, Director representing Invus
- **Cédric Moreau**, France, Director representing Sofinnova Partners
- **John Furey**, USA, Independent Director
- **Eric de la Fortelle**, France, Independent Director
- **Aniz Girach**, UK, Independent Director
- **Jean-François Morin**, France, Director representing BPI Investment

## 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 internal capabilities to ensure successful execution



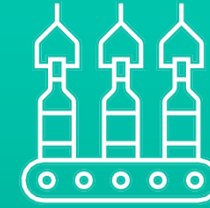
## PRECLINICAL CAPABILITIES FOR SMALL MOLECULES & GT PROGRAMS

- **In Vitro platform:** assays development, target & drug discovery, biomarkers
- **In Vivo platform:** from the POC to the dose-finding studies in disease-relevant rodent models
- **AAV screening 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



## CMC GENE THERAPY FACILITIES

- **Process development lab:** non-GMP manufacturing at small scale: set-up a platform for AAV productions
- **Analytical development lab:** development of product-specific analytical methods, internalize generic assays to support process development and AAV productions



## REGULATORY EXPERTISE

- Multiple regulatory interactions with the EMA and the FDA
- Informative discussions about how to shape the treatment guidelines and standardize clinical endpoints



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**SENS-401**

**TREAT  
AND  
PREVENT**

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# 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*

# Sudden Sensorineural Hearing Loss SSNHL

## 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

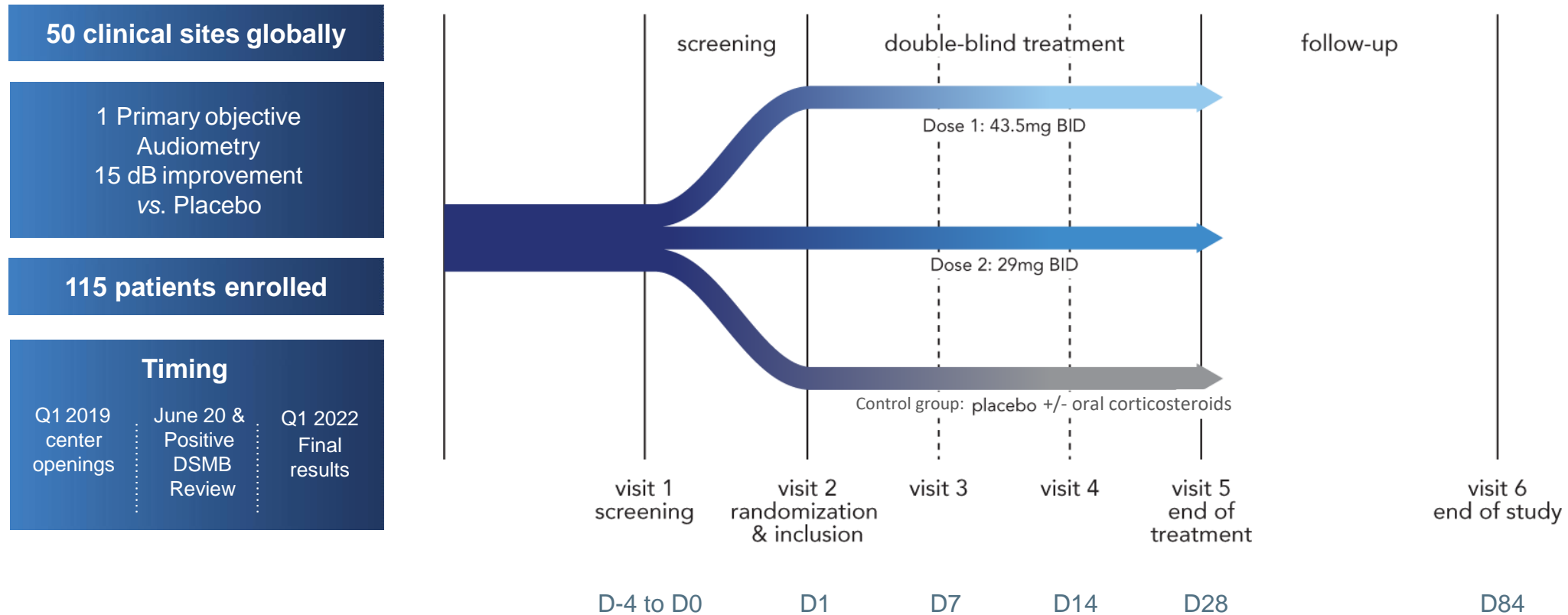
**Incidence:** 27-35 per 100,000 (218,000 patients in 2017 in G7 countries)<sup>1</sup>

<sup>1</sup> 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

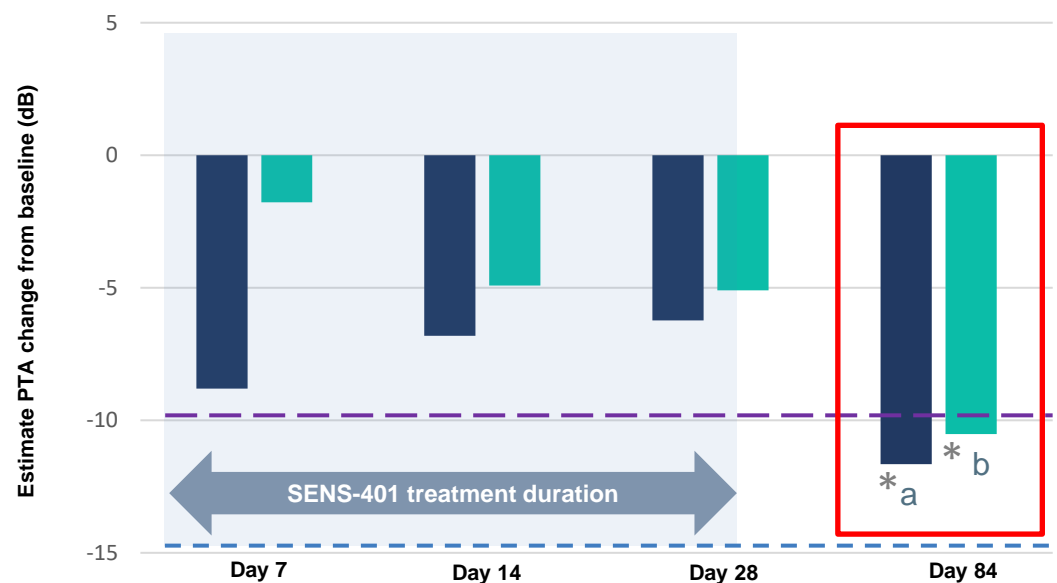


**Primary endpoint definition:**

“...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 shows a clinically meaningful effect at Day 84 in a large sub-population

## 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**.

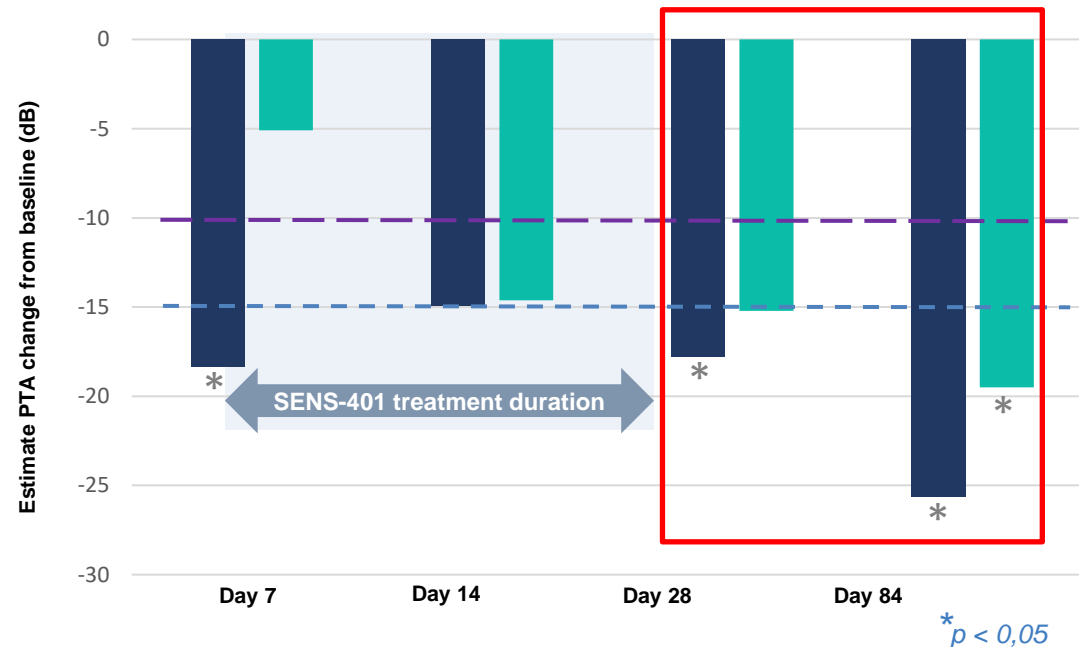
— **10 dB change from baseline** considered as clinically meaningful.

### 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



### Legend

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

- 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**.

	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.

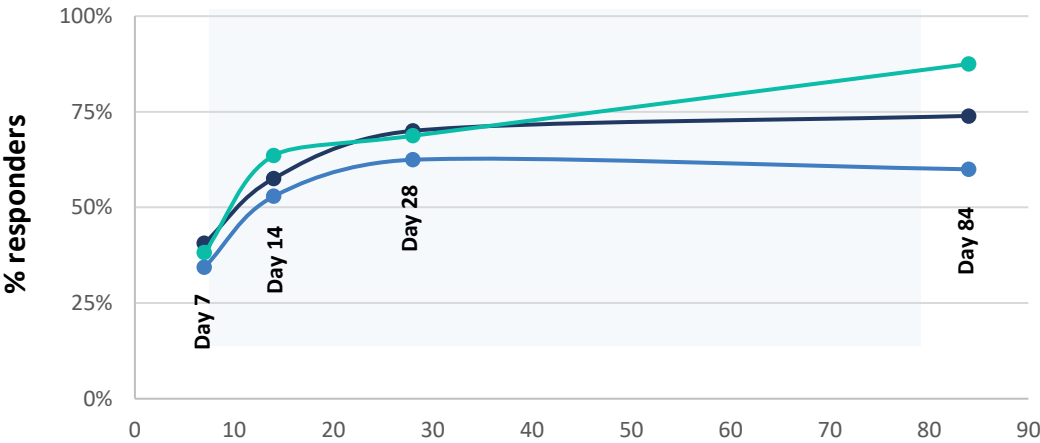
### Sub-population

Homogeneous idiopathic population of patients with profound hearing loss (PTA  $\geq 80$  dB) treated with corticosteroids.

# Responder rate is always better in the treated groups compared to placebo

## Responder analysis on ITT population

Population showing an improvement greater than 30 dB



Legend

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

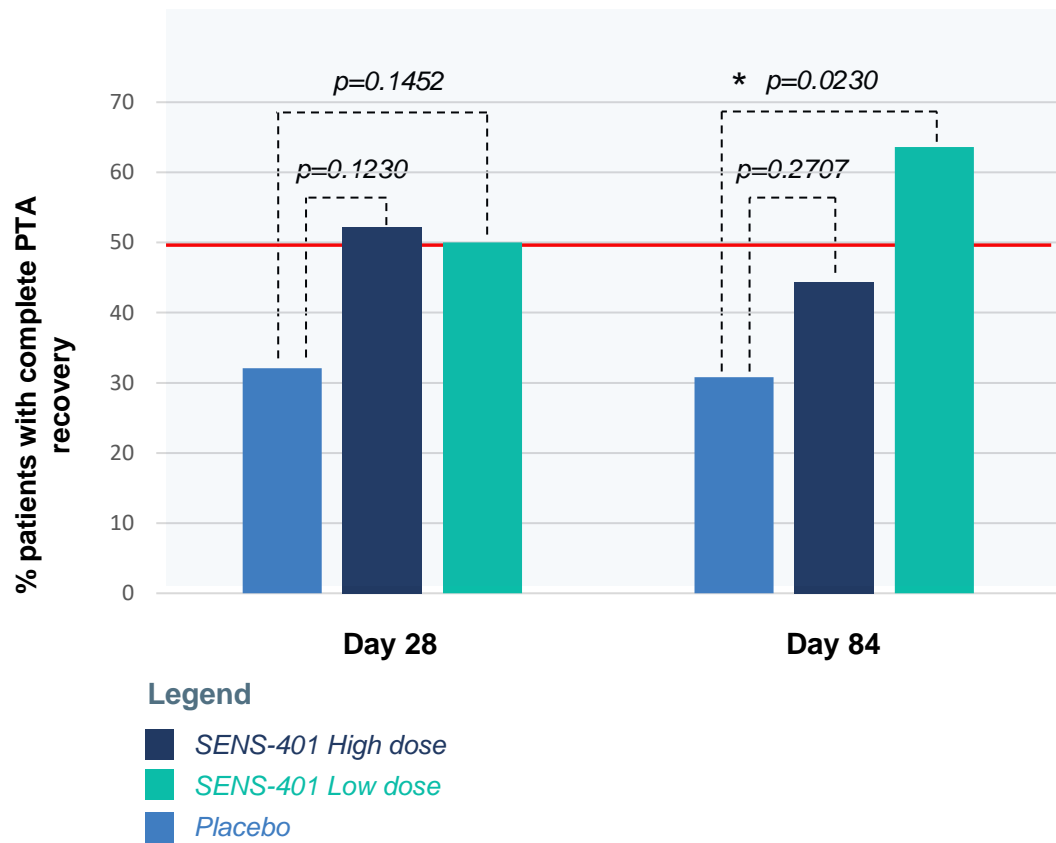
- Responder rate is **always better** in the treated groups compared to placebo.
- Difference between treated groups and placebo **increases over time**.

n	Day 7	Day 14	Day 28	Day 84
High Dose	13	19	21	17
Low Dose	13	21	22	21
Placebo	11	18	20	18

Responder rate  
Calculated with the data available at each visit

# 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

- 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 SSNHL phase 2 results summary

## Exploring partnering opportunities

### AUDIBLE-S SECONDARY ENDPOINT RESULTS

- Safe and well tolerated in 115-patient SSNHL study; primary endpoint not met
- 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**
- **Responder rate is always better in the treated group** compared to Placebo and difference with Placebo increases over time
- 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**
- **Complete PTA recovery is achieved in 50% of the SENS-401 treated patients**

# 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



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

**36,450**

Implants sold by Cochlear® globally in 2021<sup>1</sup>  
~60% global market share

**\$1.5bn**

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

**Market penetration**

80% in children,  
in developed markets<sup>1</sup>  
3% in adults<sup>1</sup>

<sup>1</sup>Cochlear® FY21 Result Presentation ([link](#))

<sup>2</sup>Market estimates ([link](#))

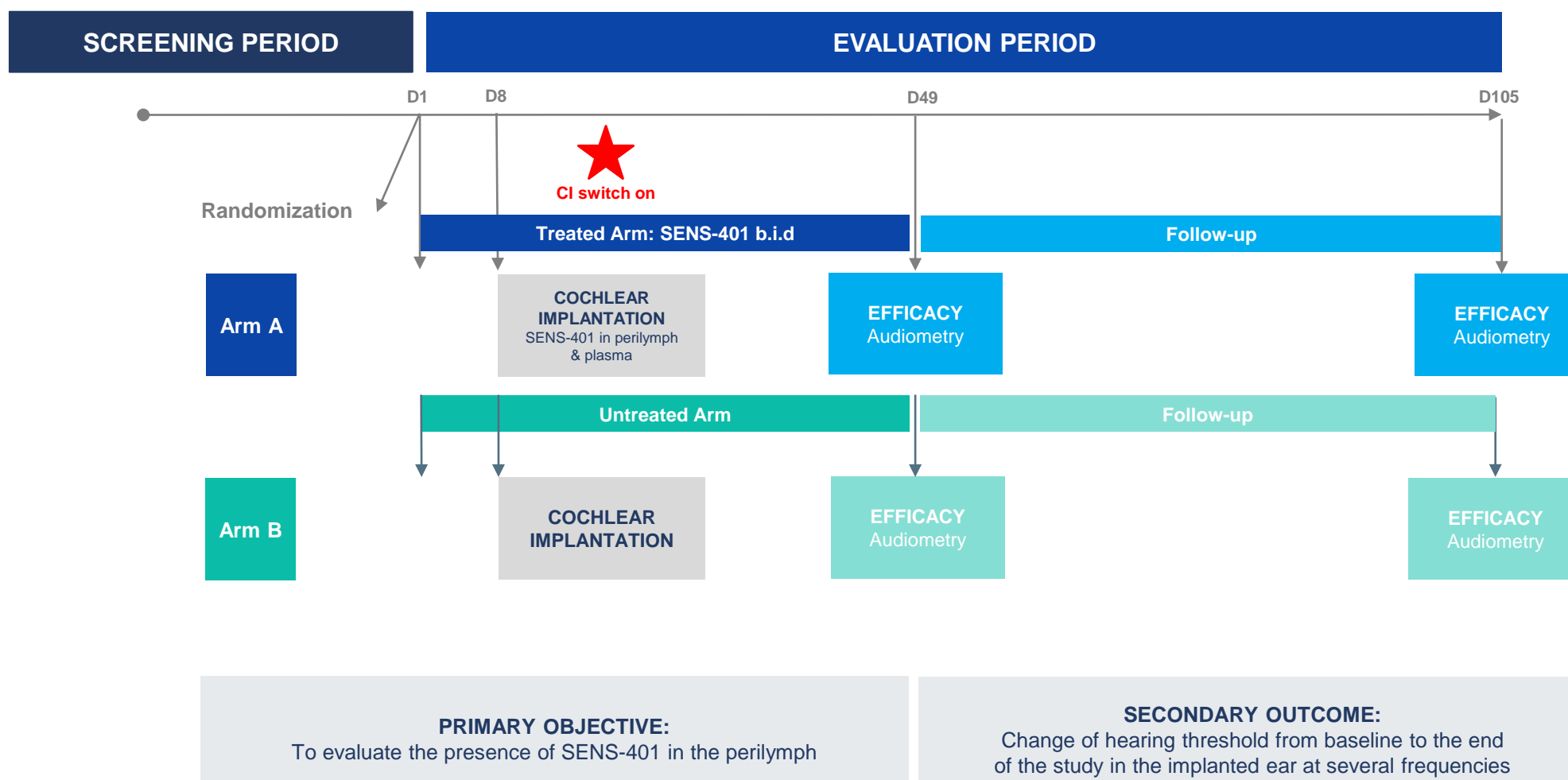


- Collaboration with Cochlear® started in Q4 2017 and Cochlear® invested €1.6m in Sensorion equity
- Cochlear® received at that time a right of first negotiation for a global license to use SENS-401 in combination with its implantable devices

# SENS-401 proof-of-concept clinical study design approved in France and Australia with first patient enrolled in Sept. 2022



## A PHASE IIA, MULTICENTER, RANDOMIZED, CONTROLLED, OPEN-LABEL STUDY



# Cisplatin administration for chemotherapeutic treatment of cancer 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 countries<sup>1</sup>

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

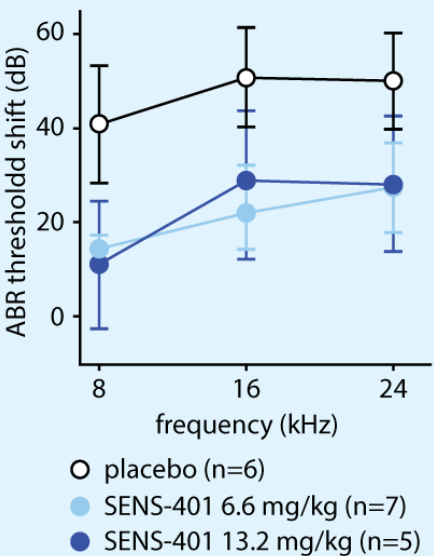
# SENS-401 CIO NOTOXIS to prevent ototoxicity induced by cisplatin

SIGNIFICANTLY REDUCES CISPLATIN-INDUCED HEARING LOSS AND OUTER HAIR CELL DEATH IN PRE-CLINICAL MODELS

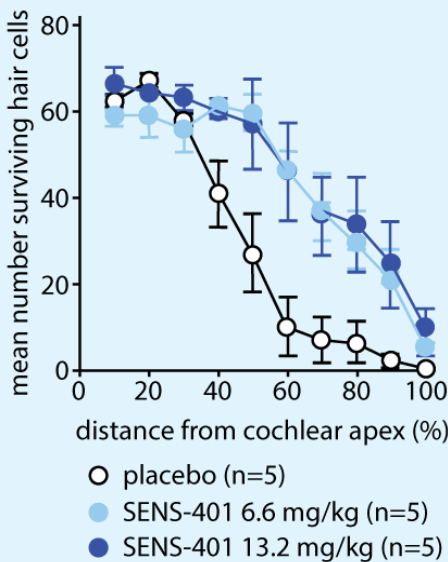
## TREATMENT PROTOCOL

SENS-401 6.6 mg/kg, 13.2 mg/kg or placebo were administered to rats once-daily for 13 consecutive days after cisplatin infusion

### Auditory brainstem response (ABR) threshold shift at day 14



### Cochleograms at day 14



Significant improvement *versus* placebo  
23-28 dB with 6.6 mg/kg  
( $p < 0.010$ )  
22-30 dB with 13.2 mg/kg  
( $p < 0.013$ )

Significant enhancement  
of outer hair cells survival  
22-264%  
for both doses

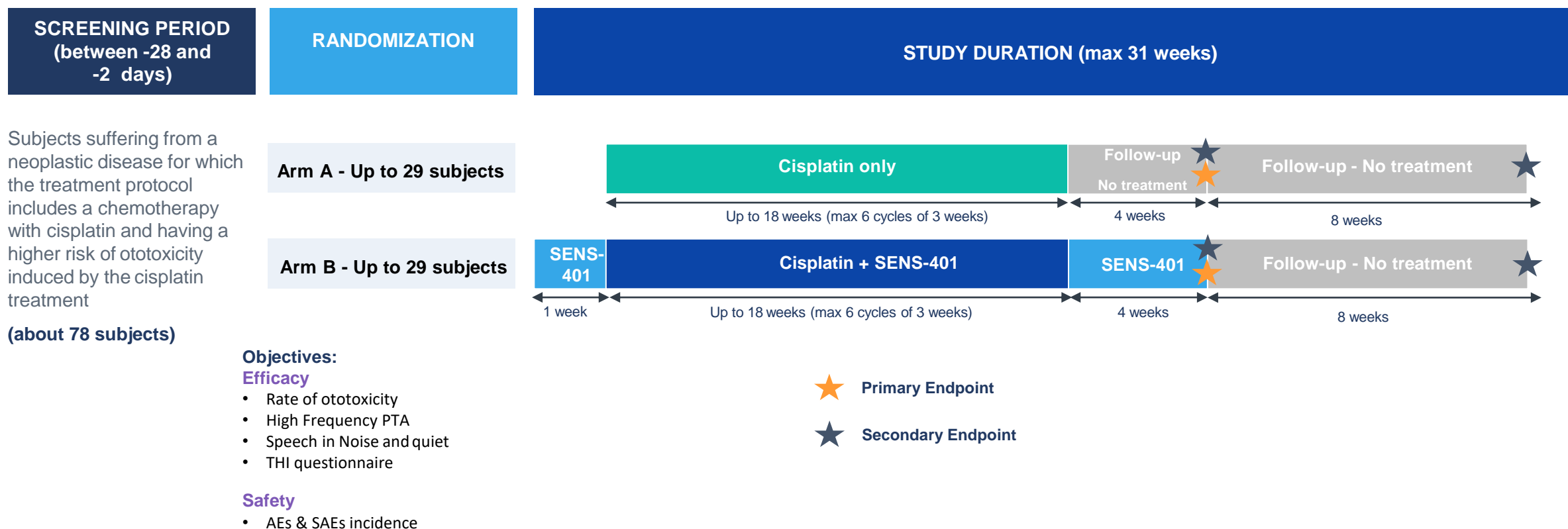
Significantly  
more surviving outer hair  
cells were present  
after SENS-401 treatment  
compared with placebo  
( $p < 0.001$ ), with up to 11-fold  
more in the basal  
turn of the cochlea

Source: Petremann et al. 2017, Otol Neurotol: Oral Administration of Clinical Stage Drug Candidate SENS-401 Effectively Reduces Cisplatin-induced Hearing Loss in Rats ([link](#))



# SENS-401 amended Phase 2a proof-of-concept clinical study design approved in France in October 2022

## 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



## SENS-401 program next steps

SENS-401 CIO NOTOXIS CTA  
amendment approved 2H 2022



First patient enrolled in SENS-401 CIO  
NOTOXIS 2H 2022



SENS-401 in combination with cochlear  
implants first results 1H 2023



SENS-401 CIO NOTOXIS  
first results 1H 2023





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# GENE THERAPY RESTORE

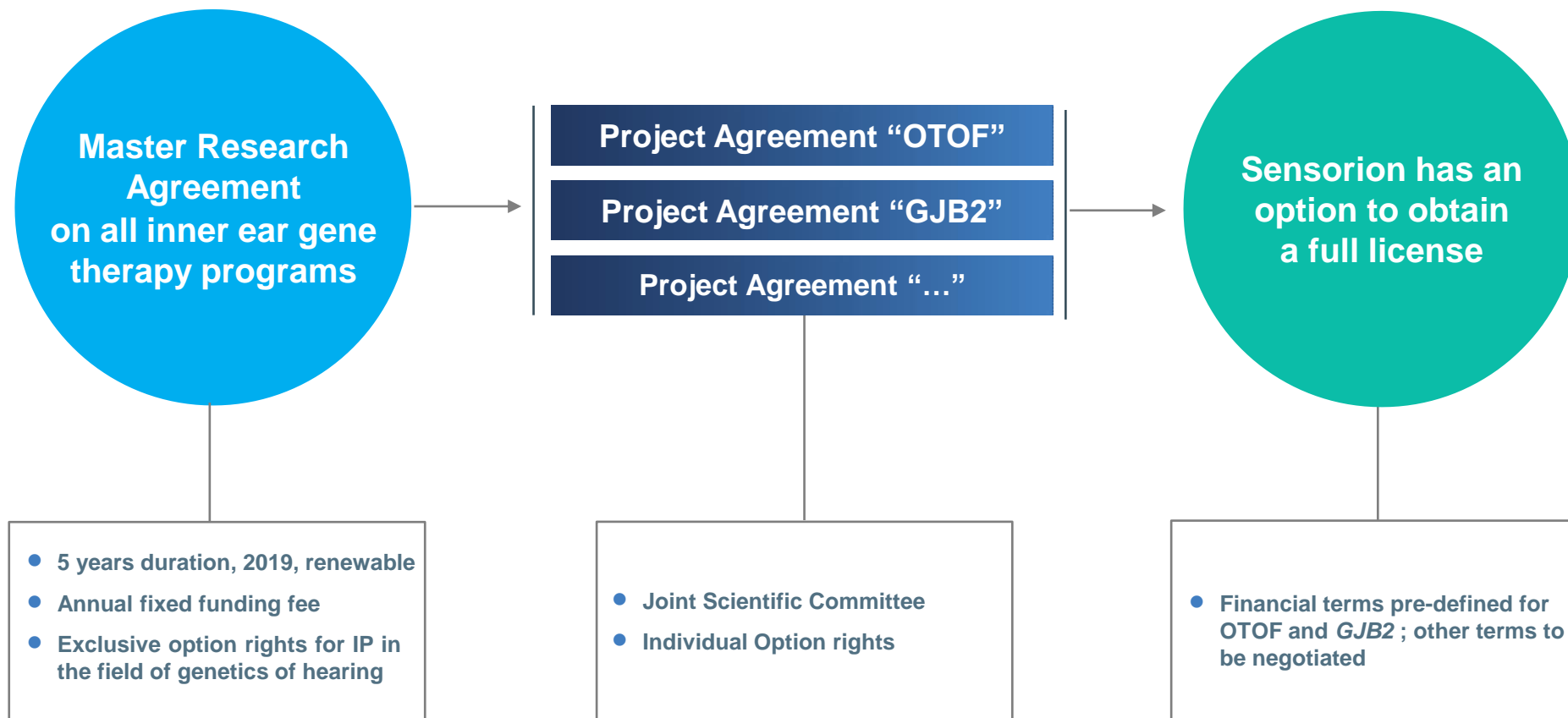
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# Strategic R&D collaboration with Institut Pasteur on genetics of hearing

## 2 PROGRAMS INITIATED UNDER THE COLLABORATION AGREEMENT WITH INSTITUT PASTEUR

Rare disease, high unmet medical need



# Sensorion's gene therapy programs to treat rare auditory diseases

## 2 PROGRAMS INITIATED UNDER THE STRATEGIC COLLABORATION AGREEMENT WITH INSTITUT PASTEUR

### 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
- EMA issued a positive opinion for 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

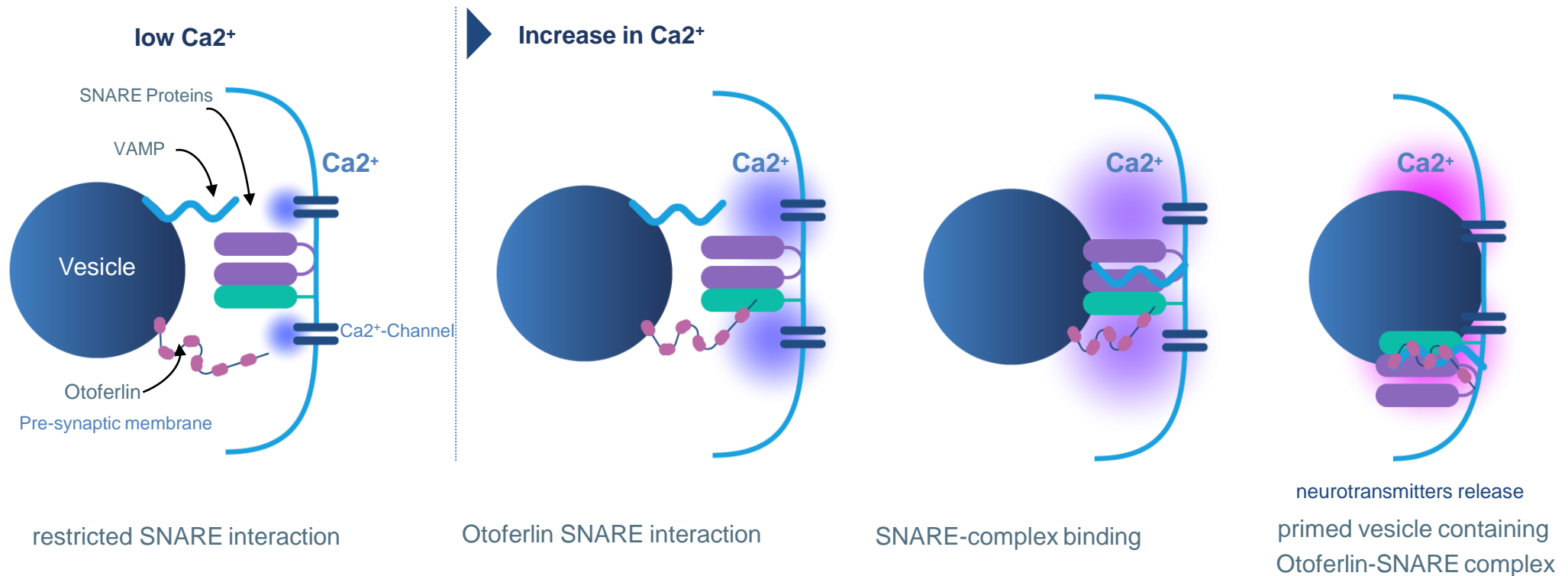
Sources: Akil et al. 2019 ([link](#)), Orphanet ([link](#)), NIH ([link](#)), company estimates based on publicly available population data, Chardan 2020 report, Bryan, Garnier & Co 2019 report, Institut Pasteur, Boucher et al. 2020 ([link](#))

**DELAYED DIAGNOSIS – NOT SUSPECTED AT FIRST SIGHT**

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



# OTOF Gene encodes otoferlin, a key $\text{Ca}^{2+}$ sensor protein

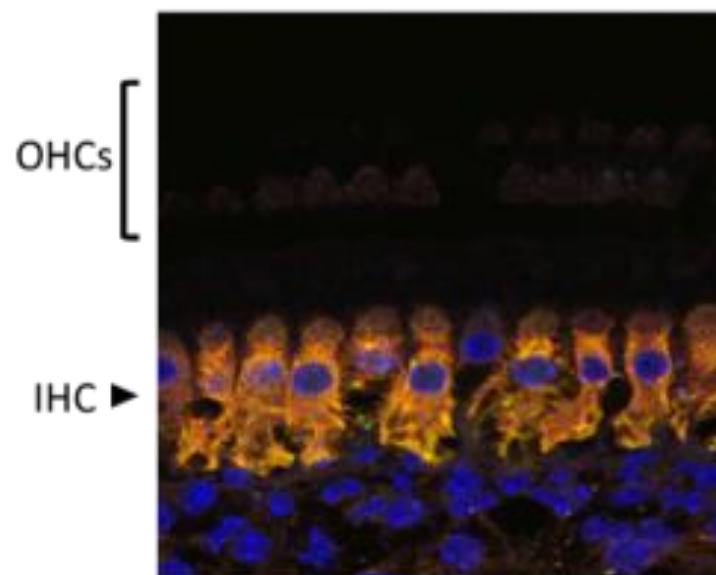


Model illustrating calcium regulation of otoferlin/SNARE interaction in the hair cell – Adapted from Ramakrishnan *et al.* 2014

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

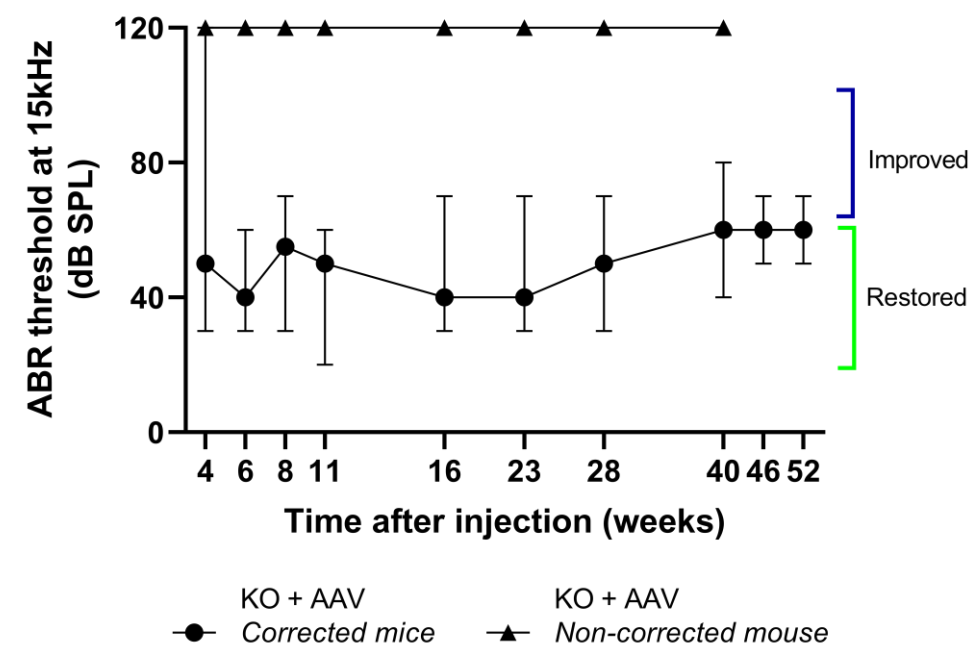
# Dual AAV-OTOF resulted in IHCs specific expression and hearing restoration in DFNB9 mice

## 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

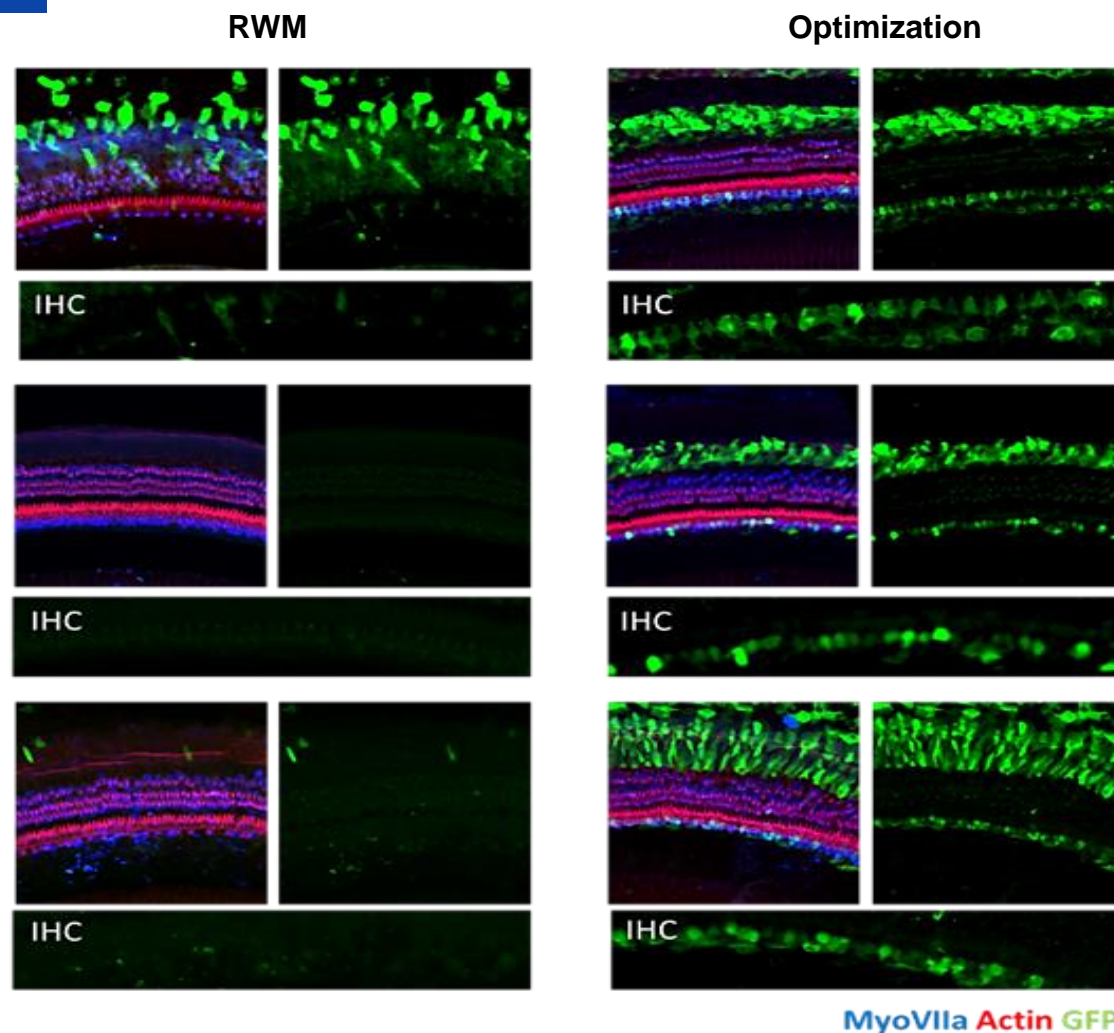


- **Durable hearing restoration** in *Otof*<sup>-/-</sup> mice by dual AAV-OTOF directly delivered to the inner ear up to one year post-injection

# 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<sup>+</sup> 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

# 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

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

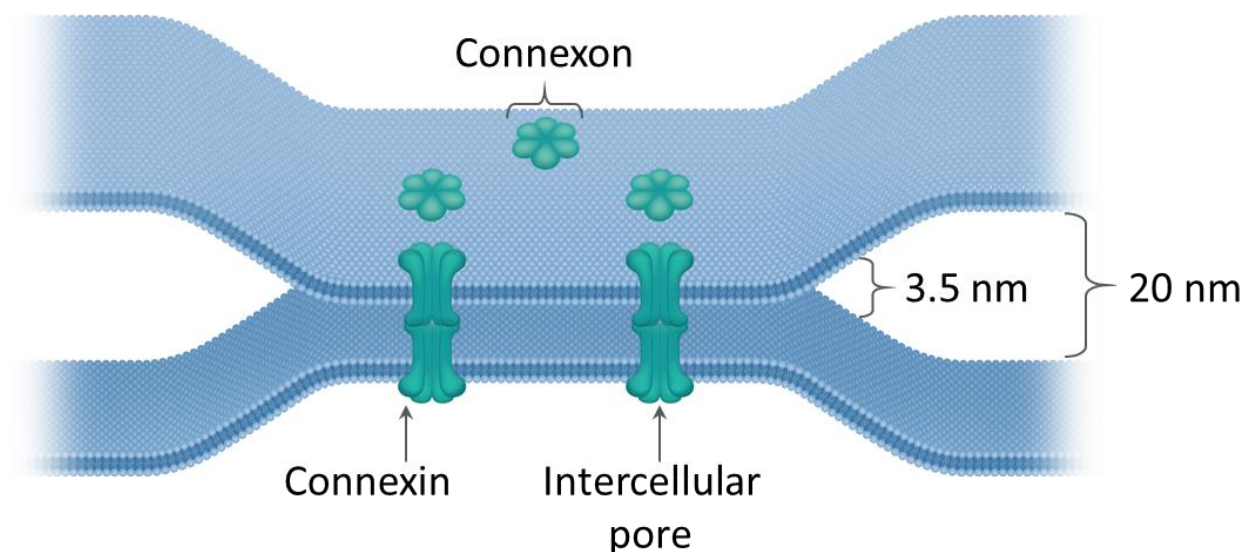


Clinical Trial Application 1H 2023



# 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<sup>[1]</sup>



*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

## GJB2 gene therapy program next steps

Submission of European Natural  
History Study OTOCONEX



Submission of Natural History Study  
in collaboration with Sonova



Candidate selection 2H 2022



Preclinical IND enabling studies





# Sensorion potential newsflow [estimated timelines]

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- Mid-2022 – OTOF-GT: delivery of batches for toxicology study
- 2H 2022 – OTOF-GT: EMA's positive opinion for ODD
- 2H 2022 – SENS-401 CIO: NOTOXIS CTA study amendment approval
- 1H 2023 – OTOF-GT: FDA approval for RPDD
- 2H 2022 – GJB2-GT candidate selection
- 1H 2023 – SENS-401 in combination with cochlear implantation: first results
- 1H 2023 – SENS-401 CIO: NOTOXIS first results
- 1H 2023 – OTOF-GT: approval for U.S. ODD
- 1H 2023 – OTOF-GT: submission of the Clinical Trial Application (CTA)



# THANK YOU

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