

# Sensorion



July 2021

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# INVESTMENT HIGHLIGHTS

- Sensorion is focused on **innovative treatments** that can **restore, treat and prevent hearing loss**
- **Three novel gene therapy programs** targeting unmet needs in **Otoferlin Deficiency, GJB2-related hearing loss** and **Usher Syndrome Type 1**
  - **Promising pre-clinical data** demonstrating improvement and restoration of hearing and vestibular functions (OTOF/USH1)
- **Exclusive relationship with Institut Pasteur** for all Inner Ear Gene Therapy Programs during the timeframe of the agreement
- Phase 2 study for **Sudden Sensorineural Hearing Loss with an oral small molecule**
  - Global, randomized study with **data expected in Q4 2021**
- **Experienced management team** with broad expertise in gene therapy and drug development
- Strong shareholder support from **leading blue-chip investors**



SOFINNOVA

bpi**france**

## FINANCIAL OVERVIEW

Date Established.....	2009
IPO .....	2015
Euronext Paris .....	ALSEN.PA
Cash (Dec 31, 2020): .....	€62.2m
<i>Cash runway until end of H2 2022</i>	



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# SENSORION

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# MANAGEMENT TEAM



**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

**BAXTER**  
(2006-2014)  
Vice President



**GÉRALDINE HONNET**  
*Chief Medical Officer*

**SENSORION**  
(Since 2020)

**GENETHON**  
(2011-2020)

Director of Development

**TRANSGENE**  
(2007-2011)

Responsible of development of infectious diseases programs

**JANSSEN-CILAG EMEA**  
(2005-2007)

European Project Manager Virology

**PAREXEL INTERNATIONAL**  
(2001-2005)  
Medical Director



**NORA YANG**  
*Chief Scientific Officer*

**SENSORION**  
(Since 2021)

**STRATIFY**  
(2020-2021)

Cofounder and CSO

**NIH**  
(2010-2019)

Director of portfolio management and strategic operations

**AMGEN**  
(2004-2006)

Sr Global Project Manager

**ELI LILLY**  
(1992-2004)

Project team leader, new drug discovery



**OTMANE BOUSSIF**  
*Chief Technical Officer*

**SENSORION**  
(Since 2021)

**NOVARTIS**  
(Since 2015)

Head Cell & Gene Therapy T. Dev.

**SANOFI**  
(Since 2006)

Director Purification & Formulation processes, vaccines

**MERCK SERONO**  
(Since 2004)

Manager Pre-formulation downstream processing

**AVENTIS**  
(Since 2000)

Manager Formulation & Preclinical manufacturing

# SENSORION

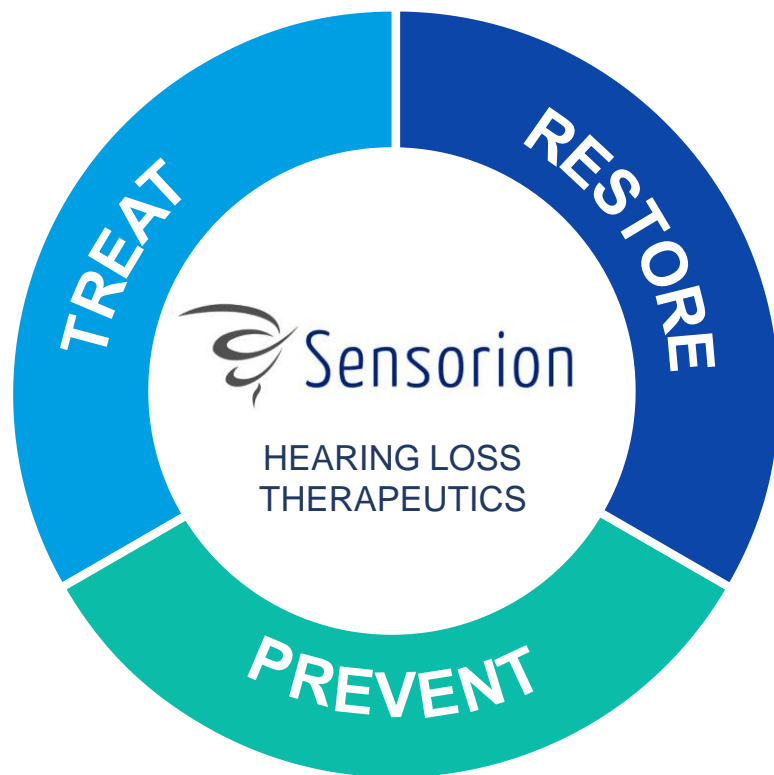
## Sensorion is building up a gene therapy franchise in collaboration with Institut Pasteur

- Management team highly experienced in gene therapy and drug development
- **RESTORE**, **TREAT** and **PREVENT** in the field of hearing loss: Phase 2 small molecule and new focus on gene therapies
- High profile collaborations and partners attracted high profile investors:
  - Institut Pasteur, Cochlear®, French Armed Forces Biomedical Research Institute (IRBA) and Necker Hospital
  - ~€69.1m raised with key investors including Invus, Sofinnova Partners, Wuxi Apptec and 3SBio

### FINANCIAL OVERVIEW

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<i>Cash runway until end of H2 2022</i>	

# STRATEGY: RESTORE, TREAT & PREVENT HEARING LOSS



## 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
- Program to **RESTORE** hearing in Usher Syndrome Type 1

## SMALL MOLECULE APPROACH

- Phase 2 PoC study ongoing with SENS-401 to **TREAT** Sudden Sensorineural Hearing Loss
- Pre-clinical study completed with SENS-401 to **PREVENT** cell death following cochlear implant procedure.
- SENS-401 to **PREVENT** Cisplatin-induced Ototoxicity

# INSTITUT PASTEUR IS LEADING THE WAY IN THE GENETICS OF HEARING



**CHRISTINE PETIT**  
*MD, PhD*

- Chair of Genetics and Cellular Physiology, Professor at College de France
- Professor at Institut Pasteur (Paris)
- Head of the Laboratory of Genetics and Physiology of Hearing at Institut Pasteur
- Founding Director of the French Hearing Institute
- **Chair of the Scientific Advisory Board at Sensorion**

## Awards and Distinctions

- Louisa Gross Horwitz Prize
- Kavli Prize in Neuroscience
- ARO Lifetime Achievement Award of Merit
- International Brain Prize from Grete Lundbeck Foundation
- Hughes Knowles Prize
- Louis-Jeantet for Medicine Prize
- L'Oréal-UNESCO for Women in Science Award
- Inserm Grand Prix
- Member of the French and American Sciences Academies and the American Medical Academy



## GENETICS AND PHYSIOLOGY OF HEARING UNIT AT INSTITUT PASTEUR LED BY PROFESSOR CHRISTINE PETIT

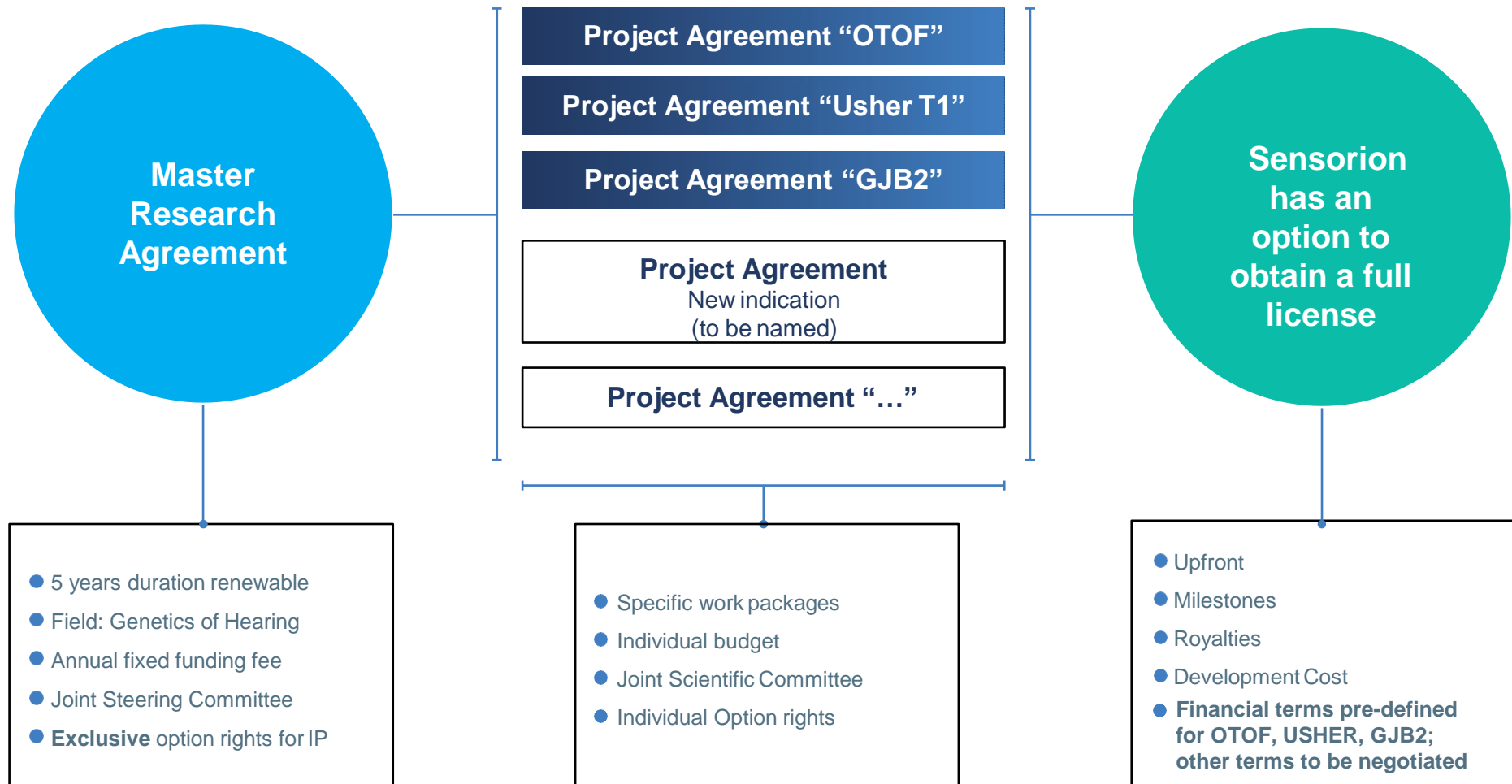
- >300 publications
- Mapped the first 2 genes (GJB2 and MYO7A) underlying childhood autosomal recessive deafness
- Identified more than 20 causative genes of hearing impairment
- Developed an interdisciplinary approach involving study of mouse models of various forms of human deafness as well as cell- and temporal-specific conditional KO mice
- Unraveled the pathogenic processes of a large spectrum of deafness

<https://research.pasteur.fr/en/team/genetics-physiology-of-hearing/>



# SENSORION HAS ENTERED INTO A BROAD STRATEGIC R&D COLLABORATION WITH INSTITUT PASTEUR ON GENETICS OF HEARING

SENSORION HAS A RIGHT OF FIRST REFUSAL ON ALL GENE THERAPY PROGRAMS IN THE FIELD OF INNER EAR AT INSTITUT PASTEUR



# SCIENTIFIC ADVISORY BOARD



**Pr Christine Petit**

Chair of the Scientific Advisory Board



**Pr Alain Fischer**

- Professor at College de France
- 2009-2016: Director and Founding Member of the Institute for Genetic Diseases (Imagine)
- 1996-2012: Director of the pediatric immunology department at Necker Hospital
- Pr Fischer notably led pioneering research on gene therapy



**Dr Diane Lazard**

- ENT Surgeon
- Principal Associate Investigator at the Hearing Institute (Paris)
- Currently pursuing research on deciphering language processing variability in deafness



**Dr Hernán López-Schier**

- Senior Group Leader and Research Unit Director at the Helmholtz Center (Munich)
- Currently pursuing research on fundamental sensory biology and sensory dysfunction
- His group was the first to visualize the regeneration of mechanosensory hair cells in their natural context



**Pr Paul Avan**

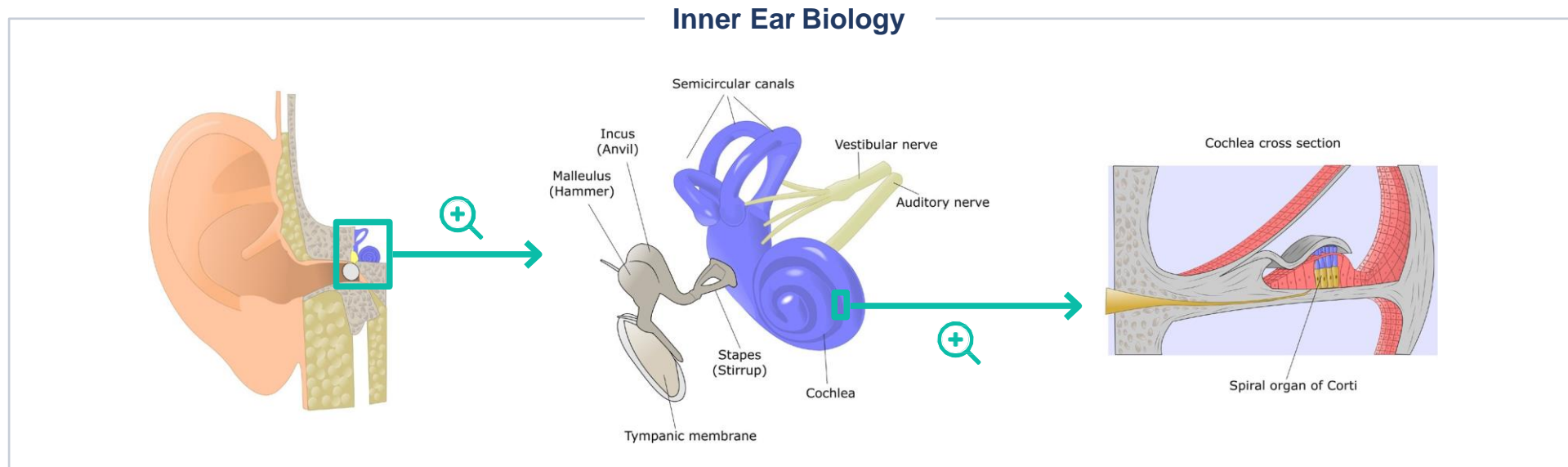
- Physicist and Medical Doctor in Biophysics
- Head of the Center for Research and Innovation in Human Audiology at Hearing Institute (Paris)
- Designed original objective methods of exploration of the cochlea and auditory pathways



**Dr Rob Dow**

- >37 years of experience in the pharmaceutical and biotech industry
- Former Chief Medical Officer at PPD Inc.
- Substantial experience across therapeutic areas from pre-clinical to Phase 3 development

# THE INNER EAR IS ONE OF THE MOST DELICATE ORGANS IN THE HUMAN BODY



ACCORDING TO THE WORLD HEALTH ORGANIZATION\*:

**~1.5bn**

PEOPLE AFFECTED BY HEARING LOSS WORLDWIDE

**~2.5bn**

PEOPLE PROJECTED TO BE AFFECTED BY 2050

\*2021 WHO World report on Hearing

## KEY FACTS


- Every human is born with a specific number of sensory hair cells
  - 3,500 Inner Hair Cells
  - 12,000 Outer Hair Cells
  - Hair cells do not naturally regenerate

# PIPELINE: BUILDING AN ATTRACTIVE PIPELINE IN THE HEARING SPACE

TREAT

PREVENT

RESTORE

Product	Indication	Discovery	In vivo PoC	Pre-clinical	Phase 1	Phase 2	Phase 3	Next milestones (estimated timelines)	
SENS-401	Sudden sensorineural hearing loss								Phase 2 topline results (Q4 2021)
SENS-401	Cisplatin induced ototoxicity								Start of natural history clinical study (mid-year 2021)
SENS-401	Hearing preservation after cochlear implantation								Cochlear and Sensorion assessing next steps
SENS-401	Aminoglycoside induced ototoxicity								
OTOF-GT*	Otoferlin deficiency								Discussion with reg. authorities (mid-year 2021)
Usher-GT*	Usher syndrome Type 1								Pre-clinical Confirmatory PoC studies (mid-year 2021)
GJB2-GT*	GJB2-related early presbycusis								Candidate selection
GJB2-GT*	Pediatric progressive GJB2-related hearing loss								Candidate selection
GJB2-GT*	Congenital GJB2-related hearing loss								Candidate selection

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

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



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**GENE  
THERAPY  
RESTORE**

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# SENSORION'S FIRST GENE THERAPY PROGRAMS TO TREAT RARE AUDITORY DISEASES

## 3 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 ~1100 per year in USA + EU

### 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

### USHER SYNDROME TYPE 1

Patients with Usher Syndrome Type 1 are born with severe to profound congenital bilateral sensorineural hearing loss and congenital vestibular dysfunction. Progressive vision loss appears during childhood

Prevalence of Usher Syndrome: 4-17 per 100,000 people (~13k-55k patients in EU5 countries; ~13k-56k patients in USA)

Usher Syndrome Type 1 represents ~40% of all cases of Usher Syndrome

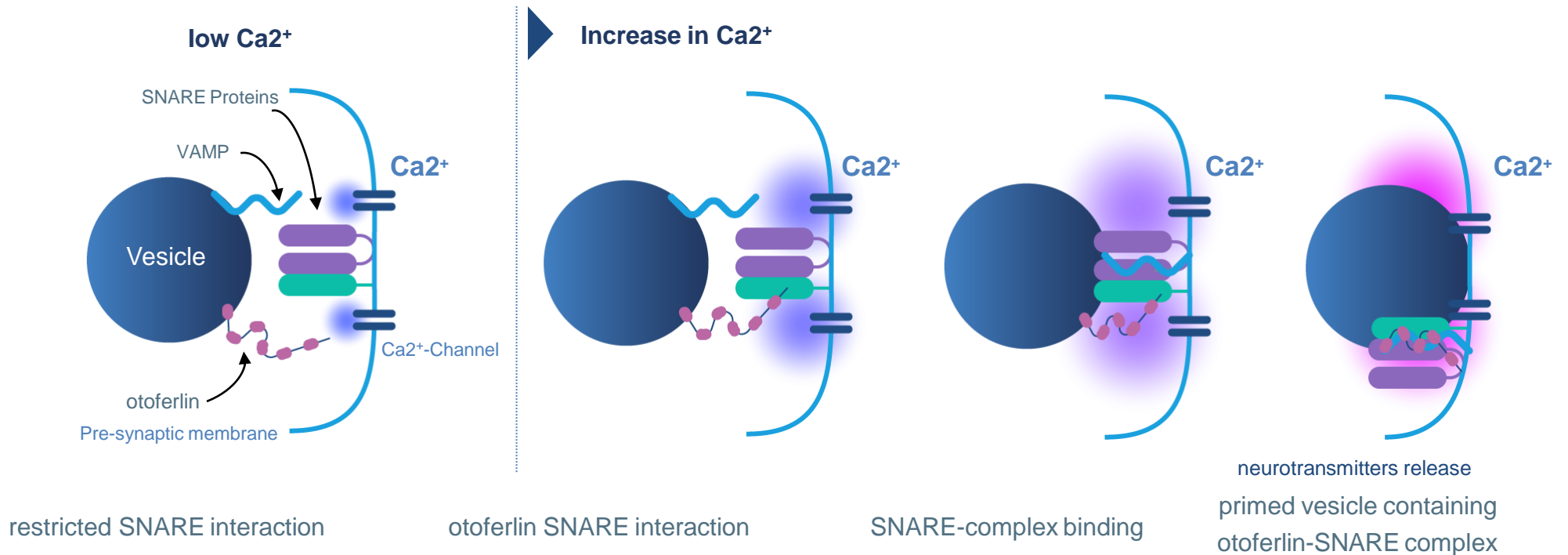
We are addressing the USH1G mutations

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**

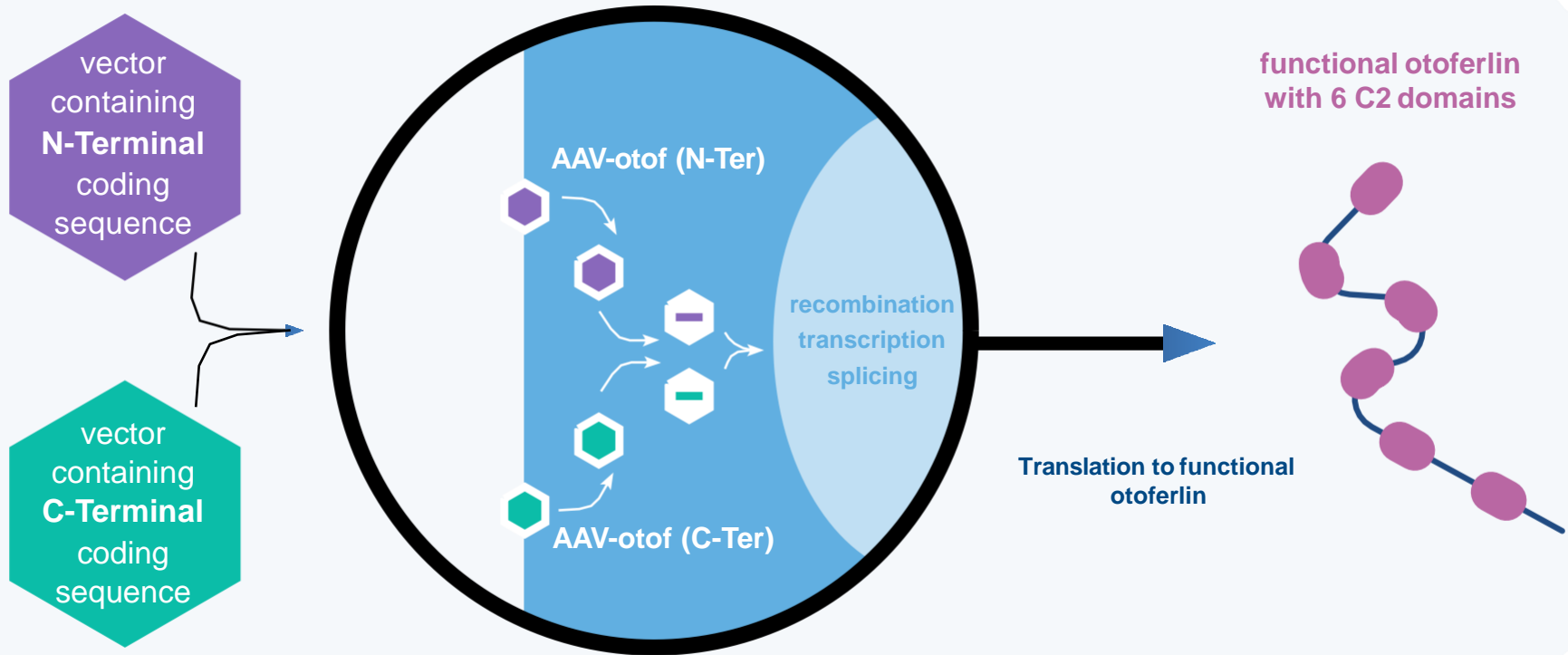
# OTOF GENE ENCODES OTOFERLIN, A KEY $\text{Ca}^{2+}$ SENSOR PROTEIN



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**

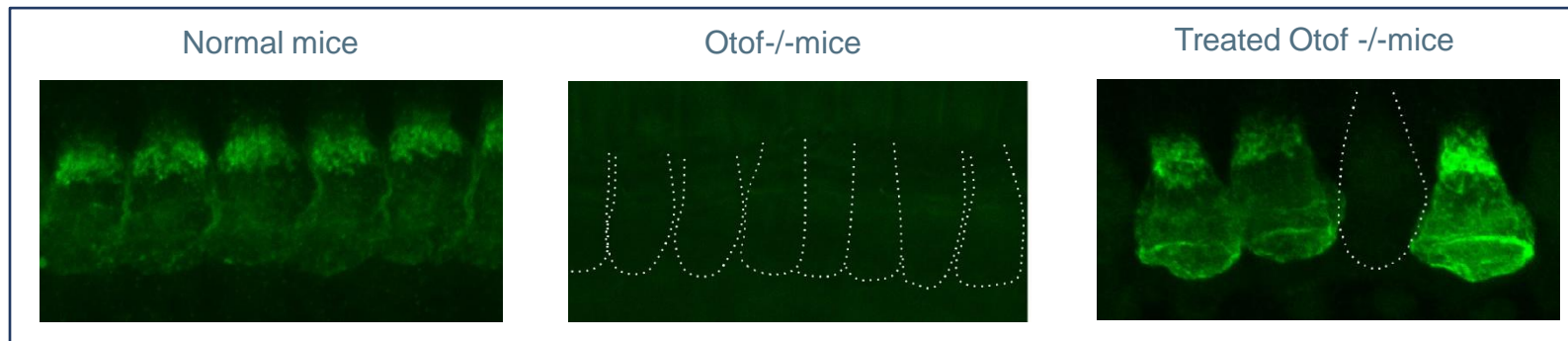
# DUAL AAV OTOF GENE THERAPY - MECHANISM OF ACTION



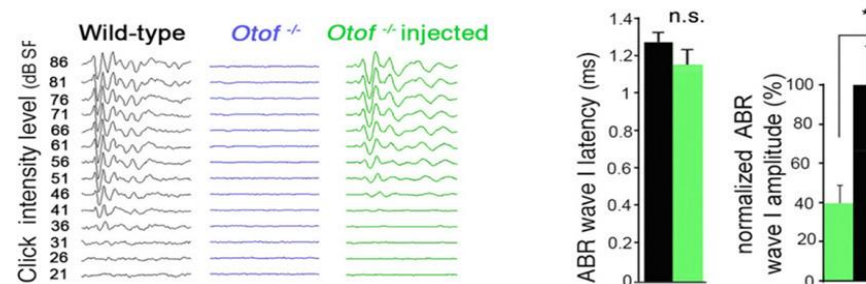


# PRE-CLINICAL OTOF GENE THERAPY PROOF OF CONCEPT DURABLY RESTORES COCHLEAR RECEPTOR FUNCTION IN A KNOCK-OUT MOUSE MODEL

Immunostained inner hair cells in wild type, *Otof*<sup>-/-</sup> and *Otof*<sup>-/-</sup> injected with dual AAV2 quadY-F OTOF vector expression of *Otof* protein in cochlear receptors



## Restoration of auditory function in *Otof*<sup>-/-</sup> using Dual AAV2 quadY-F OTOF



Akil *et al.* 2019 ([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
- Natural history: clinical evaluation and selection of patients
- Database compilation with genotypic and phenotypic characterization of children with congenital hearing loss
- Phase 1 gene therapy study (financing up to 1st patient in the clinical study)

This 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
- Today one of the largest children’s hospital in Europe

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



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

## AUDINNOVE CONSORTIUM MEMBERS



# OTOF GENE THERAPY PROGRAM STATUS

PoC data in mouse



PoC preliminary data in Non-  
Human Primates



Product Development and  
Manufacturing Agreement

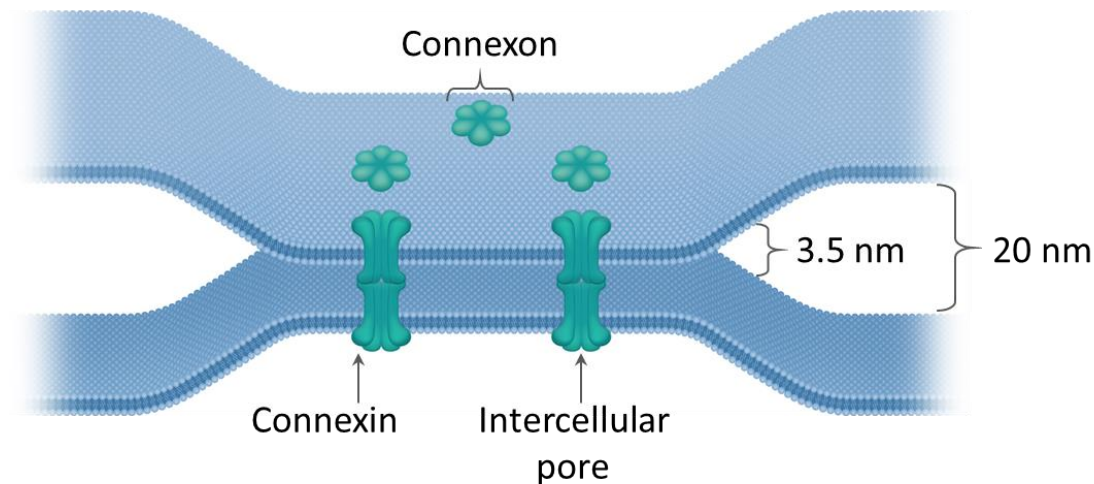


Next step:  
Advice from regulatory authorities

# CONNEXIN 26 IS A GAP-JUNCTION PROTEIN ENCODED BY GJB2 GENE AND RESPONSIBLE FOR TISSUE HOMEOSTASIS MUTATIONS IN THE GENE LEADS TO DEAFNESS

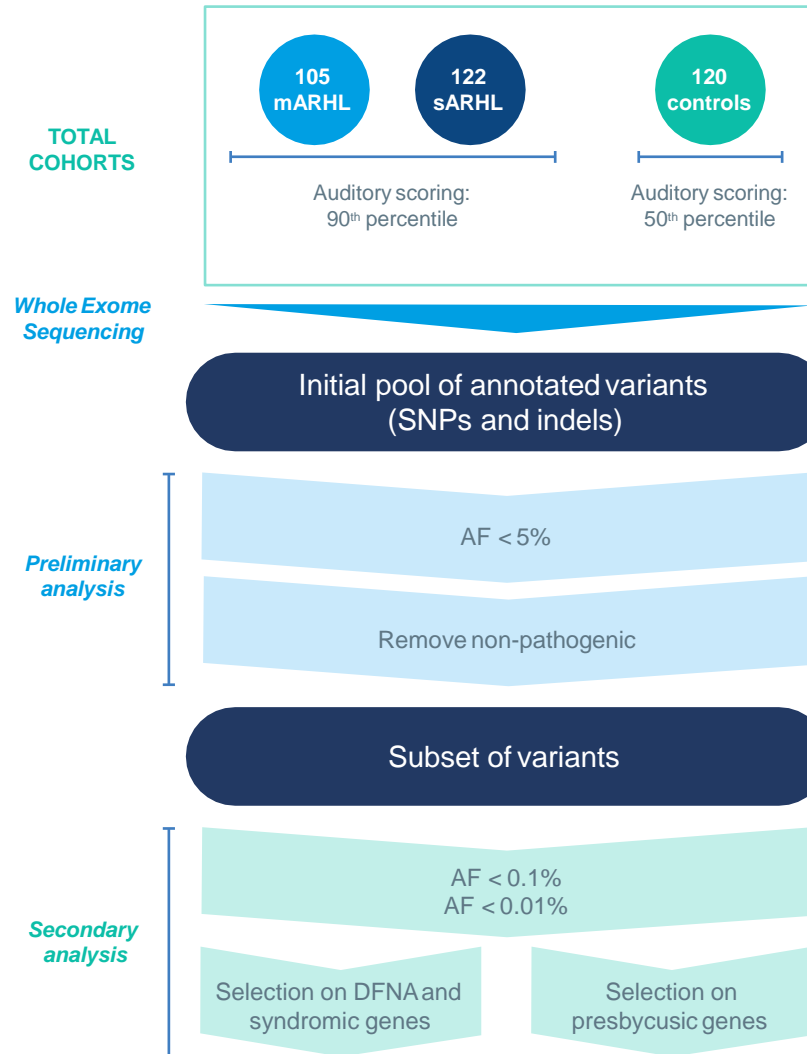
- **GJB2** is the gene encoding for the **Connexin 26** protein; one of 20 known connexins in humans and almost endemic to the cochlea (together with Cx30); **a hexamer of 6 proteins forms Gap Junctions**
- Gap Junctions are **key for the intercellular exchange of molecules** (miRNA, glucose, ions, etc.) 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 being **diagnosed during the newborn screening** routine and current SoC is cochlear implantation prior 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*

# GJB2 HAS BEEN IDENTIFIED AS PART OF INSTITUT PASTEUR'S DELIBERATE AND SYSTEMATIC PROCESS TO IDENTIFY MONOGENIC FORMS OF EARLY ONSET OF SEVERE PRESBYCUSIS



Boucher et al. 2020

- Severe presbycusis is a bilateral progressive loss of hearing starting from a high-frequency region of the hearing spectrum with an onset as early as 30-40 years old.
- Rare predicted pathogenic variants present in genes responsible for early onset forms of deafness explain 25% of all mARHL cases and 25% of sARHL cases. These mutations were not present in the normal population.
- Institut Pasteur's results establish the existence of a continuum of auditory phenotypes, from early-onset forms of deafness to severe presbycusis caused by mutations in the same set of genes.
- They indicate that many severe cases of presbycusis are likely monogenic disorders.

mARHL: family members presenting severe and early onset of presbycusis  
 sARHL: subjects presenting the « worst » severe presbycusis phenotype  
 AF: Allele Frequency

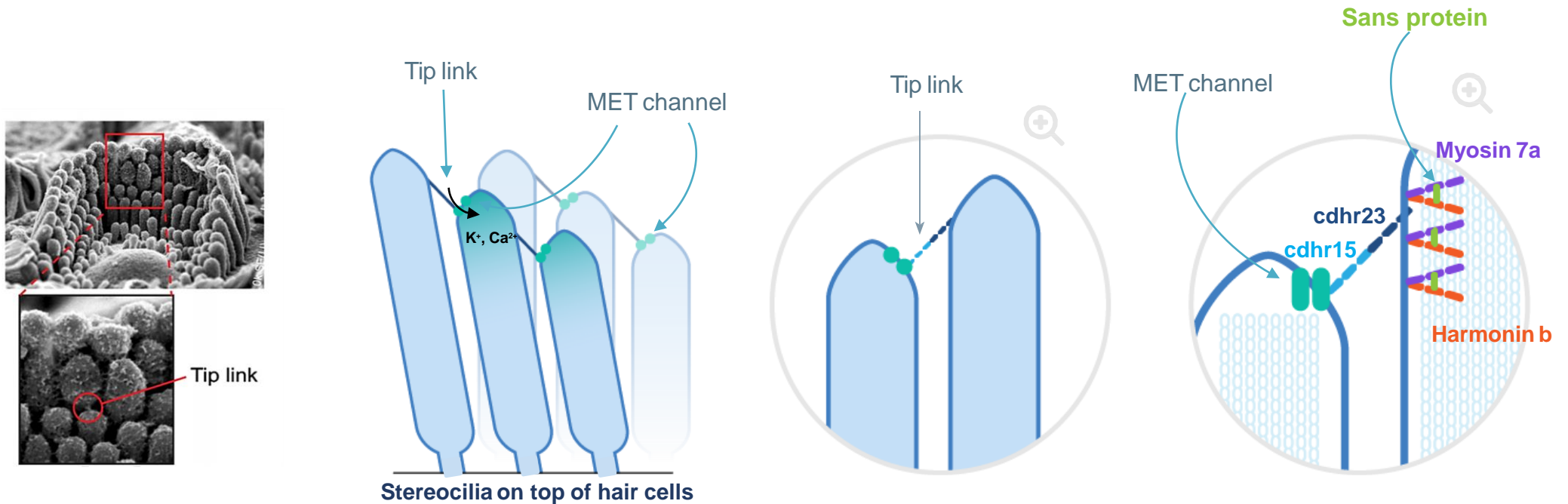
# GJB2 GENE THERAPY PROGRAM NEXT STEPS

Natural history study

Candidate selection

Preclinical IND enabling studies

# USH1G GENE ENCODES "SANS", AN ESSENTIAL PROTEIN FOR MECHANOELECTRICAL TRANSDUCTION



Adapted from Mathur and Yang. 2014

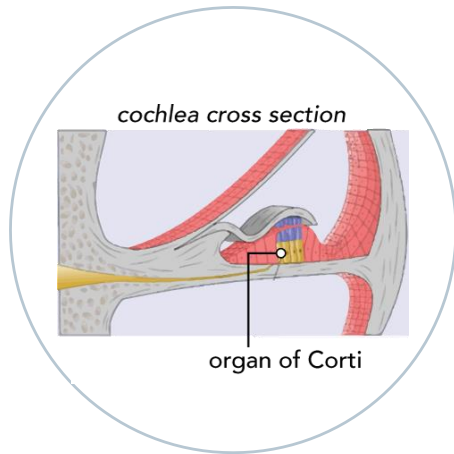
Adapted from Emptoz *et al.* 2017 ([link](#))

Tip links on top of hair cells are translating a vibration due to acoustic stimulation into electrical depolarization by mechanically opening ion channels

The "sans" protein encoded by the USH1G gene is essential for the structural properties of the tip links

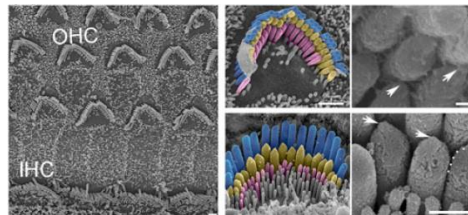
# USH1G GENE THERAPY RESTORED HEARING & VESTIBULAR FUNCTIONS

PROOF OF CONCEPT IN A KNOCK-OUT MOUSE MODEL BY INSTITUT PASTEUR

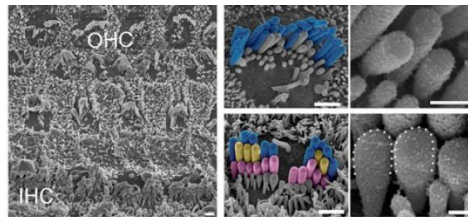


## Cochlear stereocilia

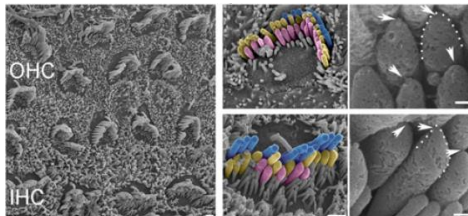
Normal mice



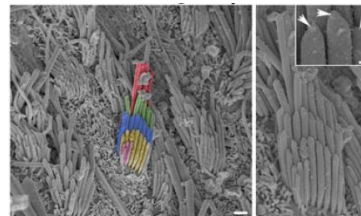
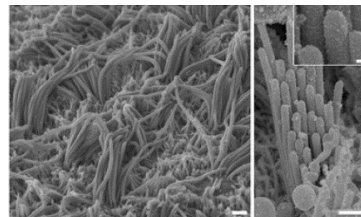
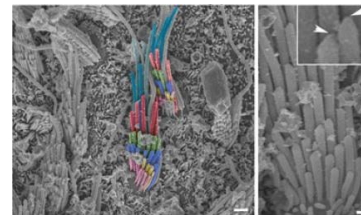
Ush1g<sup>-/-</sup> mice



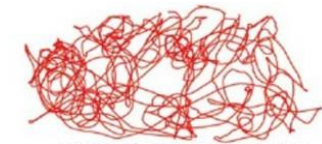
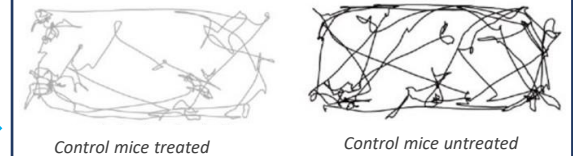
Treated Ush1g<sup>-/-</sup> mice



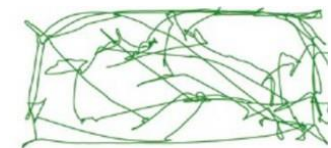
## Vestibular stereocilia



## Mouse displacement recordings in Open Field Test



Ush1g<sup>-/-</sup> untreated mice



Ush1g<sup>-/-</sup> treated mice

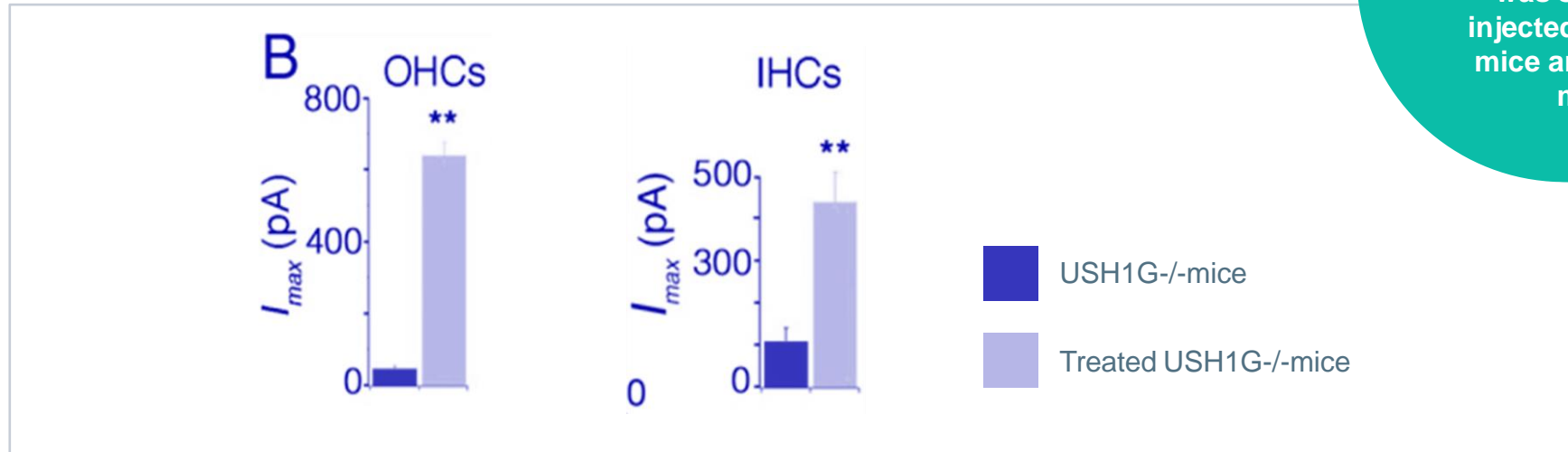
Source: Emptoz *et al.*, "Local gene therapy durably restores vestibular function in a mouse model of Usher syndrome type 1G," 2017 ([link](#))



# USH1G GENE THERAPY RESTORED HEARING & VESTIBULAR FUNCTIONS (CONT.)

PROOF OF CONCEPT IN A KNOCK-OUT MOUSE MODEL BY INSTITUT PASTEUR

Mechanoelectrical transduction (MET) currents recorded *ex vivo* (recording of peak amplitude of the MET currents)



Source: Emptoz *et al.* 2017 (link)

Restoration of stereocilia physiology using AAV8-SANS restored electrical excitability of sensory cells

The sensitivity of the transduction current response to hair bundle displacement was similar in injected USH1G-/- mice and control mice

# USH1G GENE THERAPY PROGRAM STATUS

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PoC data in mouse



In progress: PoC data in mouse with an extended therapeutic window

Next step:  
PoC Non-Human Primates study

Next step:  
Advice from regulatory authorities



**3**

**SENS-401**

**TREAT**

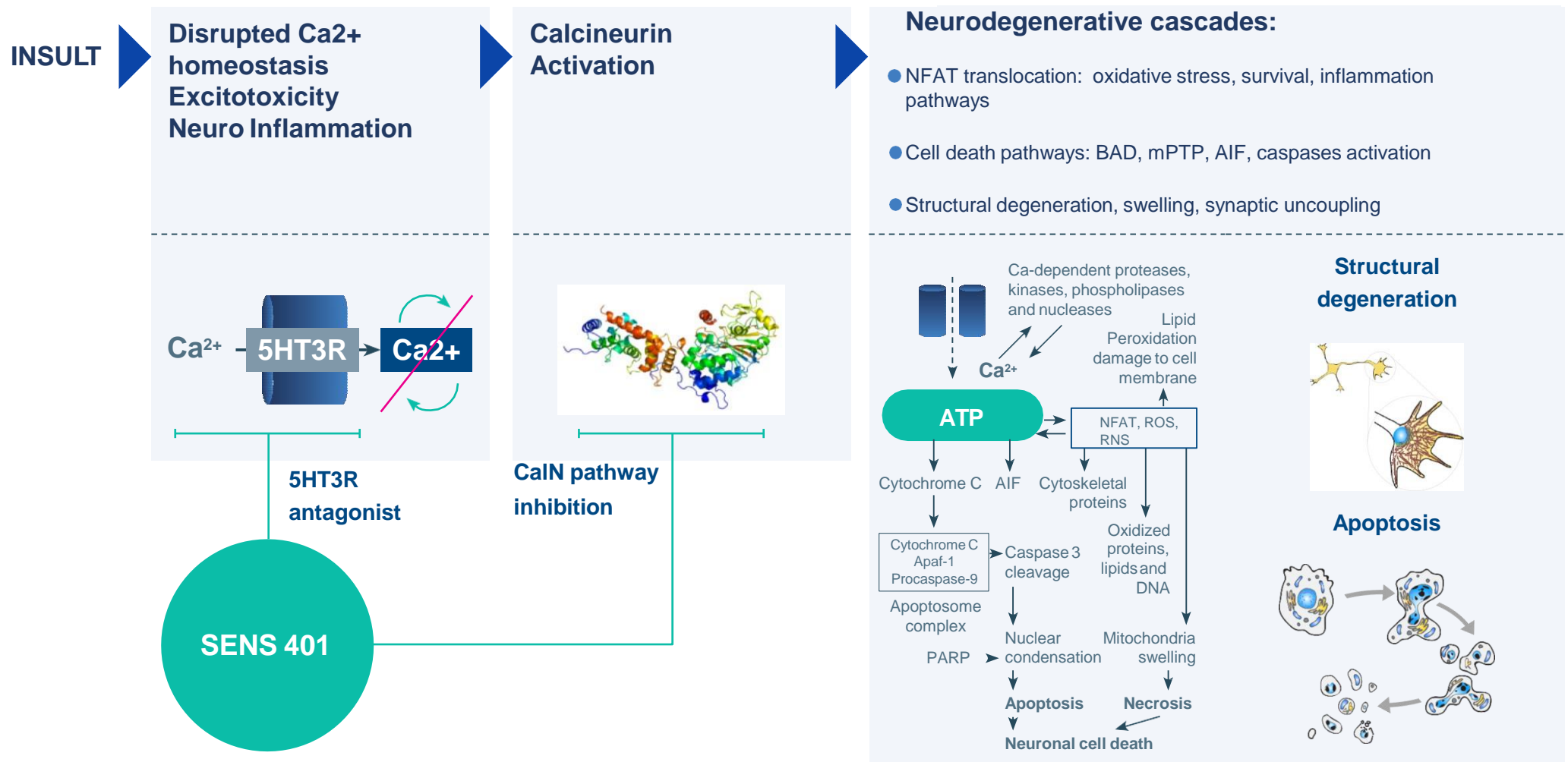
**AND**

**PREVENT**

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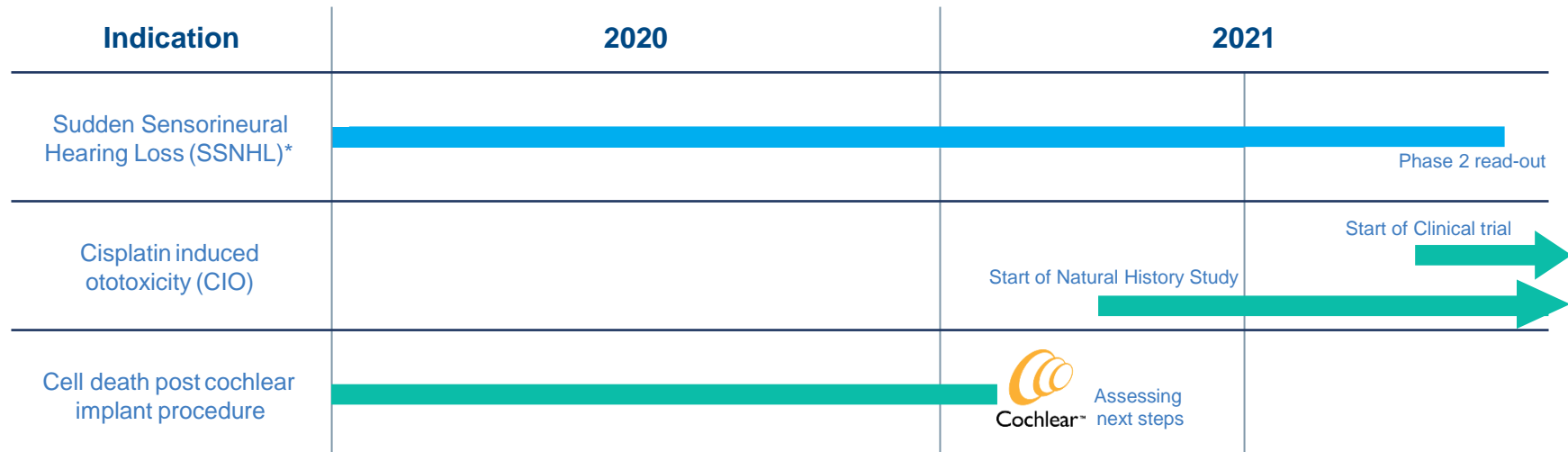


# SENS-401 MECHANISM OF ACTION CREATES THE OPPORTUNITY TO TARGET MULTIPLE INDICATIONS WITH ONE COMPOUND



# SENS-401: MULTIPLE INDICATIONS PURSUED TO TREAT AND PREVENT HEARING LOSS

## ORALLY AVAILABLE SMALL MOLECULE 5HT3 RECEPTOR ANTAGONIST & CALCINEURIN INHIBITOR – ESTIMATED TIMELINES



\* "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 participating in the ongoing Phase 2 study

# SUDDEN SENSORINEURAL HEARING LOSS AND CISPLATIN INDUCED OTOTOXICITY CAN LEAD TO PERMANENT DISABLING HEARING LOSS

## 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>

## 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 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 DEVELOPED TO TREAT SUDDEN SENSORINEURAL HEARING LOSS

## SENS-401 DEMONSTRATED SAFETY IN PHASE 1

- 36 healthy volunteers enrolled in a double-blind, randomized, multiple ascending dose design (7 days)
- No serious or significant adverse event reported, safety profile comparable to placebo
- Pharmacokinetics match effective systemic exposures in pre-clinical model

## SENS-401 MARKET EXCLUSIVITY

- Strong IP with 2 patent families
- Orphan Drug Designation from EMA
- Pediatric Investigation Plan approved in EU

# DAILY ADMINISTRATION OF SENS-401 REDUCES AUDITORY DEFICIT IN RATS

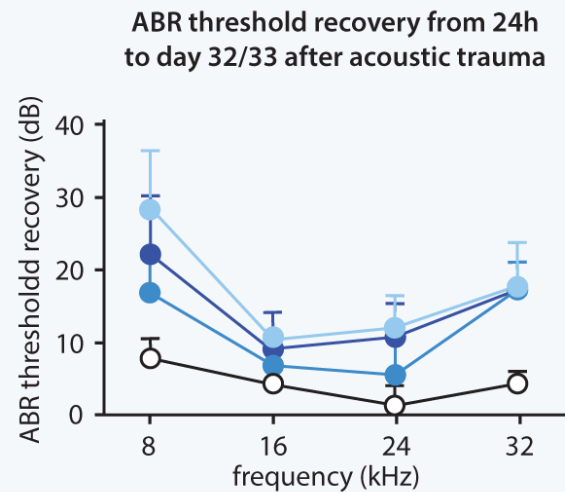
A daily oral administration of SENS-401 (13.2 mg/kg bid) reduces auditory deficit and improves recovery

## MODEL

- Randomized treatment post-noise induced trauma (2h exposure at 120 dB) in rats receiving either twice daily placebo or SENS-401 PO for 28 days

## BENEFIT

- Regulatory threshold for efficacy (>10 dB improvement)
- Significant effects with treatment initiation delay up to 96 hrs



- placebo (n=7)
- SENS-401 from 24h (n=7)  $p < 0.001$
- SENS-401 from 72h (n=8)  $p < 0.012$
- SENS-401 from 96h (n=9)  $p < 0.006$

Petremann *et al.* 2018



# SENS-401 PHASE 2 TO TREAT SSNHL

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

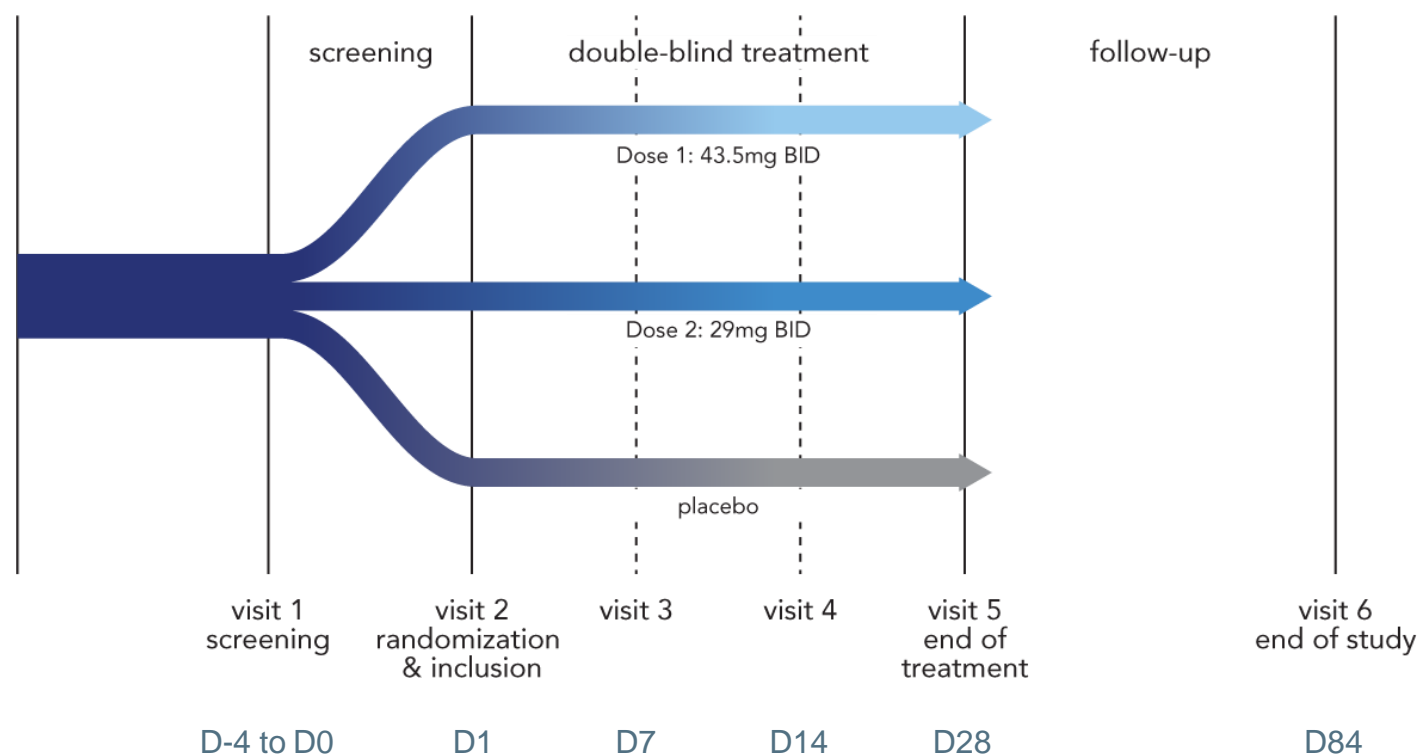
50 clinical sites globally

1 Primary endpoint  
Audiometry  
10dB improvement  
vs. placebo

Enrollment is ongoing\*

## Timing

Q1 2019 center openings	June 2020 Positive DSMB Review	Q4 2021 Final results
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\*After review of the statistical analysis plan, an amendment to the study is currently under review by the regulatory authorities. Should it proceed satisfactorily, this would reduce significantly the sample size without compromising the quality and potential outcome of the trial.

# SENS-401 PRE-CLINICAL PROOF OF CONCEPT IN CISPLATIN INDUCED HEARING LOSS

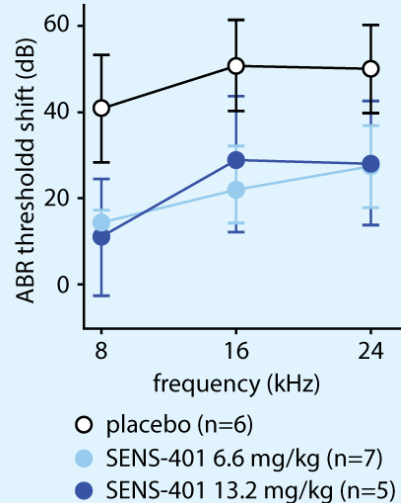
**SIGNIFICANTLY REDUCES CISPLATIN-INDUCED HEARING LOSS AND OUTER HAIR CELL DEATH IN PRE-CLINICAL MODELS**

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

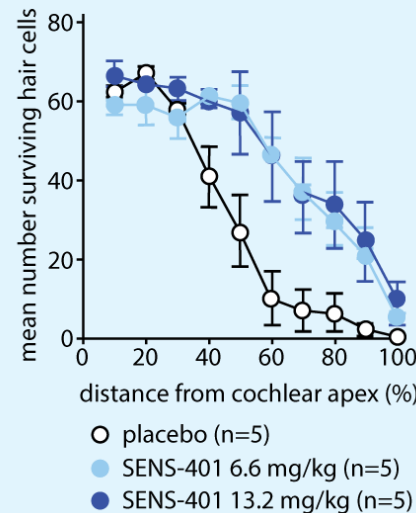
## TREATMENT PROTOCOL

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

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](#))

# COLLABORATION WITH COCHLEAR® LTD

## 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



**34,000**

Implants sold by Cochlear® globally in 2019<sup>1</sup>

**\$1.5bn**

Cochlear implant market in 2018<sup>2</sup>

- In Q4 2017 Sensorion and Cochlear® entered into an agreement to evaluate whether SENS-401 in combination with Cochlear's cochlear implants can reduce cell-death from the implant procedure.
- Cochlear® invested €1.6m in Sensorion equity. In exchange, Cochlear® received a right of first negotiation for a global license to use SENS-401 in combination with its implantable devices
- Cochlear and Sensorion assessing next steps, including options for clinical studies with SENS-401 in cochlear implant patients after encouraging pre-clinical results showing loss of residual hearing at a frequency located beyond the electrode array as well as electrode impedance reduction


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

<sup>1</sup>Cochlear® 2019 annual report ([link](#))

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

# SENSORION

## Potential Newsflow [Estimated timelines]

- **Q1 2021** – Final pre-clinical data for SENS-401 in cochlear implant study 
- **Mid-year 2021** – Start of CIO Natural History Clinical Trial
- **Mid-year 2021** – Ongoing approvals of the protocol amendment to reduce sample size for the SENS-401 Phase 2 study in SSNHL
- **Mid-year 2021** – Discussions with regulatory authorities on potential OTOF clinical study
- **Mid-year 2021** – Confirmatory pre-clinical PoC studies for USHER-GT
- **H2 2021** – Initiation of CIO Clinical Study in adults with SENS-401
- **Q4 2021** – Phase II readout from SENS-401 clinical study in SSNHL

# INVESTMENT HIGHLIGHTS

- Sensorion is focused on **innovative treatments** that can **restore, treat and prevent hearing loss**
- **Three novel gene therapy programs** targeting unmet needs in **Otoferlin Deficiency, GJB2-related hearing loss** and **Usher Syndrome Type 1**
  - **Promising pre-clinical data** demonstrating improvement and restoration of hearing and vestibular functions (OTOF/USH1)
- **Exclusive relationship with Institut Pasteur** for all Inner Ear Gene Therapy Programs during the timeframe of the agreement
- Phase 2 study for **Sudden Sensorineural Hearing Loss with an oral small molecule**
  - Global, randomized study with **data expected in Q4 2021**
- **Experienced management team** with broad expertise in gene therapy and drug development
- Strong shareholder support from **leading blue-chip investors**



SOFINNOVA

bpi**france**

## FINANCIAL OVERVIEW

Date Established.....	2009
IPO .....	2015
Euronext Paris .....	ALSEN.PA
Cash (Dec 31, 2020): .....	€62.2m
<i>Cash runway until end of H2 2022</i>	

# THANK YOU

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Chief Executive Officer

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