

Sensorion



January 2022

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1

SENSORION



Investments Highlights

- Sensorion is focused on **innovative treatments** that can **restore, treat and prevent hearing loss**
 - **Its oral small molecule asset SENS-401** currently investigated in clinical studies:
 - **In Sudden Sensorineural Hearing Loss** indication Phase 2 secondary endpoints released mid- March 2022
 - **In Cisplatin Induced Ototoxicity (NOTOXIS study)** Submission of the Phase 2 PoC CTA in December 2021
 - Sensorion and **Cochlear Ltd** to submit a CTA for SENS-401 in patients scheduled for cochlear implantation
 - **Three novel gene therapy programs** targeting monogenic forms of deafness in **Otoferlin Deficiency, GJB2-related hearing loss and Usher Syndrome Type 1**
- **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 and Sonova**
- Strong shareholders support from **leading blue-chip investors**



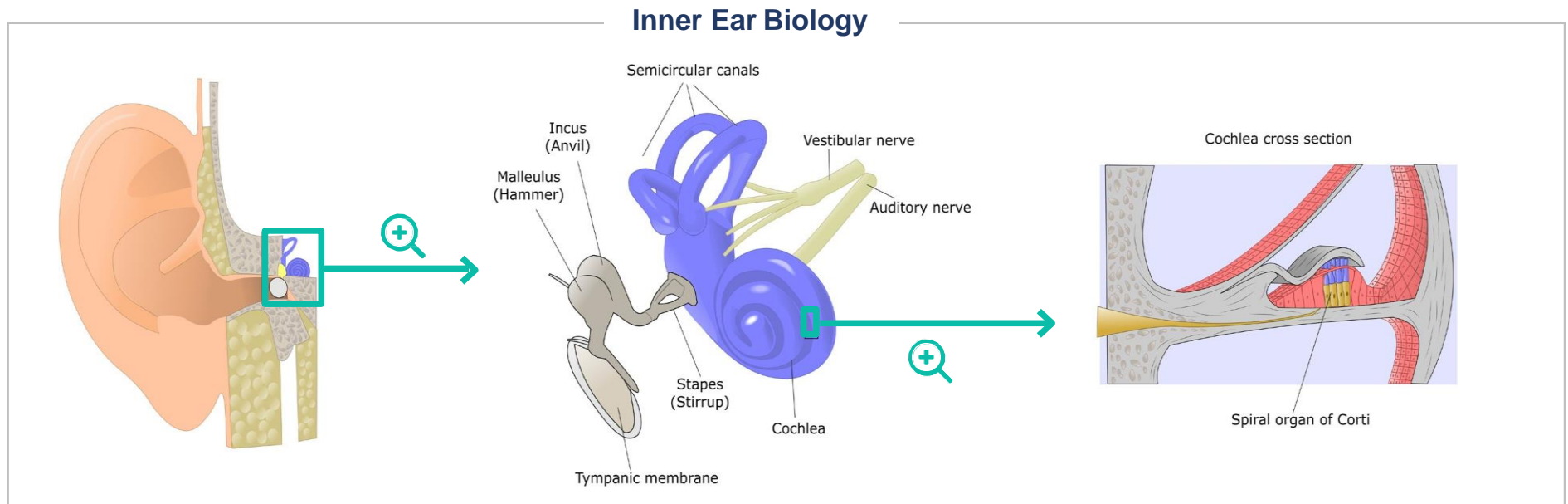
SOFINNOVA

bpifrance

FINANCIAL OVERVIEW

Date Established.....	2009
IPO	2015
Euronext Paris	ALSEN.PA
Cash (June 30, 2021)	≈€55m
<i>Cash runway until end of H2 2022</i>	

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*:

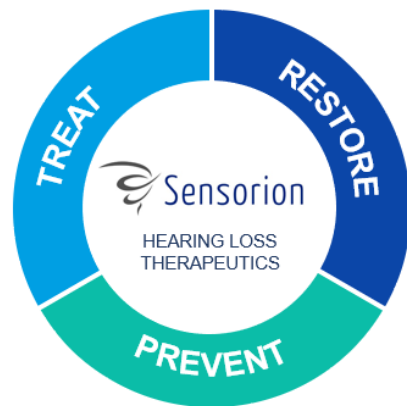
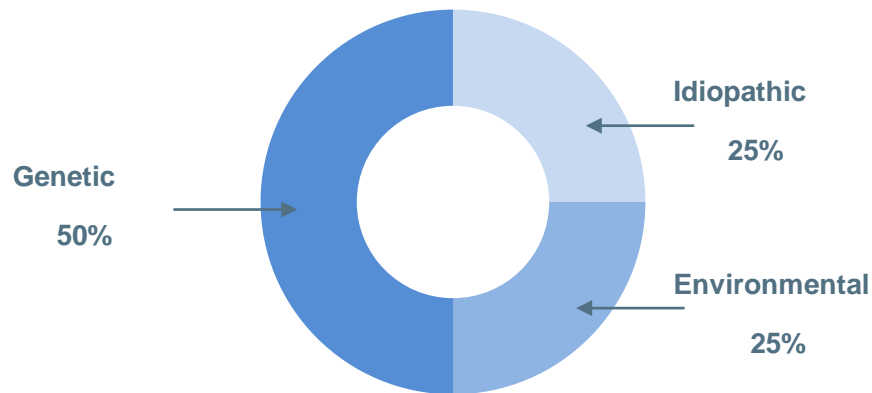
~ 466m people affected by disabling hearing loss worldwide

~ 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
- CTA submission Notoxix for Phase 2 PoC study with SENS-401 to **PREVENT** Cisplatin-induced Ototoxicity
- Pre-clinical study completed with SENS-401 to **PREVENT** cell death following cochlear implant procedure

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 and vestibular functions in Usher Syndrome Type 1

Our critical strategic alliances from bench to bedside



- 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



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

TRANSLATIONAL RESEARCH

SENSORION



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

DIAGNOSIS & PATIENT JOURNEY



- 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)

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), OTOF-GT and USHER-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

SENSORION
(Since 2017)

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



GÉRALDINE HONNET
Chief Medical Officer

SENSORION
(Since 2020)

GENETHON
(2011-2020)
Director of Development



NORA YANG
Chief Scientific Officer

SENSORION
(Since 2021)

STRATIFY
(2020-2021)
Cofounder and CSO



OTMANE BOUSSIF
Chief Technical Officer

SENSORION
(Since 2021)

NOVARTIS
(Since 2015)
Head Cell &
Gene Therapy T. Dev.



STEPHANIE FILIPE
Head of PMO

SENSORION
(Since 2020)

CELLECTIS
(2016-2020)
Program Leader &
Preclinical Manager

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, 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



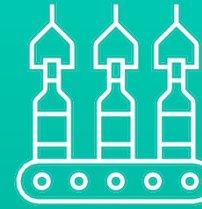
PRECLINICAL CAPABILITIES FOR SMALL MOLECULES & GT PROGRAMS

- **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



2

SENS-401

TREAT

AND

PREVENT



SENS-401: multiple indications with one compound

Sudden Sensorineural Hearing Loss

Cisplatin Induced Ototoxicity

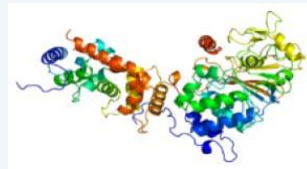
Cochlear Implantation

5-HT3 antagonist & modulates calcineurin activity

INSULT

Disrupted Ca²⁺ homeostasis
Excitotoxicity
Neuro Inflammation

Calcineurin Activation



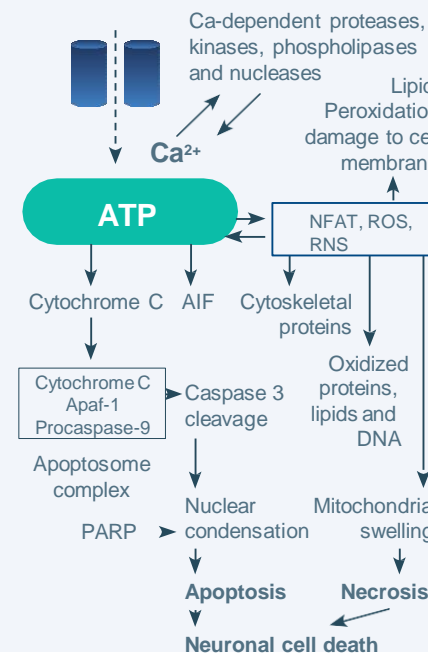
5HT3R antagonist

CaN pathway inhibition

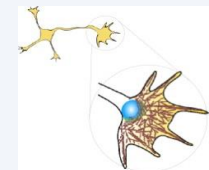
SENS 401

Neurodegenerative cascades:

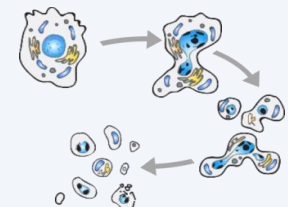
- NFAT translocation: oxidative stress, survival, inflammation pathways
- Cell death pathways: BAD, mPTP, AIF, caspases activation
- Structural degeneration, swelling, synaptic uncoupling



Structural degeneration



Apoptosis



SENS-401: Multiple indications to treat and prevent hearing loss

TREAT

PREVENT

Product	Indication	Discovery	In vivo POC	Preclinical	Phase I	Phase II	Phase III	
SENS-401	Sudden sensorineural hearing loss*							
SENS-401	Cisplatin induced ototoxicity							
SENS-401	Hearing preservation after cochlear implantation							

*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)¹

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 countries¹

¹ 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

SENS-401 SSNHL Program: Phase 2 design

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

50 clinical sites globally

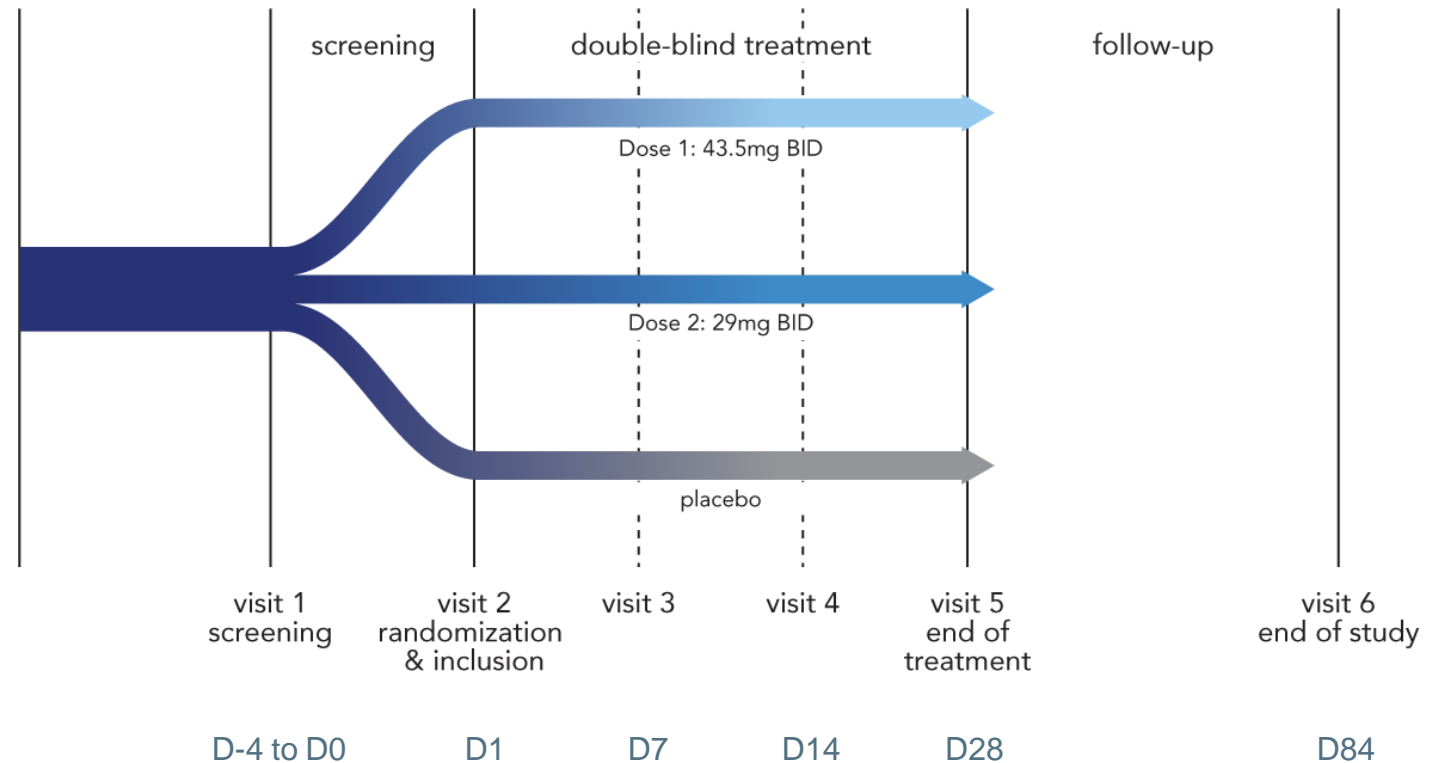
1 Primary endpoint
Audiometry
15 dB improvement vs.
Placebo

115 patients enrolled*

Timing

Q1 2019 center openings	June 2020 Positive DSMB Review	Q1 2022 Final results
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*Recruitment completed end of October 2021



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 SSNHL Program: Phase 2 results

AUDIBLE-S PRIMARY ENDPOINT RESULTS

- Safe and well tolerated in 115-patient SSNHL study; primary endpoint not met
- A sub-analysis in participants with hearing threshold ≥ 80 dB (severe hearing loss) showed a better response compared to placebo at the two doses. This subgroup accounted for 30% of the overall study population
- These results confirm the data we obtained in our preclinical model of severe noise induced hearing loss
- Sensorion will continue to analyze the data from the AUDIBLE-S study and update the market mid-March 2022 following the analysis of the secondary endpoints
- Sensorion continues to develop SENS-401 in other indications

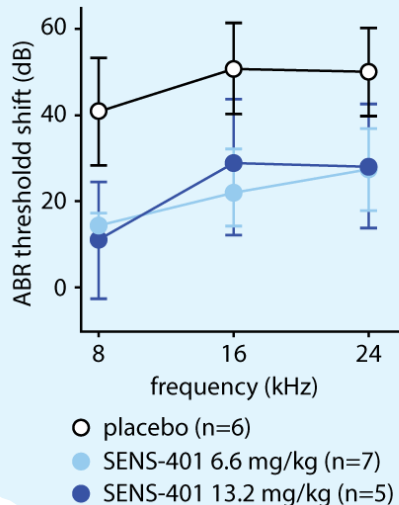
SENS-401 Cisplatin Induced Ototoxicity preclinical results led to POC clinical study submission (NOTOXIS study)

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

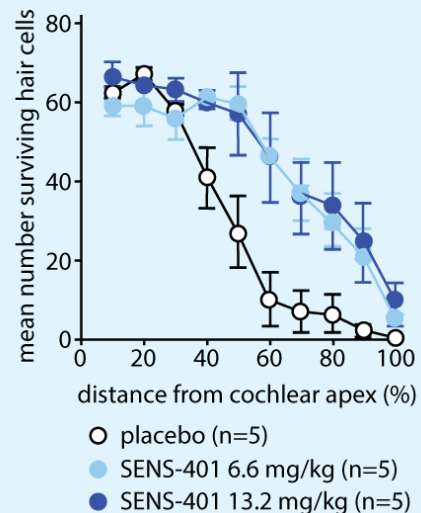
TREATMENT PROTOCOL

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



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

Submission of SENS-401 NOTOXIS clinical study in adults with CIO in H2 2021

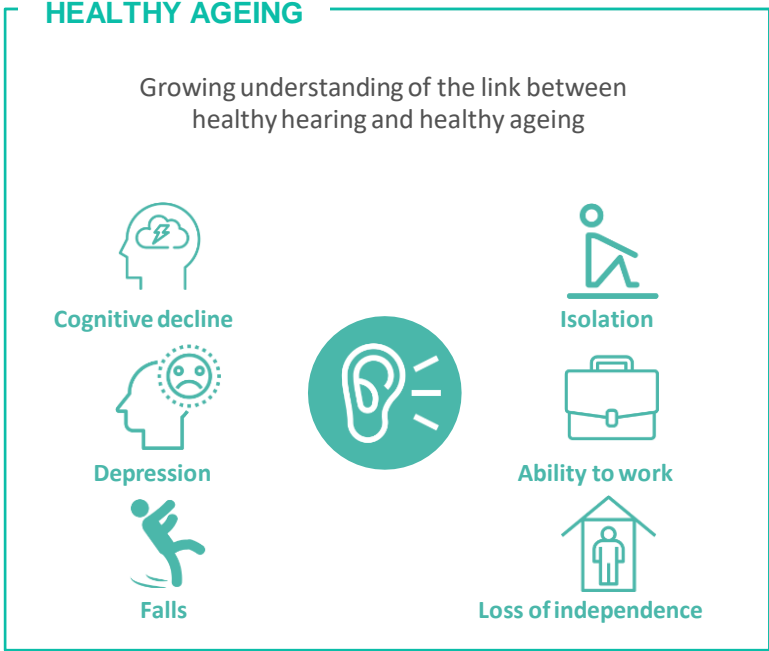
Significant improvement versus placebo
 23-28 dB with 6.6 mg/kg ($p < 0.010$)
 22-30 dB with 13.2 mg/kg ($p < 0.013$)

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](#))

SENS-401 clinical study submission to preserve residual hearing post cochlear implementation

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



31,600
Implants sold by Cochlear® globally in 2020¹

\$1.4bn
Cochlear implant market in 2020²

- 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 to begin first clinical trial of SENS-401 for hearing preservation in combination with cochlear implantation after encouraging in vivo preclinical studies showing preservation of residual acoustic hearing at statistically significant levels at a frequency located beyond the electrode array

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

¹Cochlear® 2020 financial report ([link](#))

²Market estimates ([link](#))

SENS-401 program next steps

Secondary endpoints data readout SENS-401 in SSNHL Mid-March 2022

CTA submission for SENS-401 study to preserve residual hearing post cochlear implementation H1 2022

Receive CTA approval for NOTOXIS H1 2022

Start enrolment in the NOTOXIS study

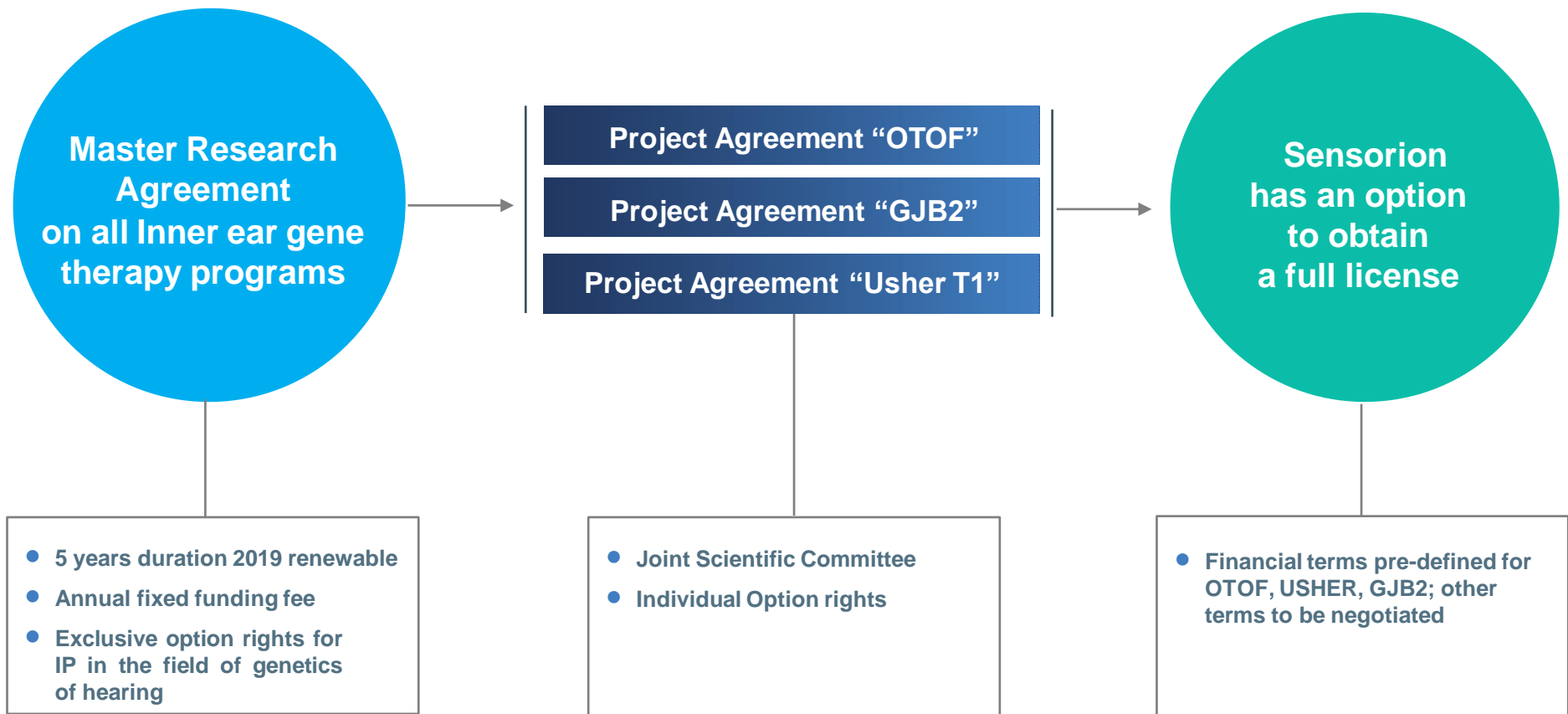


3

**GENE
THERAPY
RESTORE**

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

3 PROGRAMS INITIATED UNDER THE COLLABORATION AGREEMENT WITH INSTITUT PASTEUR
Rare disease, high unmet medical need



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

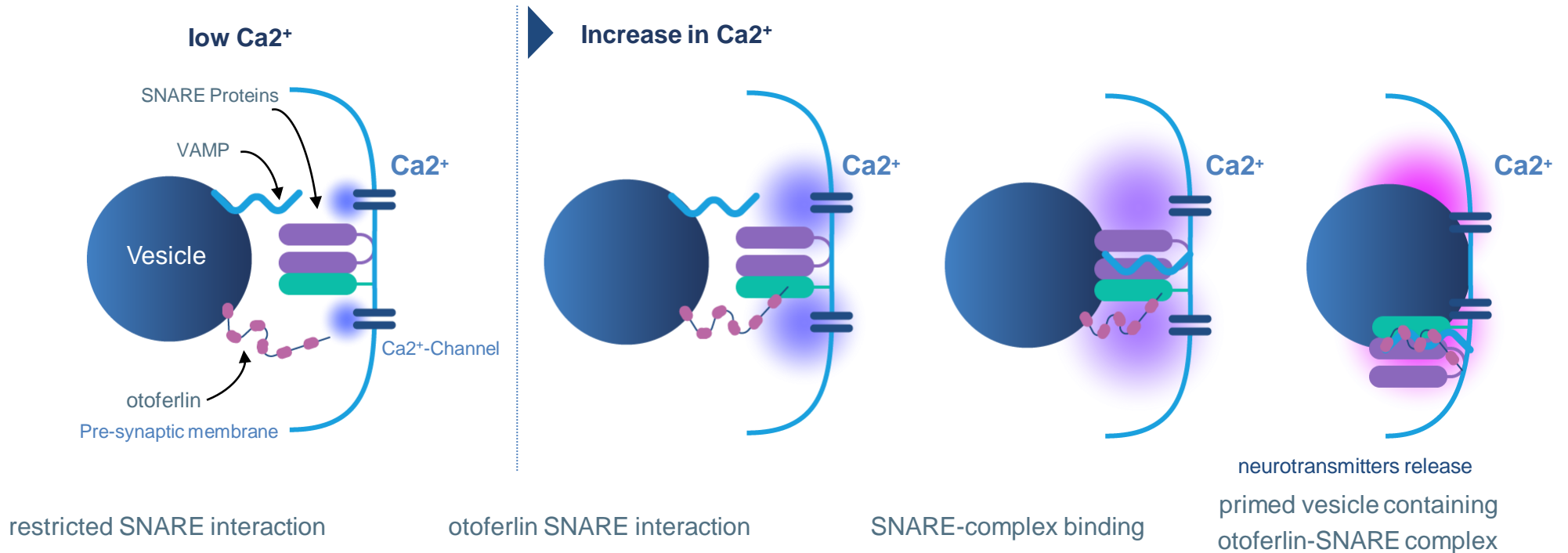
- Patients with Usher Syndrome Type 1 are born with severe to profound congenital bilateral sensorineural hearing loss and congenital vestibular dysfunction. Progressive vision loss appears during childhood
- Prevalence of Usher Syndrome: 4-17 per 100,000 people (~13k-55k patients in EU5 countries; ~13k-56k 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 Ca^{2+} sensor protein

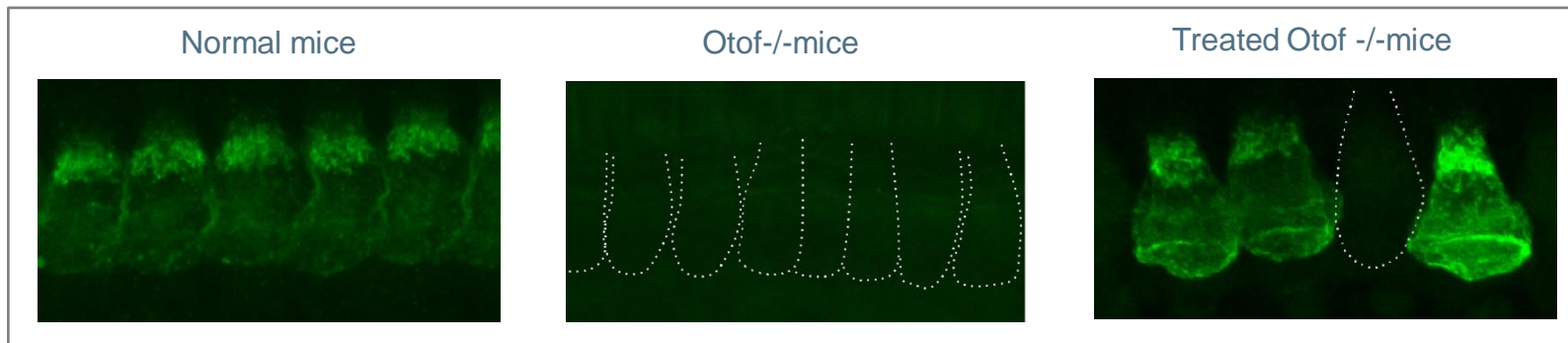


Model illustrating calcium regulation of otoferlin/SNARE interaction in the hair cell. – Adapted from Ramakrishnan *et al.* 2014

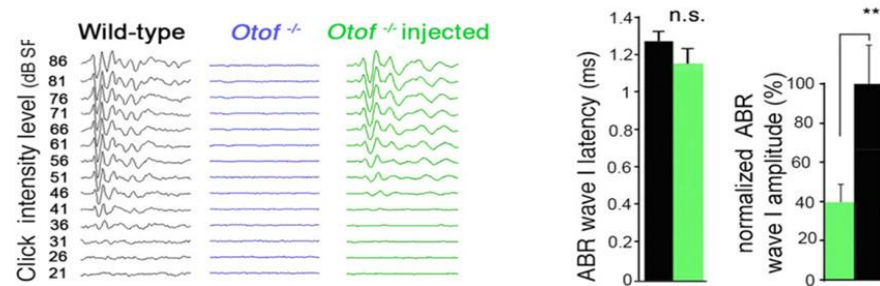
OTOF is the gene coding for the Otoferlin protein, a Ca^{2+} sensor for vesicle fusion and vesicle pool replenishment at auditory hair cell ribbon synapses

Institut Pasteur's important work that established feasibility of AAV gene therapy to restore hearing in OTOF knockout mice

IMMUNOSTAINED INNER HAIR CELLS IN WILD TYPE, OTOF $-/-$ AND OTOF $-/-$ INJECTED WITH DUAL AAV2 QUADY-F OTOF VECTOR EXPRESSION OF OTOF PROTEIN IN COCHLEAR RECEPTORS



RESTORATION OF AUDITORY FUNCTION IN OTOF $-/-$ 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
- Audioferline: Natural History Study: 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

AUDINNOVE CONSORTIUM MEMBERS




The Audinnove Consortium Members section features four logos arranged vertically. At the top is the Sensorion logo, which includes a stylized bird-like icon and the word 'Sensorion'. Below it is the Institut Pasteur logo, consisting of a stylized 'P' in a circle followed by the text 'INSTITUT PASTEUR'. The third logo is for Necker Enfants Malades Hospital, showing the word 'Necker' in a large font, 'ENFANTS MALADES' in a smaller font below it, and 'HÔPITAL UNIVERSITAIRE' at the bottom, with a colorful graphic of three stylized figures. The bottom logo is the Fondation pour l'audition logo, a circular emblem with the text 'FONDATION POUR L'AUDITION' and 'À L'ÉCOUTE DE LA VIE' around the perimeter.




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)

OTOF gene therapy program status

PoC data in mouse 

PoC preliminary data in Non-Human Primates 

Product Development and Manufacturing Agreement 

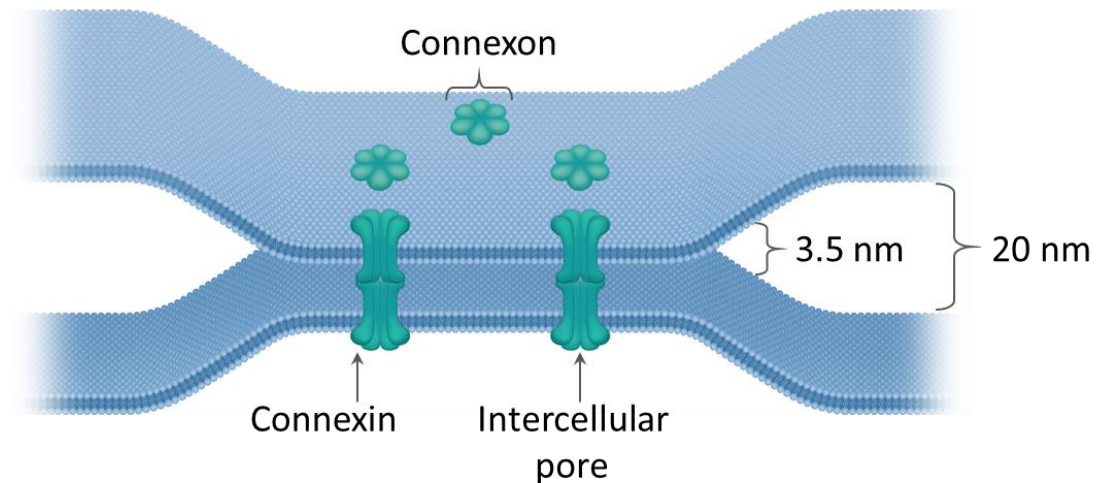
Advice from regulatory authorities 

Submission of European Natural History Study OTOCONEX

Clinical Trial Application H1 2023

CONNEXIN 26: 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 **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

GJB2 gene therapy program next steps



Submission of European Natural History Study OTOCONEX

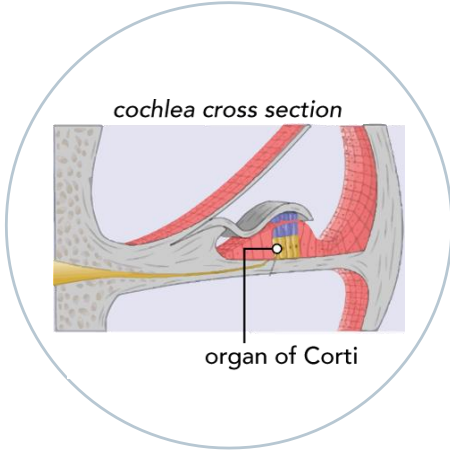
Submission of Natural History Study in collaboration with Sonova

Candidate selection mid 2022

Preclinical IND enabling studies

USH1G gene therapy restored vestibular functions

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



Cochlear stereocilia

Normal mice

OHC

IHC

Ush1g^{-/-} mice

OHC

IHC

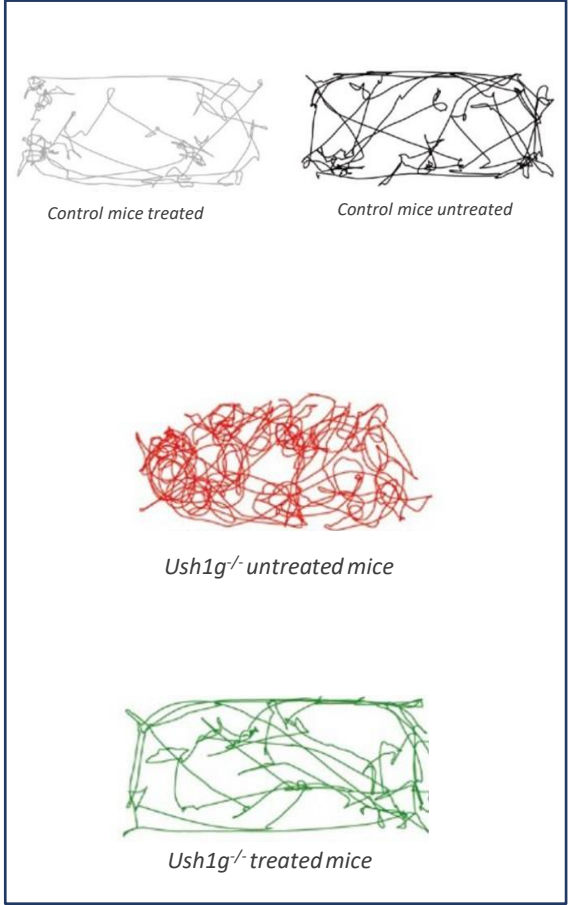
Treated Ush1g^{-/-} mice

OHC

IHC

Vestibular stereocilia

Mouse displacement recordings in Open Field Test

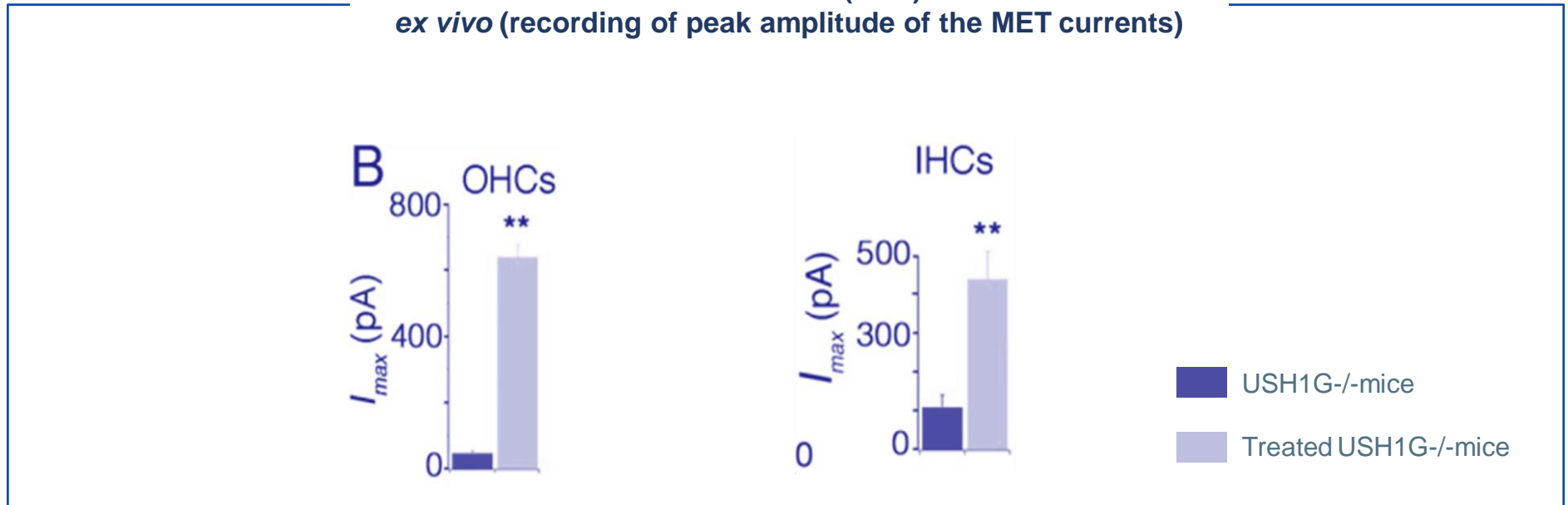


Source: Emptoz et al., "Local gene therapy durably restores vestibular function in a mouse model of Usher syndrome type 1G," 2017 ([link](#))

USH1G gene therapy restored hearing functions

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)

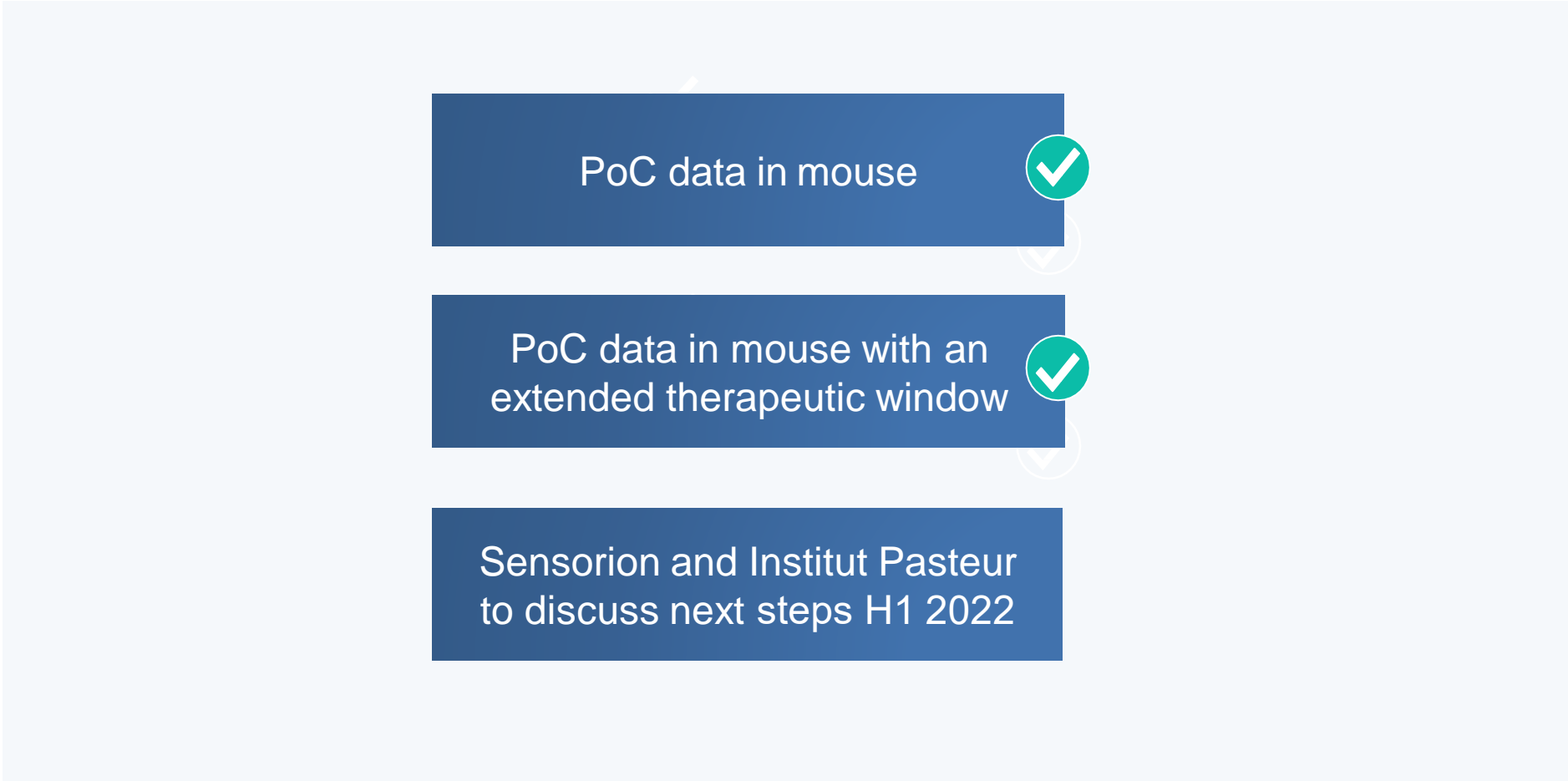


Source: Emptoz et al. 2017 ([link](#))

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

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

USH1G gene therapy program status



Sensorion potential newsflow [estimated timelines]

- Mid-March 2022 – Secondary endpoints data readout for the SENS-401 Phase 2 clinical study in SSNHL
- April 28, 2022 – Full year financial results
- H1 2022 – Start of the SENS-401 NOTOXIS study in CIO
- H1 2022 – CTA submission for SENS-401 study to preserve residual hearing post cochlear implementation
- H1 2022 – Sensorion and Institut Pasteur disclosing next steps for the USHER-GT program
- Mid-2022 – GJB2-GT Candidate selection
- H1 2023 – Submission of the clinical trial application for the OTOF-GT program (CTA/IND)

THANK YOU

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