

# 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 quarantee 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 2021 Annual Financial Report published on 9 April 2021 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

# INVESTMENT HIGHLIGHTS

- Sensorion is focused on innovative treatments that can restore, treat and prevent hearing loss
- Phase 2 study for Sudden Sensorineural Hearing Loss with an oral small molecule
  - Global, randomized study with topline data release in January 2022
- 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
- Experienced management team with broad expertise in gene therapy and drug development
- Strong shareholder support from leading blue-chip investors





# **FINANCIAL OVERVIEW**

Date Established 2009 Euronext Paris ......ALSEN.PA Cash (June 30, 2021): ....≈€55m Cash runway until end of H2 2022



# **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



STEPHANIE FILIPE Head of PMO

#### SENSORION (Since 2020)

#### CELLECTIS (2016-2020) ogram Leader & Preclini

# Program Leader & Preclinical Manager

#### OTR3 (2008-2015) R&D Director & Clinical Project Manager

# SENSORION

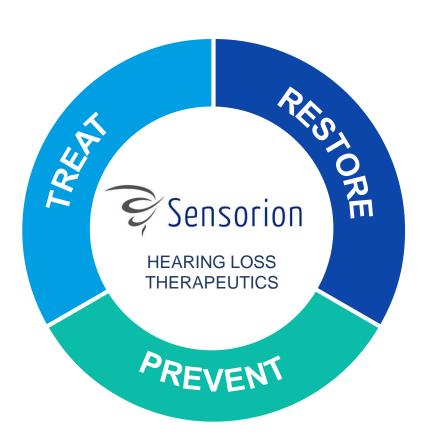
# Sensorion is building up a gene therapy franchise in collaboration with Institut Pasteur

- 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), Necker Hospital and Sonova
  - ~€69.1m raised with key investors including Invus, Sofinnova Partners, Wuxi Apptec and 3SBio

# **FINANCIAL OVERVIEW**

Date Established	2009
IPO	2015
Euronext Paris	ALSEN.PA
Cash (June 30, 2021):	≈€55m
Cash runway until and of H2 2022	

# 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

# SENSORION FORMED 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



**SENSORION** 



- Access to a military population at risk of noise-induced hearing loss
- Strong medical network, strict monitoring and precise, regular, welldocumented 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





- 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
- One of Sensorion's shareholders
- Collaboration to initiate Natural History in presbycusis



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

# 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



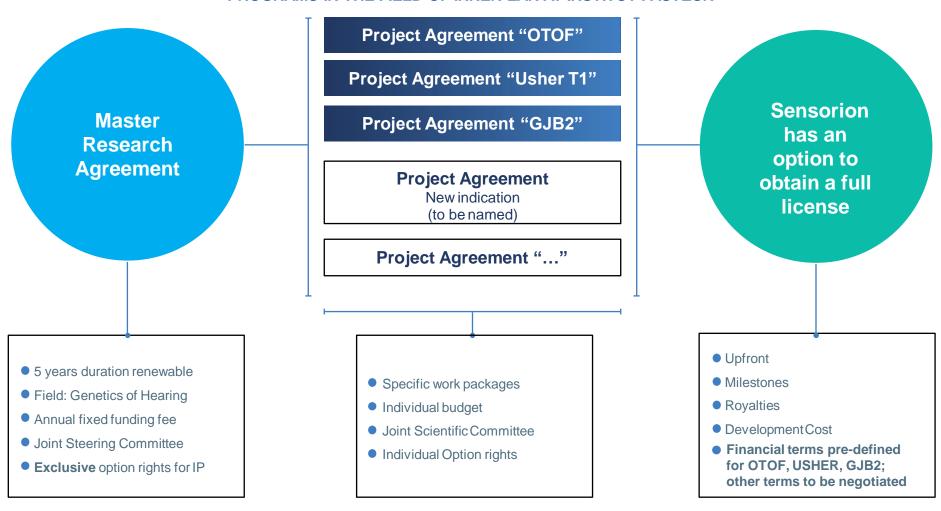
# GENETICS AND PHYSIOLOGY OF HEARING UNIT AT INSTITUT PASTEUR LED BY PROFESSOR CHRISTINE PETIT

- >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

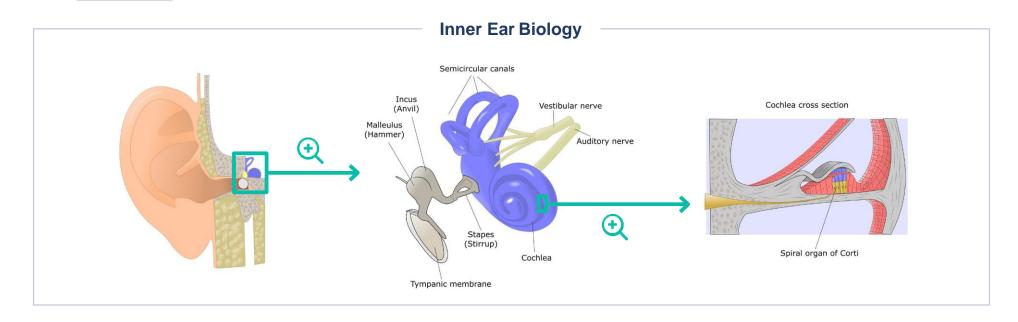
- Physicist and Medical Doctor in Biophysics
- Head of the Center for Research and Innovation in Human Audiology at Hearing Institute (Paris)
- Designed original objective methods of exploration of the cochlea and auditory pathways



**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 preclinical 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 BY

**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



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

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



# 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

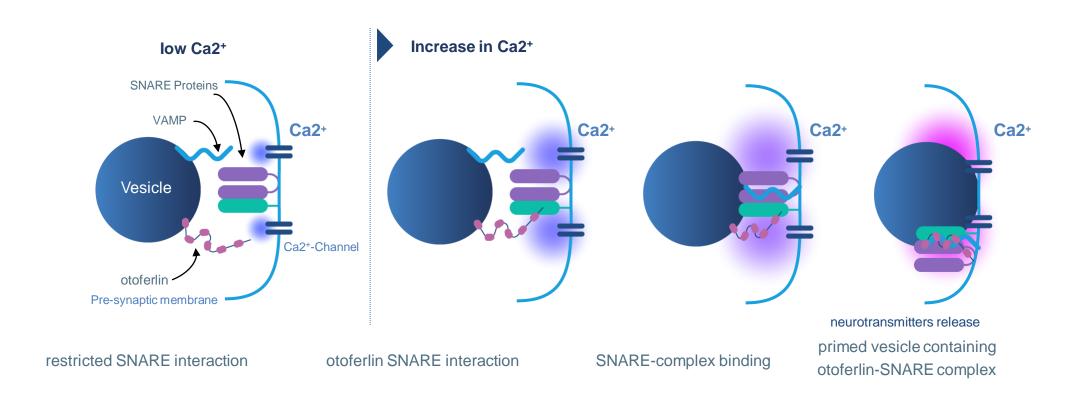
We are addressing the USH1G mutations

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

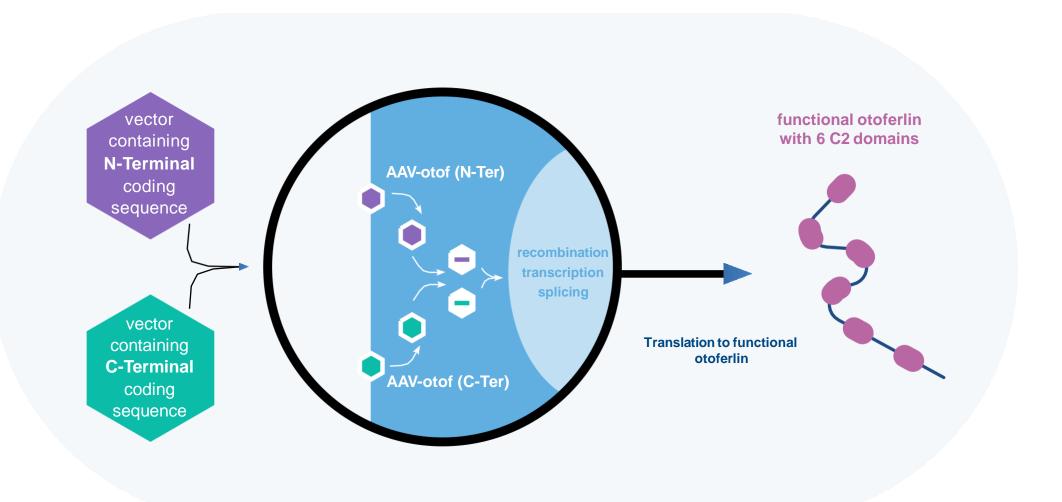
# OTOF GENE ENCODES OTOFERLIN, A KEY CA<sup>2+</sup> SENSOR PROTEIN



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 Ca2+ sensor for vesicle fusion and vesicle pool replenishment at auditory hair cell ribbon synapses

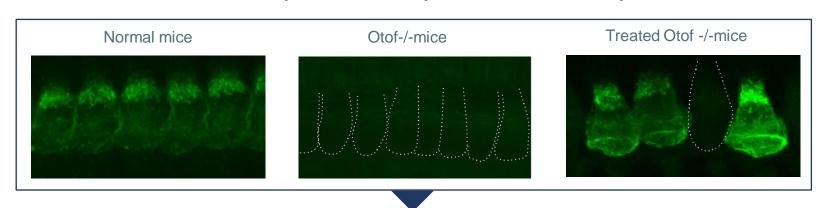
# DUAL AAV OTOF GENE THERAPY - MECHANISM OF ACTION

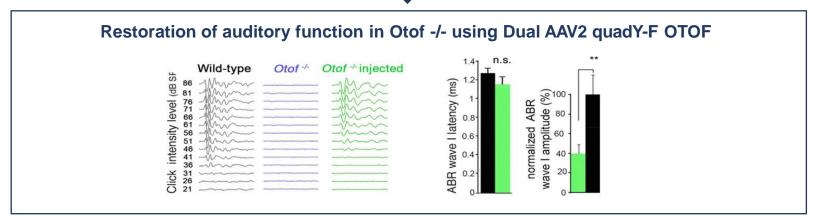




# PRE-CLINICAL OTOF GENE THERAPY PROOF OF CONCEPT DURABLY RESTORES COCHLEAR RECEPTOR FUNCTION IN A KNOCK-OUT MOUSE MODEL

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





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













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



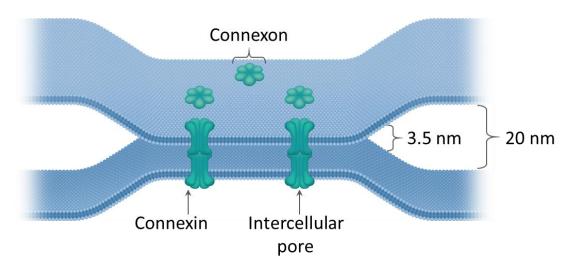
Advice from regulatory authorities



**Clinical Trial Application** 

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

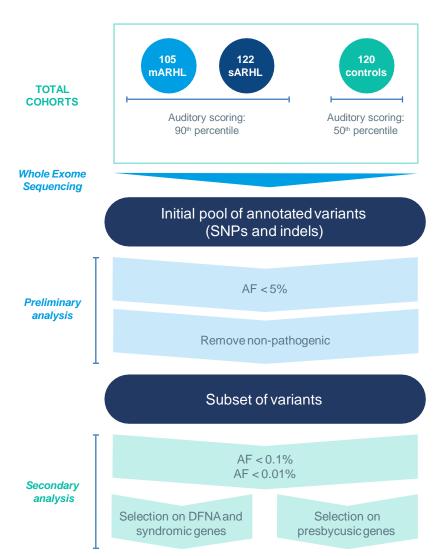
- GJB2 is the gene encoding for the Connexin 26 protein; one of 20 known connexins in humans and almost endemic to the cochlea (together with Cx30); a hexamer of 6 proteins forms Gap Junctions
- Gap Junctions are key for the intercellular exchange of molecules (miRNA, glucose, ions, etc.) hence responsible 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



- 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

Boucher et al. 2020

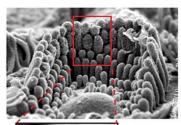
# GJB2 GENE THERAPY PROGRAM NEXT STEPS

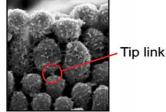
Natural History Study

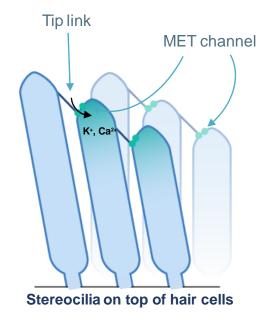
Candidate selection

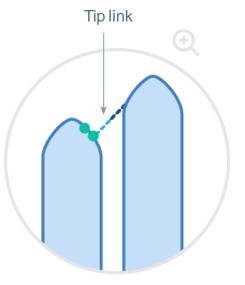
Preclinical IND enabling studies

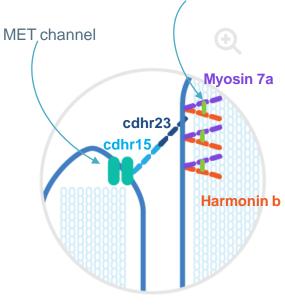
# USH1G GENE ENCODES "SANS", AN ESSENTIAL PROTEIN FOR MECHANOELECTRICAL TRANSDUCTION











Sans protein

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

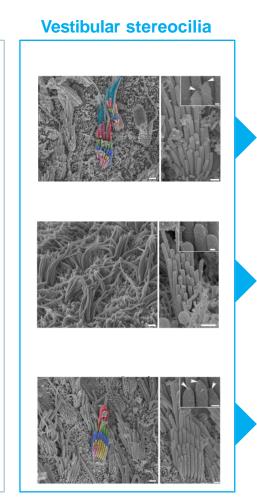
# USH1G GENE THERAPY RESTORED HEARING & VESTIBULAR FUNCTIONS

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

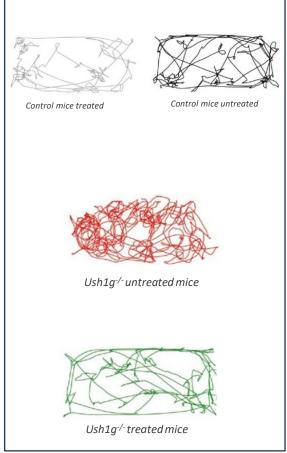
Cochlear stereocilia

Normal mice

# organ of Corti Ush1g-/-mice OHC Treated Ush1g-/-mice OHC



# Mouse displacement recordings in Open Field Test



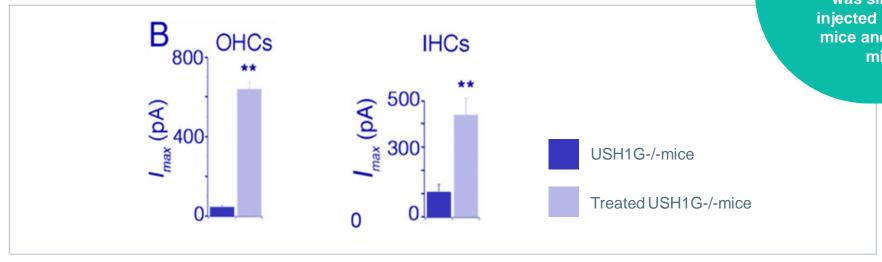
Source: Emptoz *et al.*," Local gene therapy durably restores vestibular function in a mouse model of Usher syndrome type 1G," 2017 (<u>link</u>)

# WISHIG 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)

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



Source: Emptoz et al. 2017 (link)

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

# **USH1G GENE THERAPY PROGRAM STATUS**

PoC data in mouse



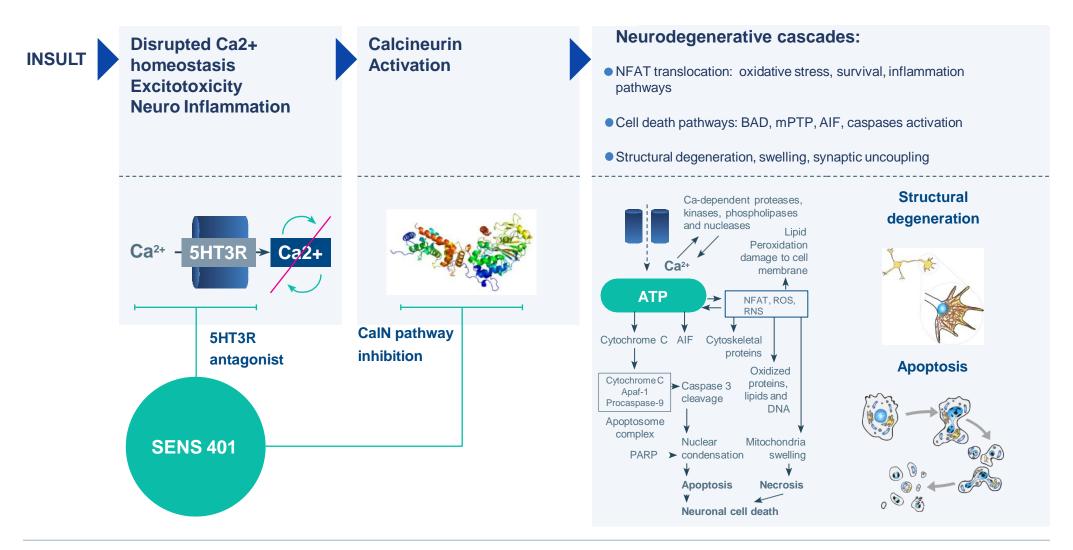
PoC data in mouse with an extended therapeutic window



Sensorion and Institut Pasteur discussing next steps

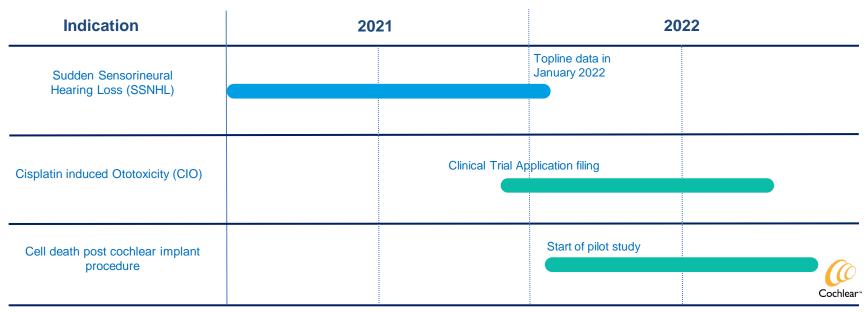


# SENS-401 MECHANISM OF ACTION CREATES THE OPPORTUNITY TO TARGET MULTIPLE INDICATIONS WITH ONE COMPOUND



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

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



<sup>\* &</sup>quot;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 preclinical 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

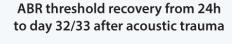
# A daily oral administration of SENS-401 (13.2 mg/kg bid) reduces auditory deficit and improves recovery

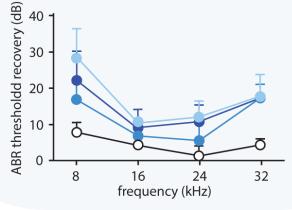
#### **MODEL**

 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 (>15 dB improvement)
- Significant effects with treatment initiation delay up to 96 hrs





Petremann et al. 2018

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

# SENS-401 PHASE 2 TO TREAT SSNHL

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

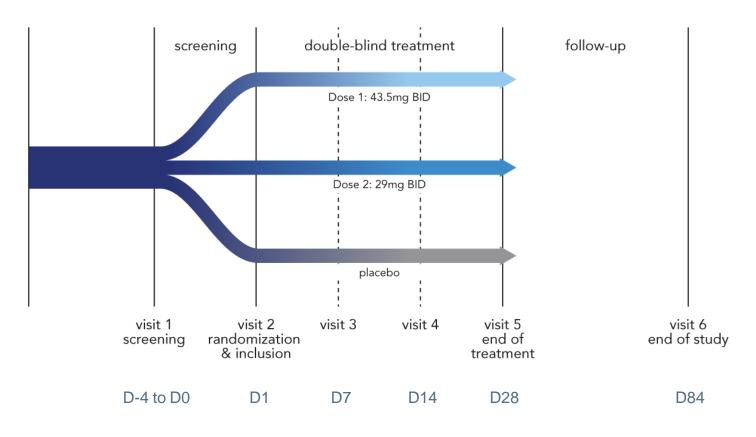
# 50 clinical sites globally

1 Primary endpoint
Audiometry
15dB improvement vs.
Placebo

# **Enrollment completed\***

# Timing

Q1 2019 center openings June 2020 Positive DSMB Review January 2022 Final results



<sup>\*</sup> New recruitment target at 111 patients for Phase 2 SENS-401 115 patients enrolled; recruitment completed end of October 2021 Amendment approved by 10 out of 10 participating countries

**PREVENT** 

# 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

Significant improvement versus placebo

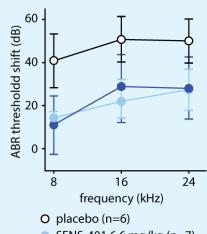
23-28 dB with 6.6 mg/kg (p<0.010)

22-30 dB with 13.2 mg/kg (p<0.013)

# TREATMENT PROTOCOL

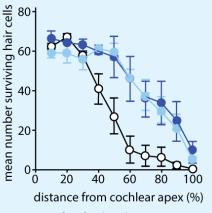
SENS-401 6.6 mg/kg, 13.2 mg/kg or placebo were administered to rats once-daily for 13 consecutive days after cisplatin infusion

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



- SENS-401 6.6 mg/kg (n=7)
- SENS-401 13.2 mg/kg (n=5)

# Cochleograms at day 14



- O placebo (n=5)
- SENS-401 6.6 mg/kg (n=5)
- SENS-401 13.2 mg/kg (n=5)

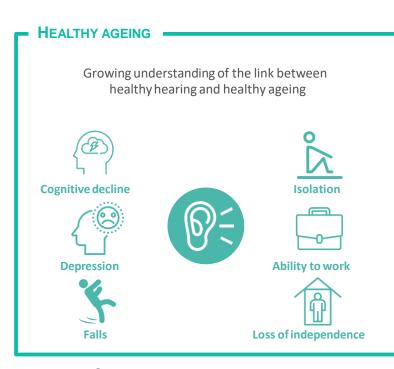
Submission of SENS-401 clinical study in adults with CIO in H2 2021

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



Source: Cochlear® 2018 investor day (link)

31,600

Implants sold by Cochlear<sup>®</sup> globally in 2020<sup>1</sup>

\$1.4bn

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

<sup>1</sup>Cochlear <sup>®</sup> 2020 financial report (<u>link</u>) <sup>2</sup>Market estimates (<u>link</u>)

- 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

# **SENSORION**

# **Potential Newsflow [Estimated timelines]**

- December 2021 Submission of the clinical trial application for the SENS-401 CIO in adults
- January 2022 Submission of the clinical trial application for the pilot study SENS-401 with cochlear implants
- January 2022 Top line data readout for the SENS-401 Phase 2 clinical study in SSNHL
- H1 2022 Start of the pilot study SENS-401 in combination with cochlear implants
- H1 2022 Sensorion and Institut Pasteur disclosing next steps for the USHER-GT program
- H1 2022 GJB2-GT Candidate selection
- H1 2023 Submission of the clinical trial application for the OTOF-GT program (CTA/IND)

# INVESTMENT HIGHLIGHTS

- Sensorion is focused on innovative treatments that can restore, treat and prevent hearing loss
- Phase 2 study for Sudden Sensorineural Hearing Loss with an oral small molecule
  - Global, randomized study with topline data release in January 2022
- 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

- Experienced management team with broad expertise in gene therapy and drug development
- Strong shareholder support from leading blue-chip investors





# **FINANCIAL OVERVIEW**

Date Established 2009 Euronext Paris ......ALSEN.PA Cash (June 30, 2021): ....≈€55m Cash runway until end of H2 2022

# THANK YOU

# **Nawal Ouzren**

Chief Executive Officer
<a href="mailto:E:contact@sensorion-pharma.com">E:contact@sensorion-pharma.com</a>



