

# Pioneering a New Category in Regenerative Medicine

Frequency Therapeutics Corporate Presentation  
January 2022

FREQUENCY  
THERAPEUTICS



# Forward-Looking Statements and Other Disclaimers

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the timing and design of Frequency Therapeutics' (the "Company") new Phase 2b trial of FX-322, including the type of SNHL that the enrolled patients will have and the ability of design features to reduce bias, the interpretation and implications of the results and learnings of other FX-322 clinical studies, the acceptance by the FDA of particular endpoints in the Company's trials, the treatment potential of FX-322, FX-345, and the novel approach for remyelination in multiple sclerosis, the timing and progress of the FX-345 and remyelination programs, the sufficiency of the Company's cash, cash equivalents and short-term investments, estimates of the size of the hearing loss population and population at risk for hearing loss, estimates of the size of the population with multiple sclerosis, estimates of the commercial opportunity of FX-322 and the impact on existing treatment paradigms, the ability of our technology platform to provide patient benefit, and the potential application of the PCA platform to other diseases.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the impact of COVID-19 on the Company's ongoing and planned clinical trials, research and development and manufacturing activities, the Company's business and financial markets; the Company has incurred and will continue to incur significant losses and is not and may never be profitable; need for additional funding to complete development and commercialization of any product candidate; the Company's dependence on the development of FX-322; the unproven approach of the PCA platform; the lengthy, expensive and uncertain

process of clinical drug development and regulatory approval; limited experience successfully obtaining marketing approval for and commercializing product candidates; the results of earlier clinical trials not being indicative of the results from later clinical trials; differences between preliminary or interim data and final data; adverse events or undesirable side effects; disruptions at the FDA and other regulatory agencies; failure to identify additional product candidates; new or changed legislation; failure to maintain Fast Track designation for FX-322 and such designation failing to result in faster development or regulatory review or approval; costly and damaging litigation, including related to product liability, intellectual property or brought by stockholders; dependence on Astellas Pharma Inc. for the development and commercialization of FX-322 outside of the United States; misconduct by employees or independent contractors; reliance on third parties, including to conduct clinical trials and manufacture product candidates; compliance with laws and regulations, including healthcare and environmental, health, and safety laws and regulations; failure to obtain, maintain and enforce protection of patents and other intellectual property; security breaches or failure to protect private personal information; attracting and retaining key personnel; and ability to manage growth.

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## 2022/2023 Milestones and Catalysts

### FX-322-208

Projected Enrollment  
Completion  
**Q3:22**

Projected Readout  
**Q4:22 or Q1:23**

### FX-345

Phase 1b Start  
**H2:22**

Phase 1b  
Readout  
**H1:23**

### Remyelination in M.S.

Candidate  
Selection  
**2022**

MS Clinical  
Trial Start  
**2023**

## A Vision Built on Regeneration

Since 2014, Frequency has focused on developing therapeutics by activating a person's innate regenerative potential, within the body, to repair tissue and restore human function.

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# Power of the Progenitor Cell Activation (PCA) Platform

## No Change to Genome

Activating native programs, reducing safety concerns

## Harnessing Innate Biology

Progenitors already located within the target tissue

## Ease of Manufacturing

Use of small molecules: no need to remove or grow cells *ex vivo*

# A Series of Firsts in Hearing Restoration

**First** PK/PD  
shown for a  
hearing therapeutic  
candidate

**First** clinical  
studies to show  
hearing  
improvements

**First** speech  
perception  
improvements  
measured

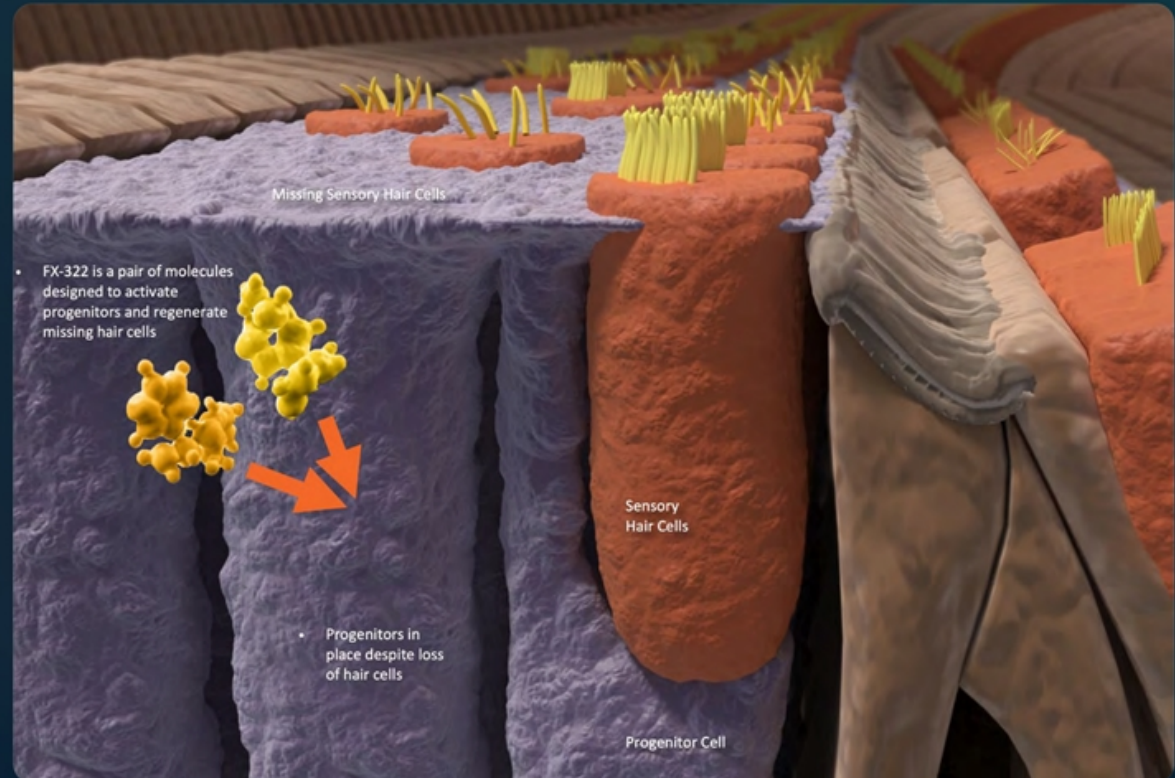
**First** to show  
sustained  
improvements  
and continued  
improvements  
over time



## FX-322:

### A Small Molecule Candidate to Address the Underlying Pathology

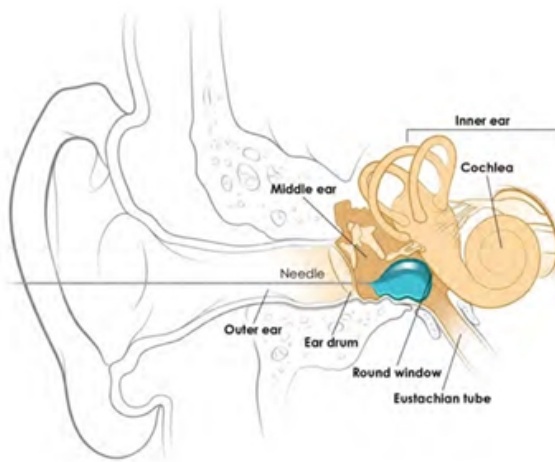
Synergy between pathways  
aims to activate progenitor  
cells and regenerate sensory  
cells in the cochlea



## FX-322:

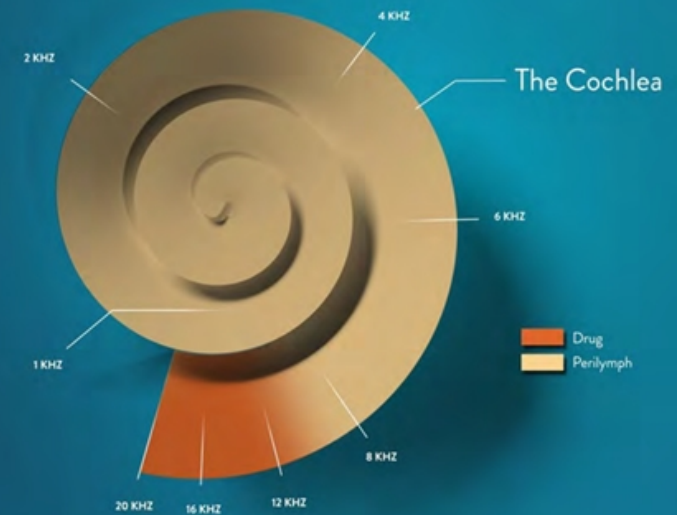
### Directly Targeting the Regeneration of Sensory Hair Cells in the Cochlea

FX-322 is administered via a standard intratympanic injection, a routine procedure performed by ENTs



*Not to scale- for illustrative purposes only.*

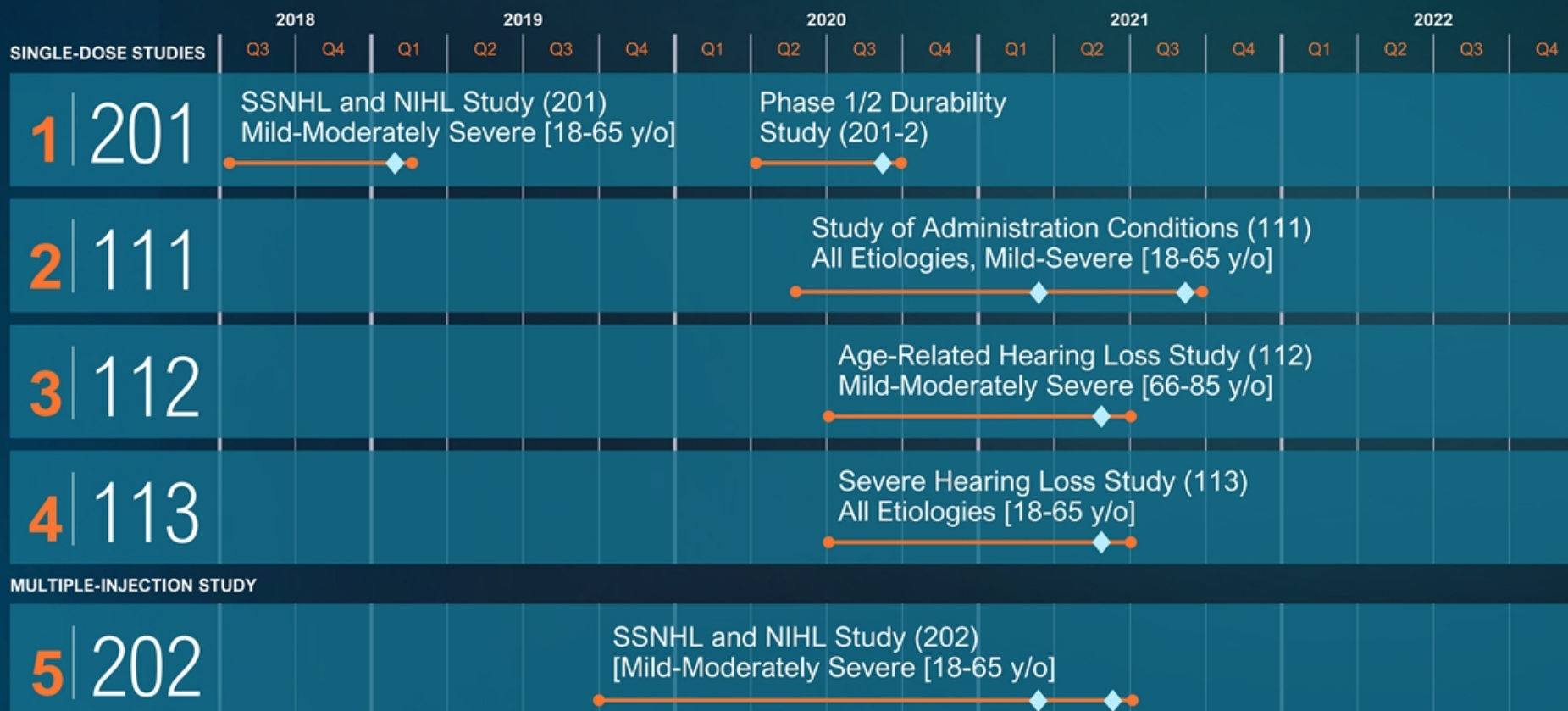
The injection concentrates FX-322 in the cochlear region critical for speech intelligibility





# Five FX-322 Completed Studies: 193 Treated Subjects

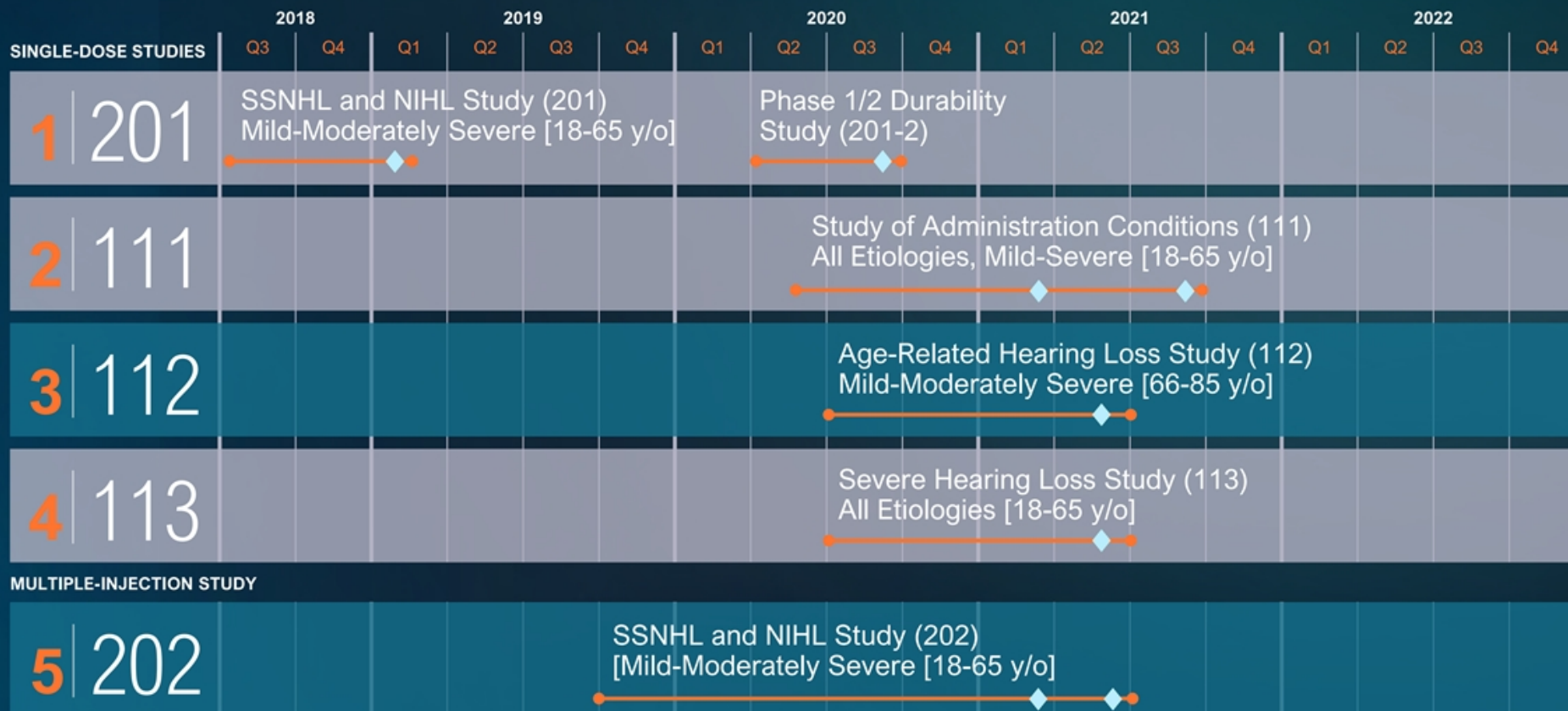
Favorable Safety Profile with No Treatment-Related SAEs



◆ = Data Readout

# FX-322-201, FX-322-111, FX-322-113

## Single-Dose Safety Studies with Hearing Improvement Signal



◆ = Data Readout



# Data from Controlled Studies (FX-322-201, FX-322-111)

## Improvement Shown in Speech Perception in Quiet with Single Dose

### Phase 1/2 Study

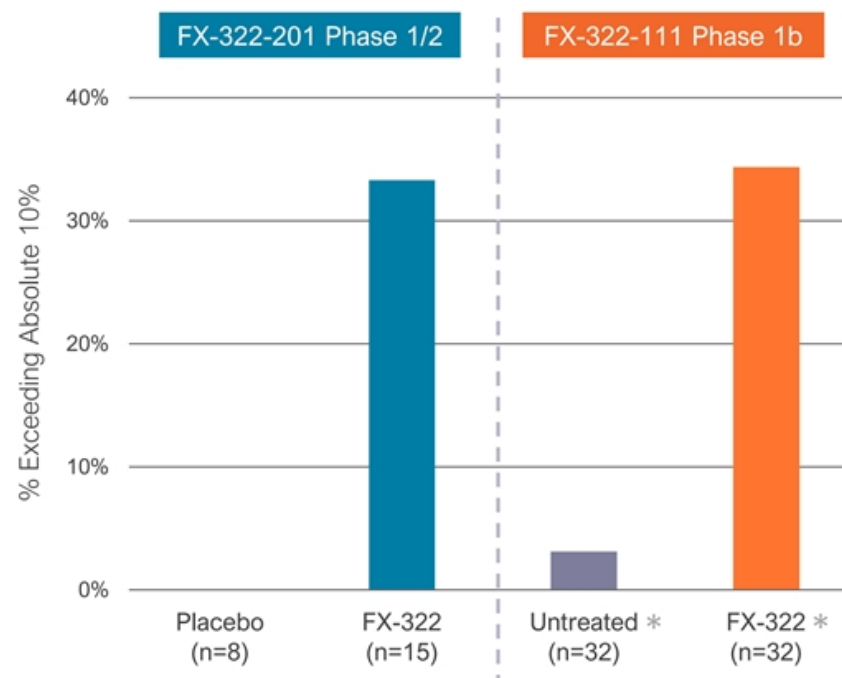
#### FX-322-201 Overview

- Placebo-controlled, multi-center, randomized study
- Mild to moderately severe subjects, age 18-65 (n=23)
- NIHL/SSNHL

### Study Results

- 33% of subjects achieved 10% or greater absolute improvement in word recognition in treated ear
- Statistically significant *and* clinically meaningful improvements in WR
- No meaningful changes in placebo group
- Favorable safety profile

Day-90 Word Recognition Scores Across Studies



### Phase 1b Study FX-322-111 Overview

- Compared different FX-322 administration conditions
- Open-label, multi-center, randomized study
- Mild to severe subjects, age 18-65 (n=33)

### Study Results

- 34% of subjects achieved 10% or greater absolute improvement in word recognition (WR) in treated ear
- Statistically significant *and* clinically meaningful improvements in WR
- Favorable safety profile

\*Total of 33 patients enrolled in study, 32 subjects completed 90-day clinical assessment period

## FX-322 Phase 1/2 Durability Data:

Patients Show Sustained Hearing Improvements 13-21 Months After Initial Dosing



\* 25W = 25 Word test performed outside an official study site at 13-18 months after dosing; results scaled to 50 words

50W = 50 Word test performed under a formal protocol at original study site at 18-21 months after dosing

\*\*Since FX-322 dosing

### Key Findings

**Preliminary evidence indicating a durable benefit of hearing clarity**

Baseline - Correct words out of 50

Day 90 - Correct words out of 50

1-2 Years - Correct words out of 50

Three patients who had durable improvements in intelligibility also had pure tone audiometry improvements of 10 – 15 dB at the highest frequency tested (8k Hz)



# Subjects in FX-322-111 Study Show Additional Hearing Improvements at Later Time Points

## Conducted longer-term, follow-up of FX-322-111 study subjects

- 25 of 33 study subjects evaluated at 8-12 months following FX-322 dosing

## Results show some FX-322 dosed subjects accumulated hearing benefits over time

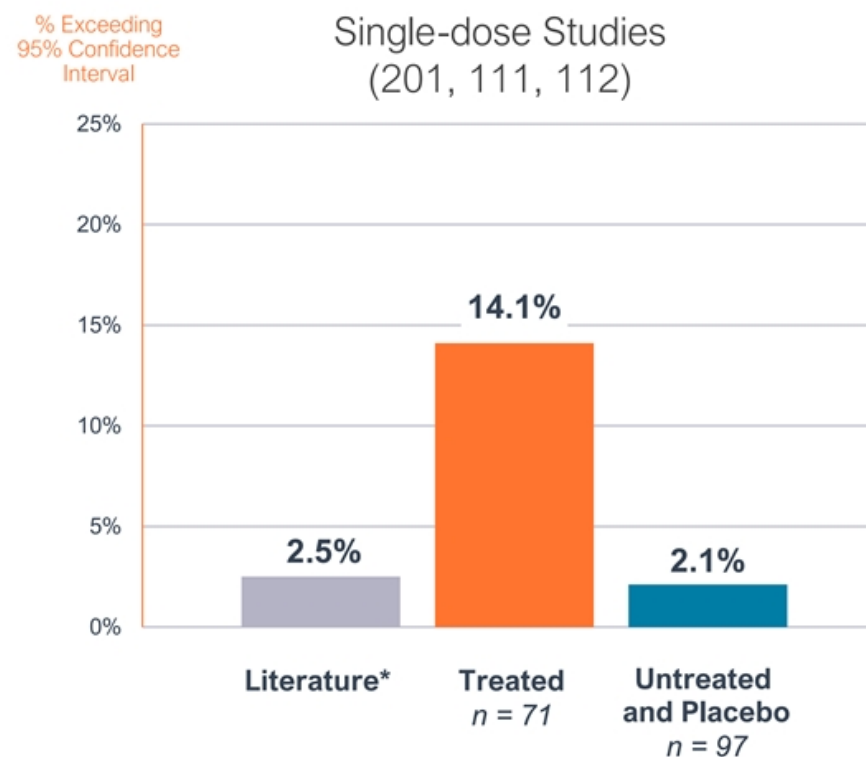
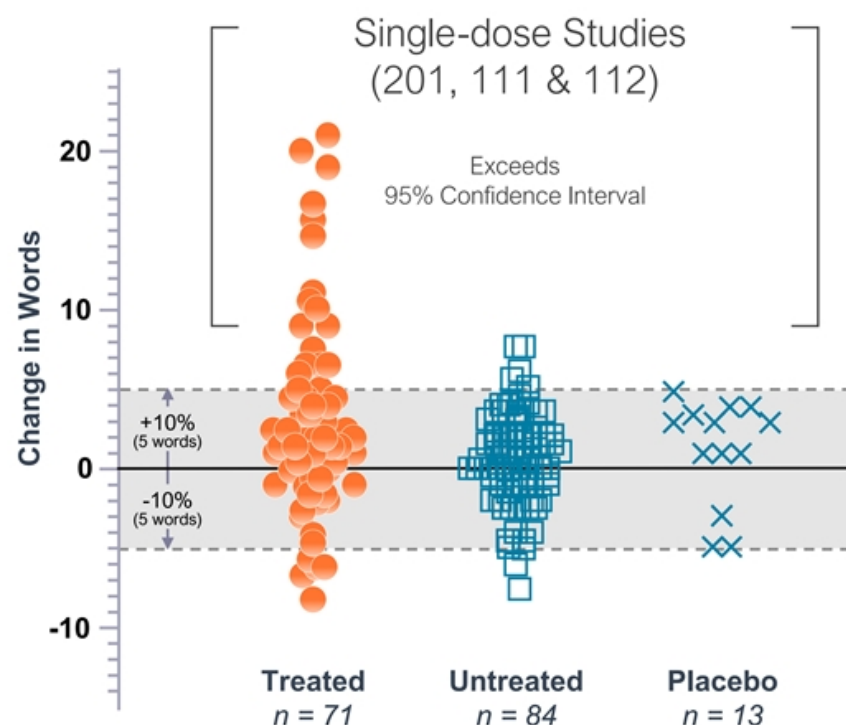
- 4 subjects that had shown improvement trends in word recognition scores at day 90, achieved statistically significant scores when tested at the later time points

## To date, 9 of 32 evaluated study subjects have shown statistically significant improvements in speech perception scores in treated ears between 90 days and 1 year

- No change observed in untreated ears

# Pooled FX-322 Data Shows Patterns of Response

Single-dose Studies (201, 111, 112) Exceed 95% Confidence Interval



95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007)

# FX-322-113: Hearing Signal and Speech Perception Improvements Observed in Subjects with Severe SNHL

## Double-blind, placebo-controlled study of 31 individuals randomized 4:1

- Pure tone average deficit between 71-90 decibel hearing level (dBHL)
- Potential cochlear implant candidates

## Improvements in Bamford-Kowal-Bench Sentence-in-Noise exam (BKB-SIN) observed in treated ears

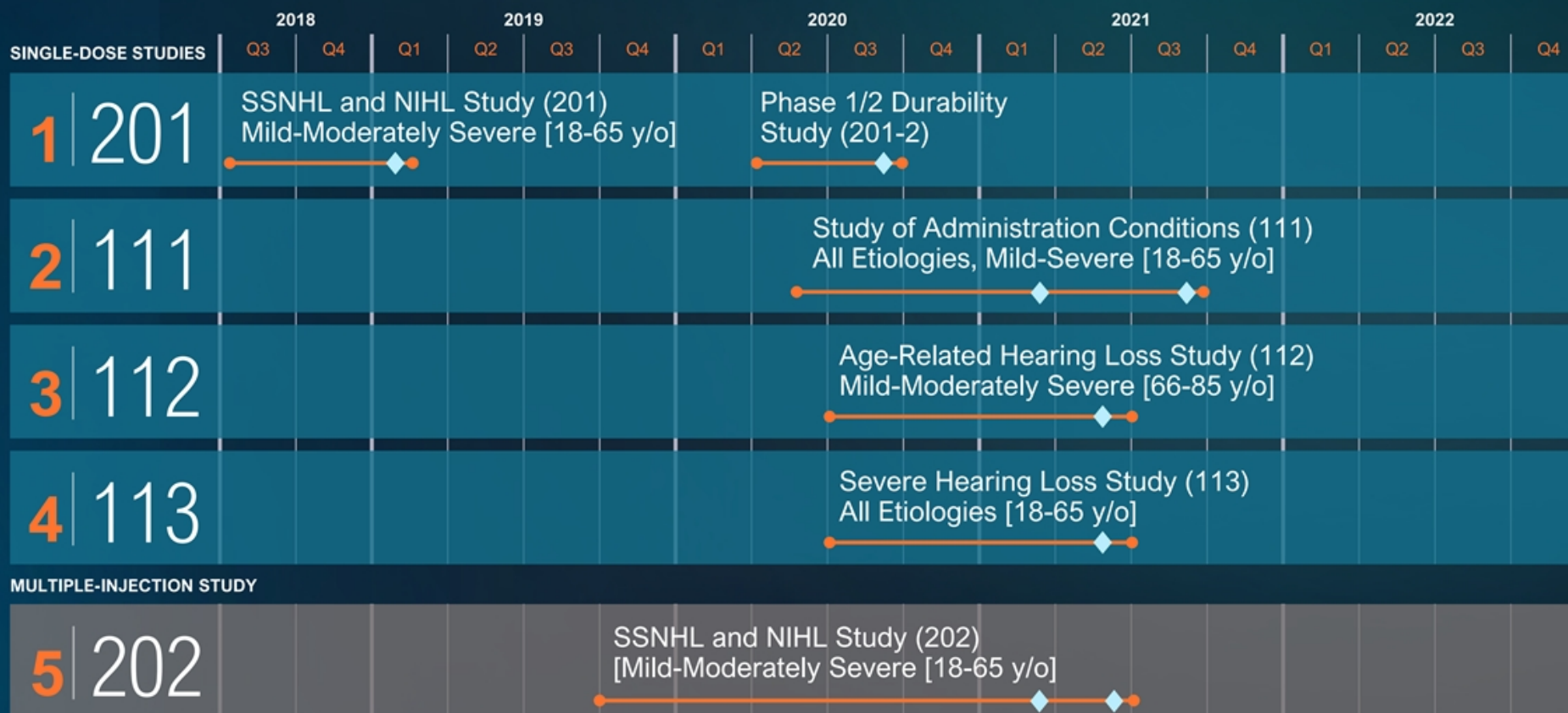
- BKB-SIN measures signal-to-noise ratios required for subjects to correctly repeat words in sentences
- Four FX-322 treated subjects show improvement, two with a 6 dB response
- A single placebo subject showed a 3.6 dB change
- No improvements observed in words-in-quiet

## Favorable safety profile

- No treatment-related SAEs



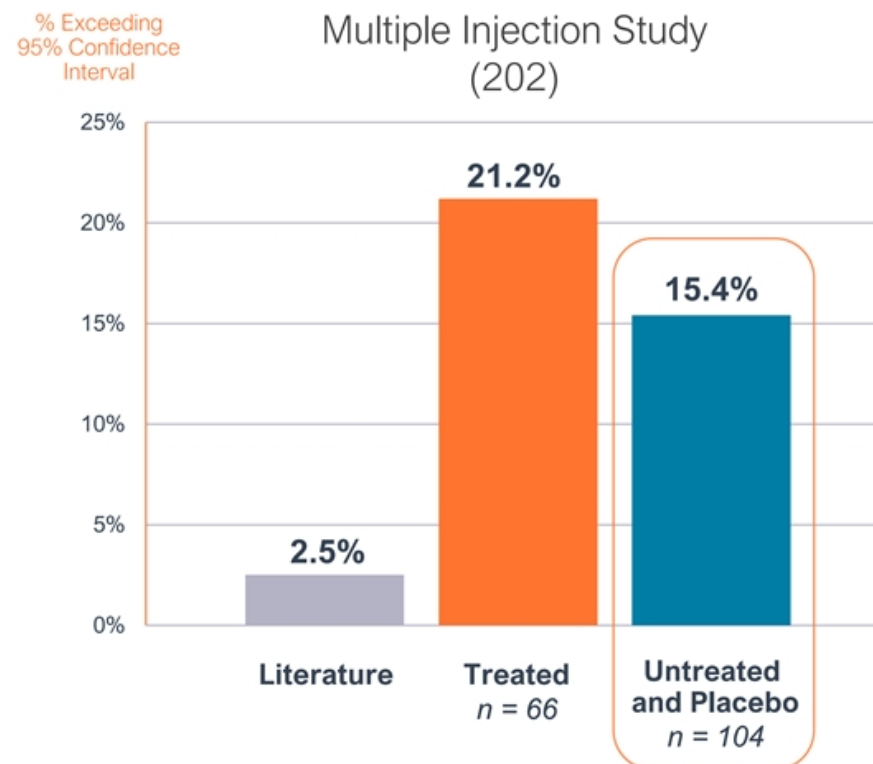
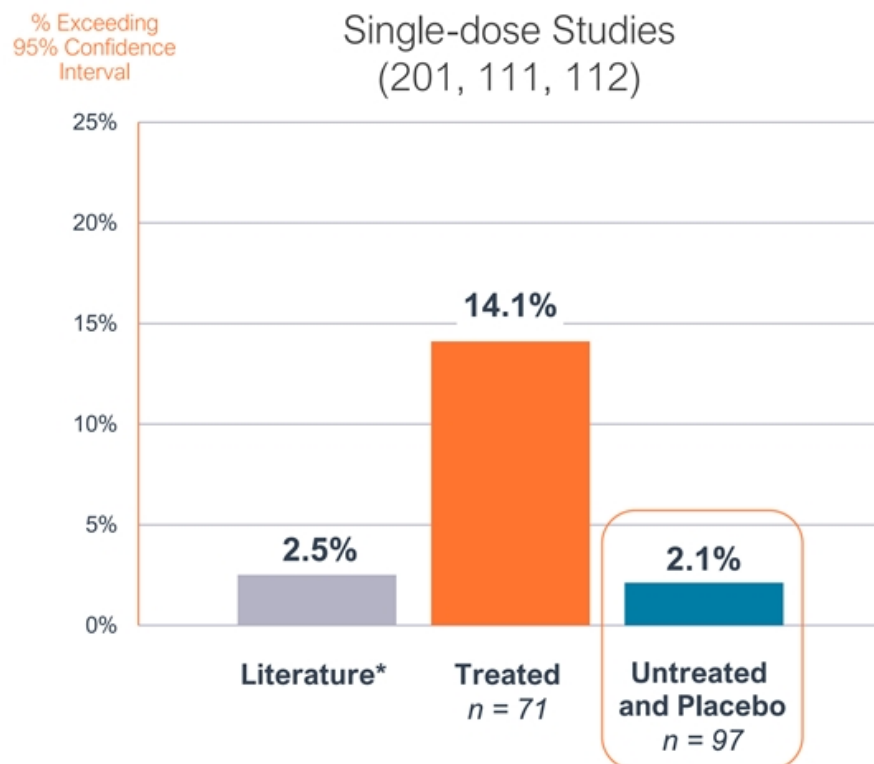
# FX-322-202: Multiple Injection Study Impacted by Inconsistent Baseline Measures



◆ = Data Readout

# Comparing Pooled Data to Multiple-Injection Study FX-322-202

Placebo-Treated and Untreated Ears are Outside 95% Confidence Interval



95% confidence intervals established by Thornton & Raffin (1978) and modified by Carney & Schlauch (2007)

# Clinical Study Data Informs New FX-322 Phase 2b Study



# New Clinical Study FX-322-208

## Designed to Advance Drug Candidate to Pivotal Trials

### Built upon insights from trials with hearing restoration signal

Etiology, severity, baseline speech perception

### Sufficient sample size to demonstrate efficacy

Approach based on pooled data

Primary endpoint of speech perception

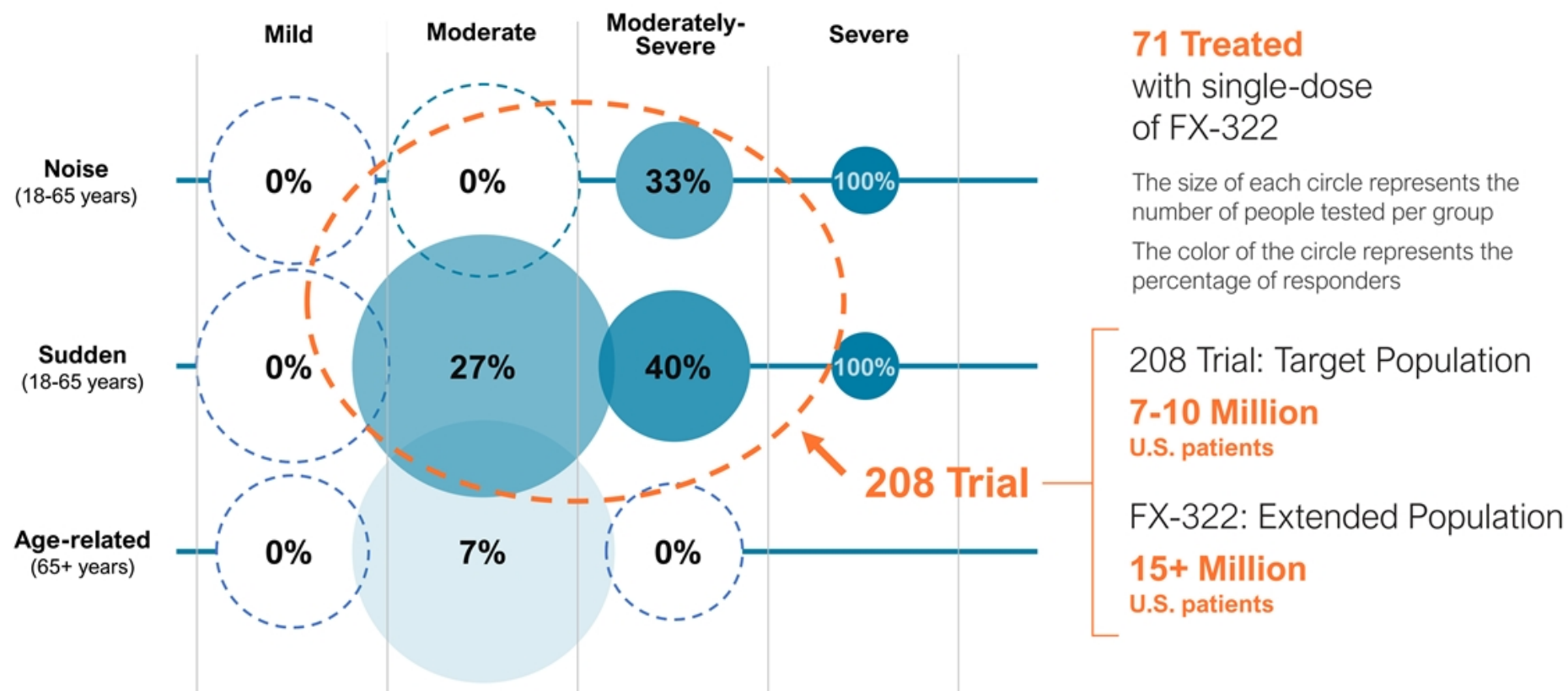
### Reduce potential for bias

Multiple baseline measures

Multiple speech perception tests

## Pooled Single-Dose Studies (201, 111, 112)

Data Suggest Patterns Between Etiology/Severity and Response



## Multiple Design Features Have Been Added to Mitigate Bias And Demonstrate Greater Separation Between Signal and Placebo

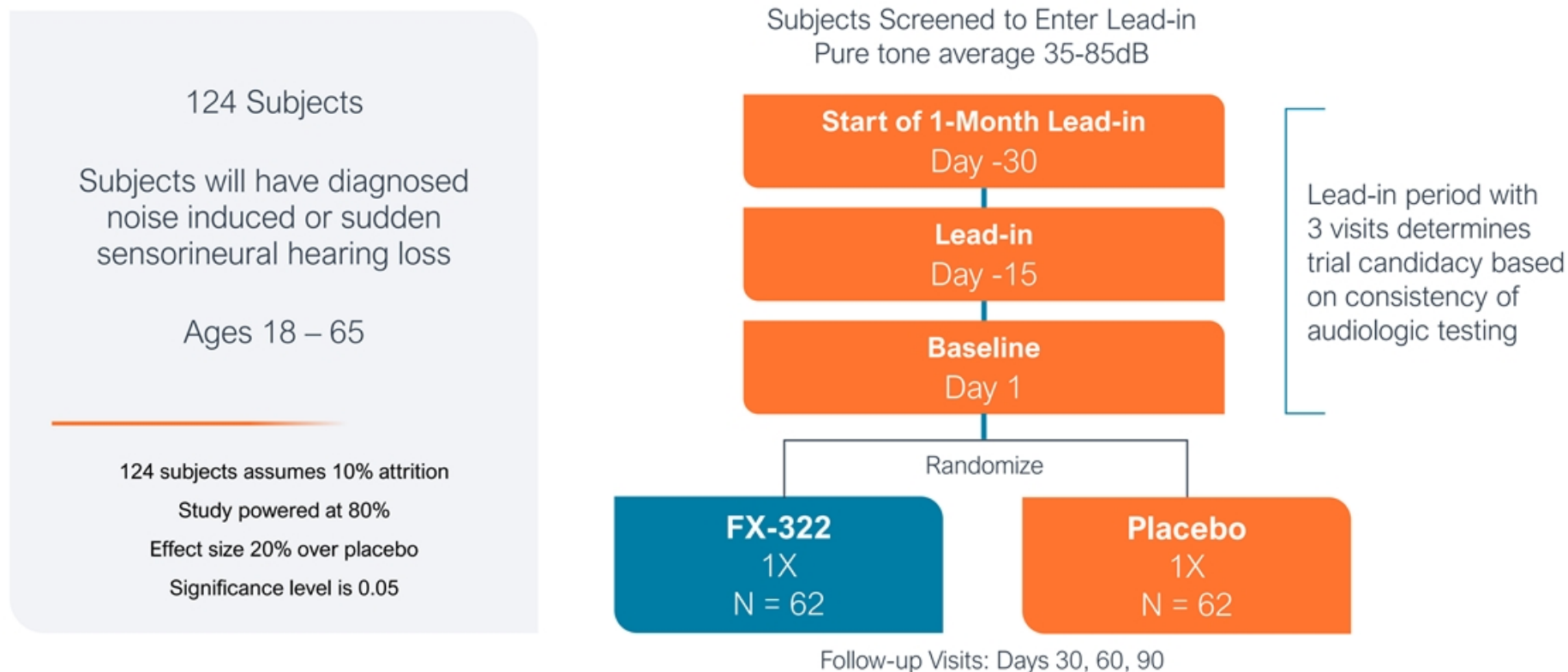
- ✓ Lead-in phase with multiple baseline measures
- ✓ Sites and patients masked to qualifying test results
- ✓ All sessions recorded and monitored
- ✓ Ability to disqualify subjects based on symptom stability





# New FX-322 Placebo-Controlled Phase 2b Study Commenced

First patient dosed in FX-322-208 Study in October 2021



## FDA Type C Meeting Held to Gain Alignment



### ALIGNMENT

#### Primary Endpoint

Gained alignment with FDA on speech perception as the primary endpoint

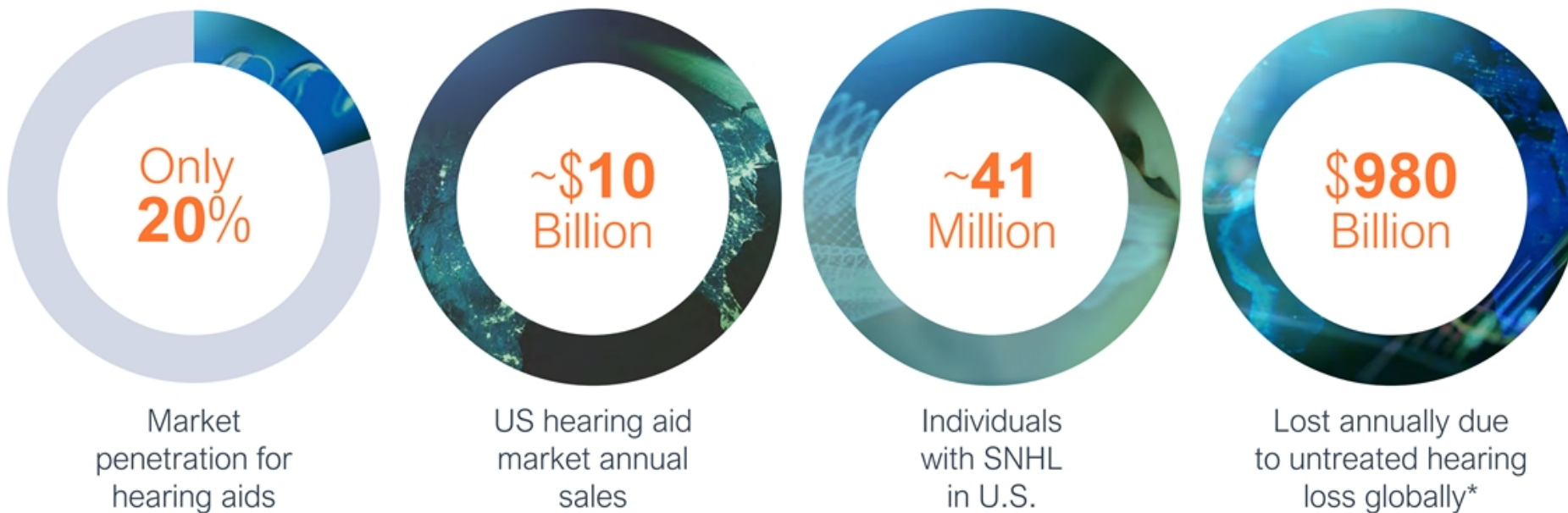
#### 208 Study Design

FDA reviewed and commented on 208 study, comments were incorporated into study protocol

#### Patient Reported Outcomes (PRO)

FDA feedback provided on novel PRO development called **RADIAL**; special meeting granted for further discussion

## Today's Hearing Loss Market Has No Restorative Treatments



\*Source: World Health Organization



# Hearing Loss Can Have a Significant Impact on Overall Health

THE LANCET  
July, 2020

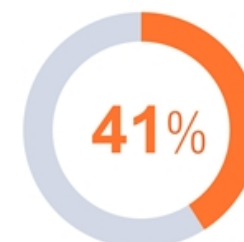
*“Hearing loss is the largest potentially modifiable risk factor for developing dementia”*

JAMA  
November, 2018

*Increased risks with untreated hearing loss*



Dementia



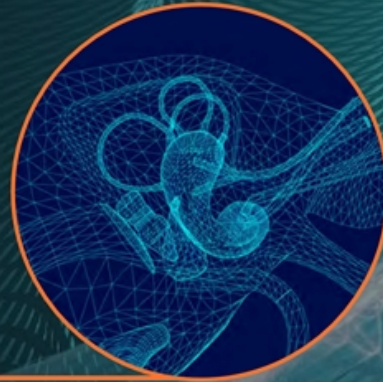
Depression

JAMA Nov 8, 2018, Deal J, et al. Incident Hearing Loss and Comorbidity. A Longitudinal Administrative Claims Study.

## Pipeline Expansion

# New Regenerative Program

What if we were able  
to get drug deeper  
into the cochlea?





## FX-345

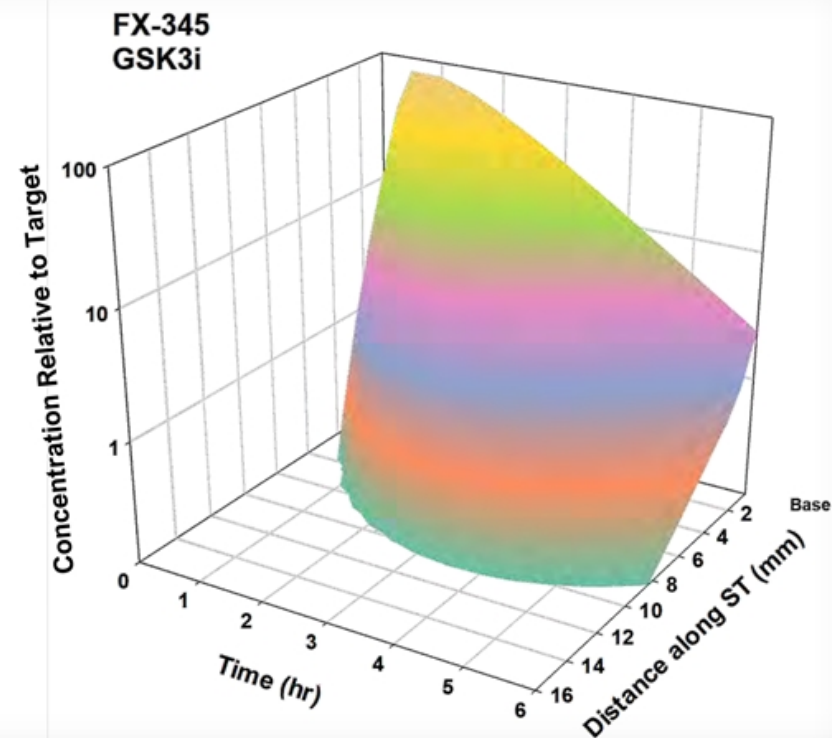
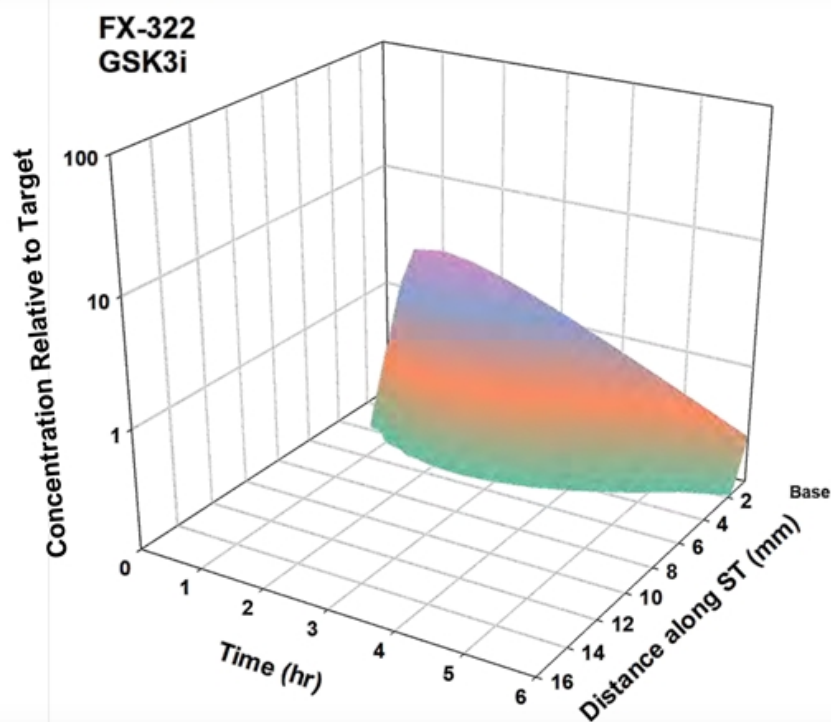
### Working to Achieve Broad Exposure Through the Cochlea

- Second clinical program focused on regrowth of sensory cells
- Enables coverage of large portion of cochlea
- Potential to address additional SNHL patient types
- Formulation enabling evaluation of a range of dose levels
- Developing in addition to FX-322. Clinical data will drive commercial positioning



# FX-345 – A New Development Candidate

Creating Effective Drug Levels Through Large Portion of Cochlea



## FX-345 Path to Clinic

Program start planned for H2:2022 for a Phase 1b study in patients with SNHL  
Enables us to clinically evaluate increased cochlear coverage across range of doses  
in multiple patient populations



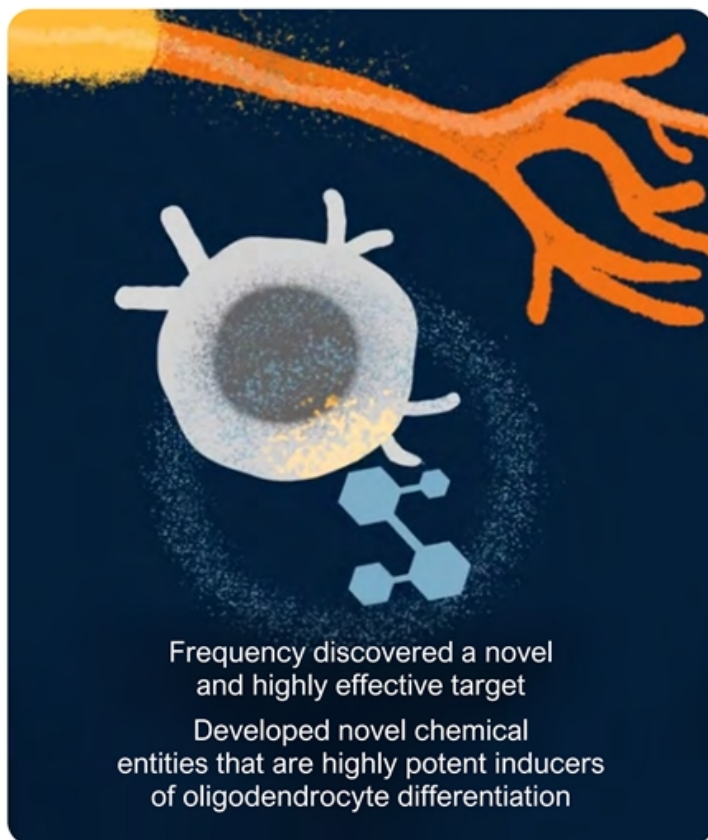


# New Regenerative Program

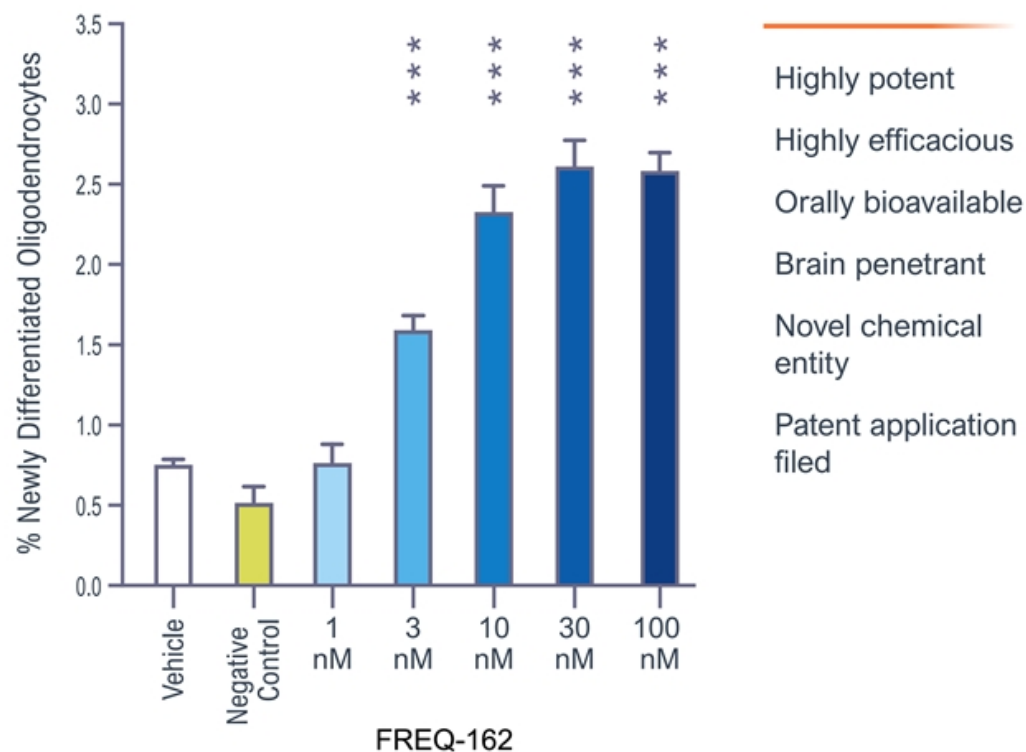


What if we could extend  
our approach to other  
degenerative diseases?

# Novel Frequency Small Molecule Inhibitors Drive Oligodendrocyte Differentiation



Lead Optimization generated FREQ-162





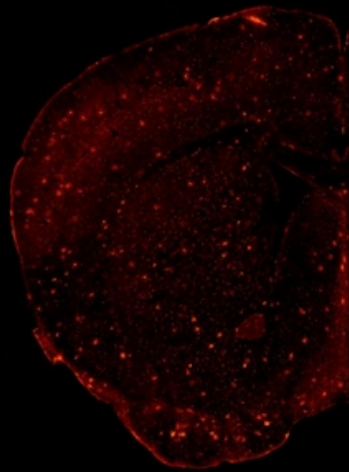
# FREQ-162 Outperforms Literature Compounds *In Vivo*

Adult mice received 3 doses of comparator compounds or a single dose of FREQ-162

Brains were stained for a marker of newly generated oligodendrocytes

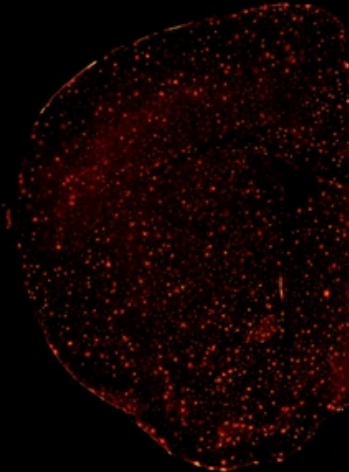
Single dose FREQ-162 induces more OPCs to differentiate than comparator compounds

Vehicle



x 3 days

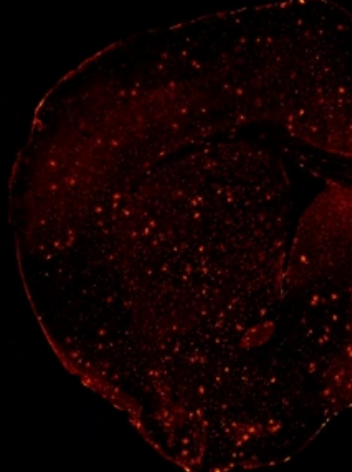
T3 / Thyromimetic



10 mg/kg x 3 days

Thyroid Hormone:  
Thyromimetic Class

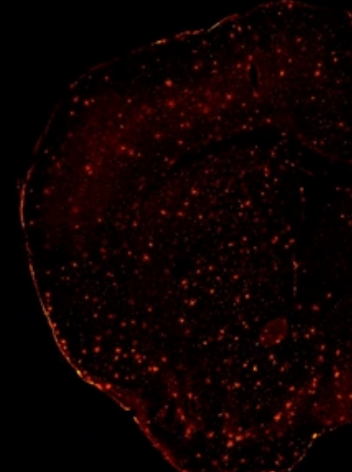
$\alpha$ -Lingo Antibody



5 mg/kg x 3 days

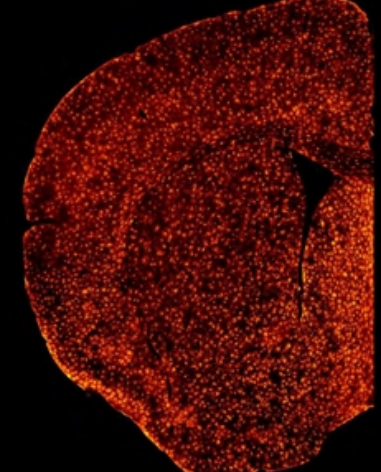
$\alpha$ -Lingo antibody:  
Blocking antibody

Clemastine / Anti-Muscarinic FREQ-162



75 mg/kg x 3 days

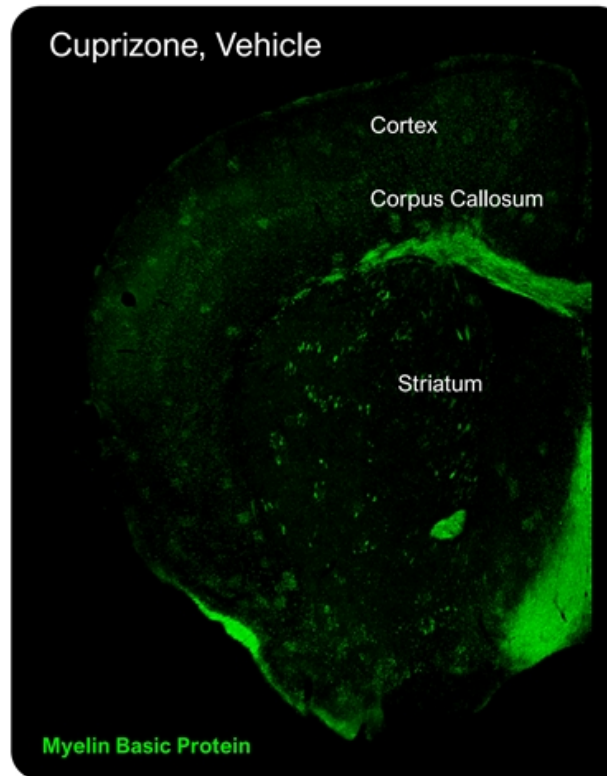
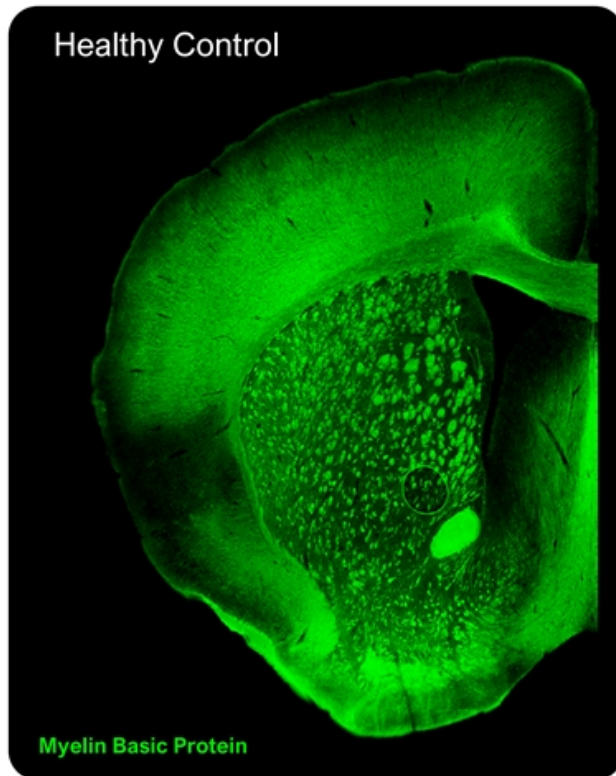
Clemastine:  
Anti-Muscarinic Class



5 mg/kg, Single Dose

FREQ-162 induces formation  
of newly differentiated  
oligodendrocytes in both  
white and gray matter

# The Cuprizone Model of Chronic Demyelination



Adult mice were demyelinated via 17 months of cuprizone administration

- Elderly mice with long term demyelination



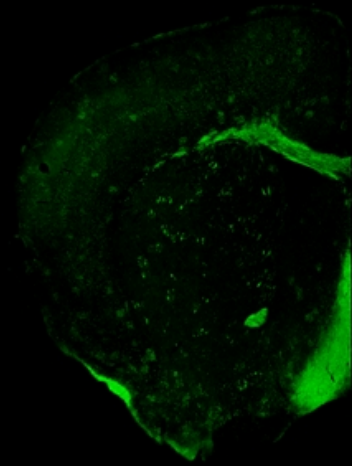
# FREQ-162 Outperforms Published Compounds *In Vivo*

Adult mice received up to 10 daily doses of comparators or a single dose of FREQ-162

Brains were stained for Myelin Basic Protein (green)

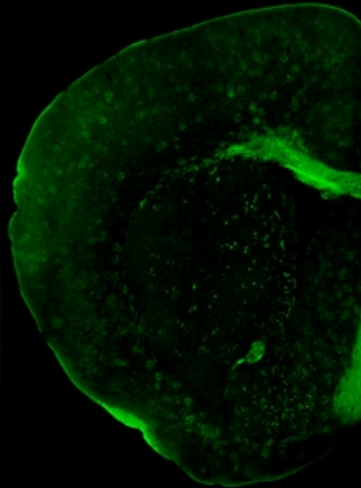
Single dose FREQ-162 induces more remyelination than comparator compounds

Vehicle



x 10 doses

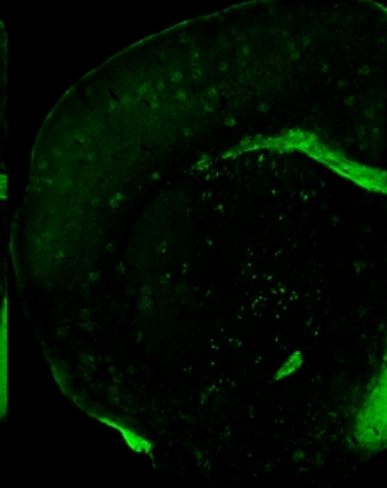
T3 / Thyromimetic



10 mg/kg x 10 doses

Thyroid Hormone:  
Thyromimetic Class

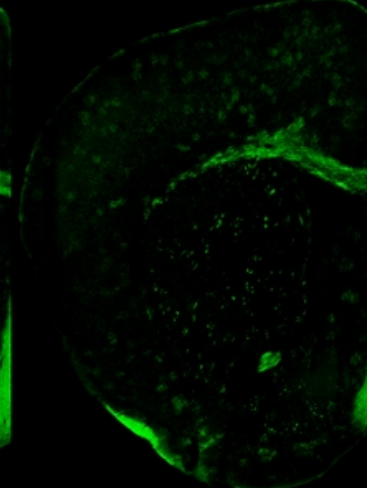
$\alpha$ -Lingo Antibody



5 mg/kg x 3 doses

$\alpha$ -Lingo antibody:  
Lingo inhibitor

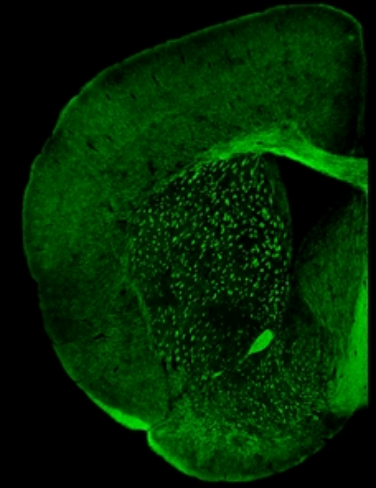
Clemastine / Anti-Muscarinic



75 mg/kg x 10 doses

Clemastine:  
Anti-Muscarinic Class

FREQ-162

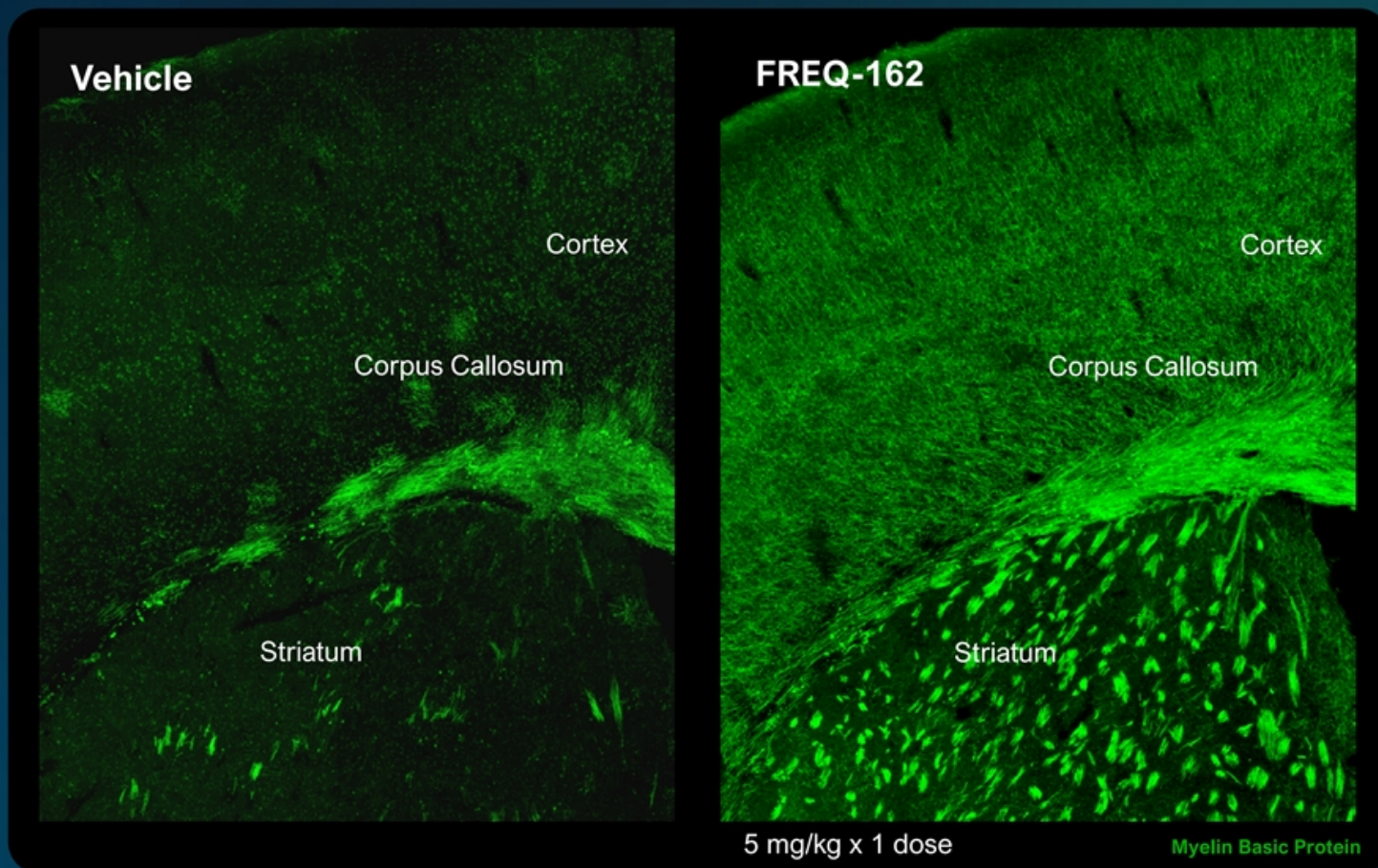


5 mg/kg, Single Dose

FREQ-162 induces formation  
of new myelin in white and  
gray matter

Animals demyelinated for 17 months via cuprizone treatment

# Frequency NCEs Outperform Competitors: High Magnification



High Magnification view reveals that FREQ-162 yields myelination

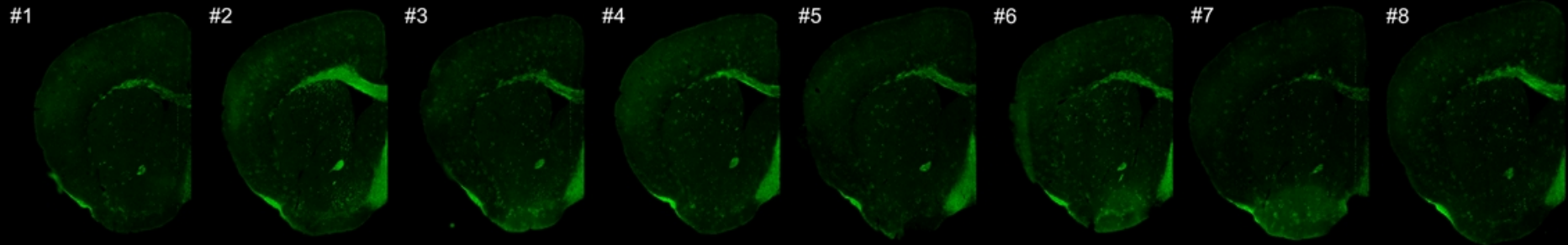
- in both white and gray matter
- In the appropriate orientation and location



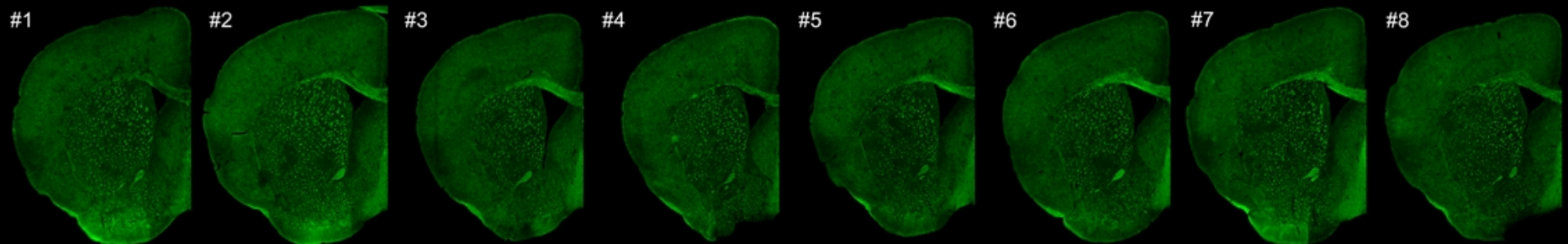
## FREQ-162: Highly Reproducible Increases in Myelination

All 8 out of 8 mice treated with FREQ-162 showed robust increases in myelination in both white and gray matter tracts

### Vehicle



### FREQ-162

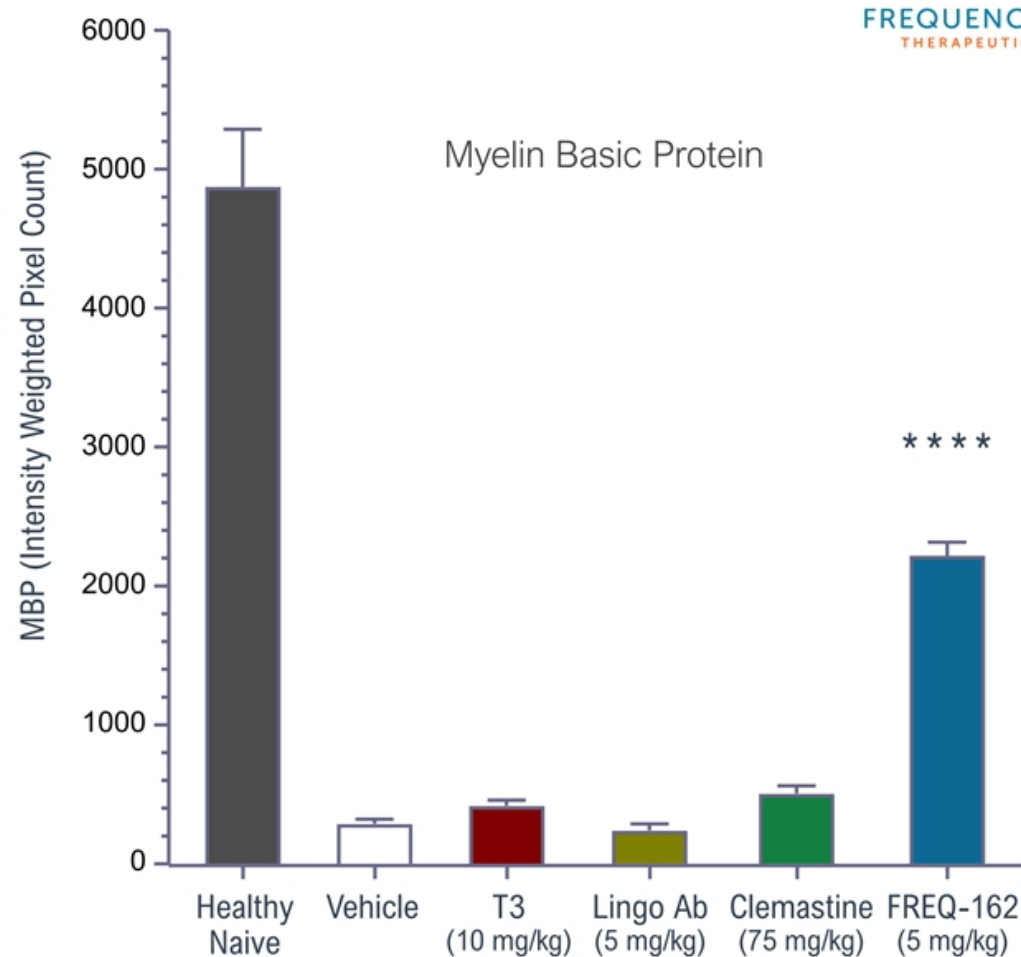


Myelin Basic Protein

## Freq-162 Induces Robust Increases in Myelination

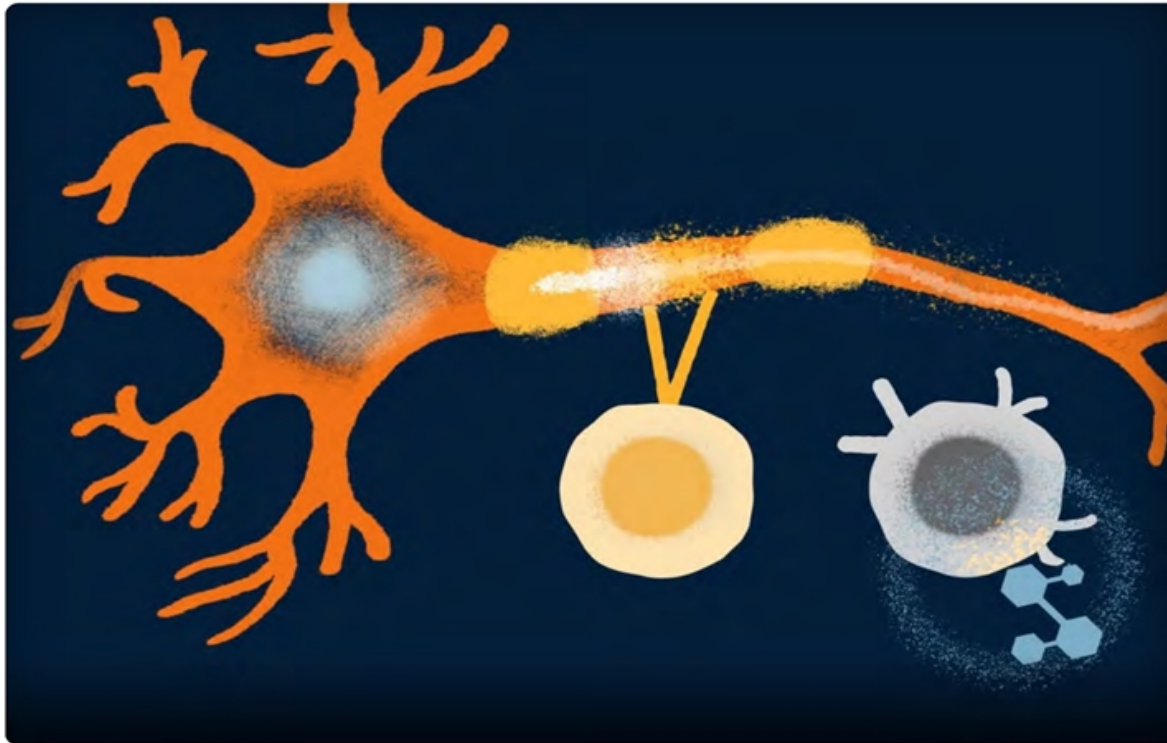
- Forebrain myelin basic protein levels quantitated
- A single dose of a Frequency compound induces robust remyelination

Compound	Dose (mg/kg)	# of doses	Fold change	P=
<b>α-Lingo antibody</b>	5	3	0.9 x	0.99
<b>Clemastine</b>	75	10	1.7 x	0.70
<b>Thyroid Hormone (T3)</b>	10	10	1.4 x	0.95
<b>FREQ-162</b>	5	1	7.7 x	<0.0001





## Remyelination: Path Forward



Discovered novel target

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Generated multiple compounds

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Induced high levels of oligodendrocyte differentiation and remyelination *in vivo*

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Initiating IND enabling studies

# Our Path Forward

- ✓ We believe FX-322 restores hearing.
- ✓ We know characteristics of FX-322 responders.
- ✓ Learnings from previous trials informed new trial design with strong controls and FDA aligned clinical endpoints.
- ✓ We have a compelling new hearing program that will allow us to explore the impact of going deeper into the cochlea.
- ✓ We also have an exciting remyelination program in multiple sclerosis with a novel target and a strong response *in vivo*.
- ✓ We are a well capitalized company with resources to deliver innovation for patients and value for investors.
  - \$160.5m in cash and cash equivalents\*, runway into 2023
  - Ex-US partnership with Astellas, significant milestones and royalties

\*Number reflects unaudited Cash, Cash Equivalents, and Marketable Securities as of 9/30/21, and does not include Restricted Cash

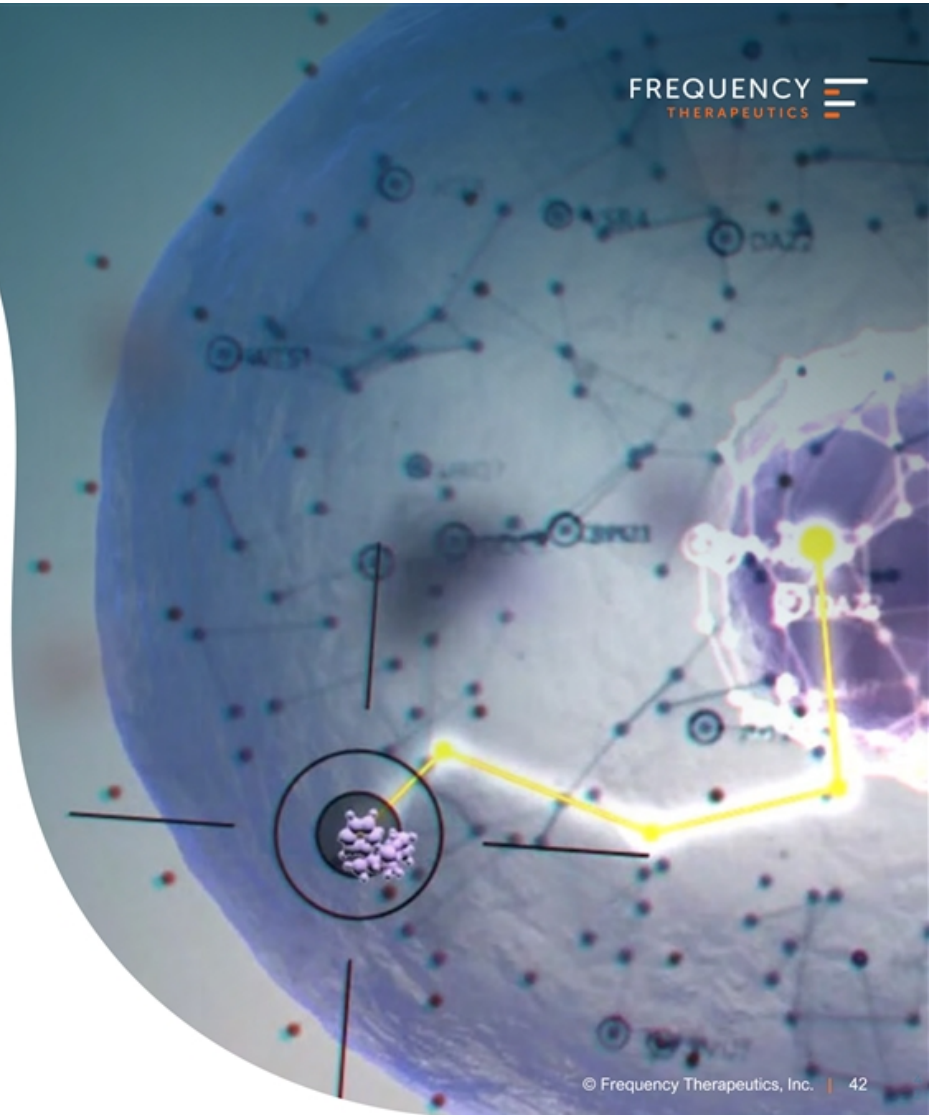




# Appendix

FREQUENCY  
THERAPEUTICS 

## Broad Potential of Progenitor Cell Activation Approach





# Origin of Frequency Therapeutics

Tissue-Specific, Pre-programmed Stem Cells

## Decoding Intestinal Regeneration

Langer and Karp publish  
small molecules activate  
intestinal progenitors



Niche-independent high-purity cultures of  
Lgr5+ intestinal stem cells and their progeny

## Enabling Cochlear Regeneration

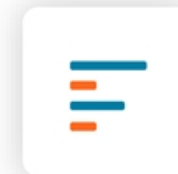
Same cues reactivate  
normally inactive  
progenitors in the cochlea



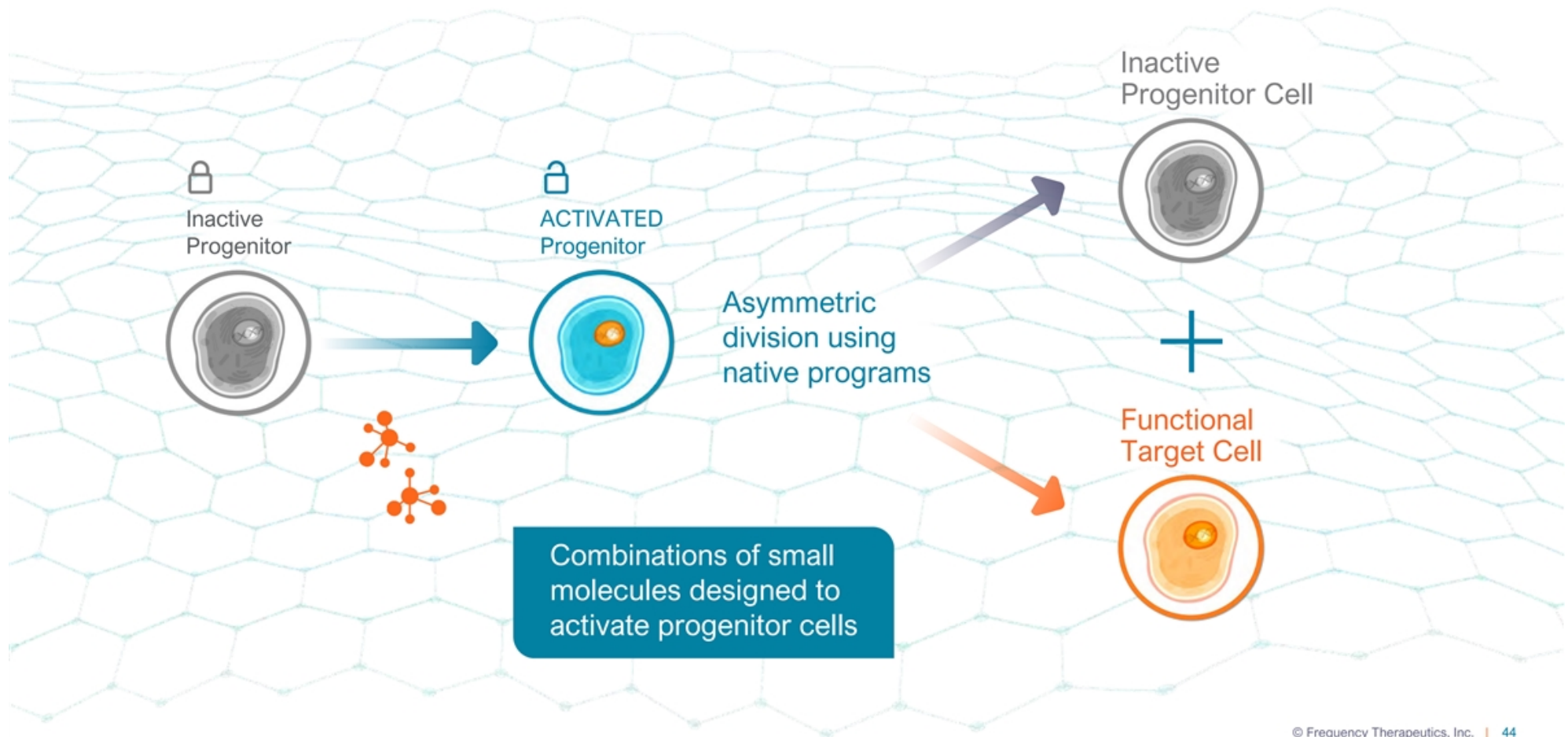
Clonal Expansion of Lgr5-Positive Cells  
from Mammalian Cochlea and High-  
Purity Generation of Sensory Hair Cells

## Frequency Therapeutics

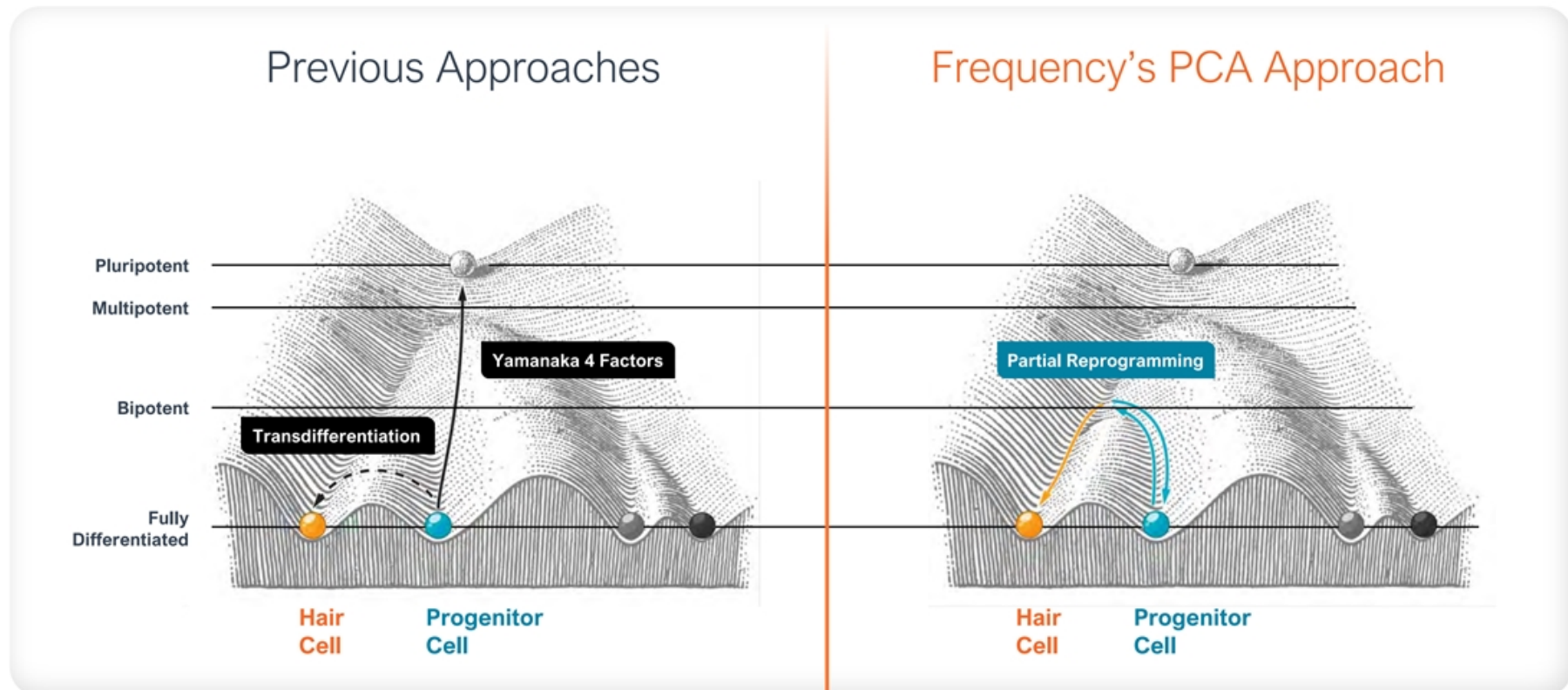
Small molecule  
therapeutics show  
clinical proof  
of concept



# Frequency Progenitor Cell Activation (PCA) Approach



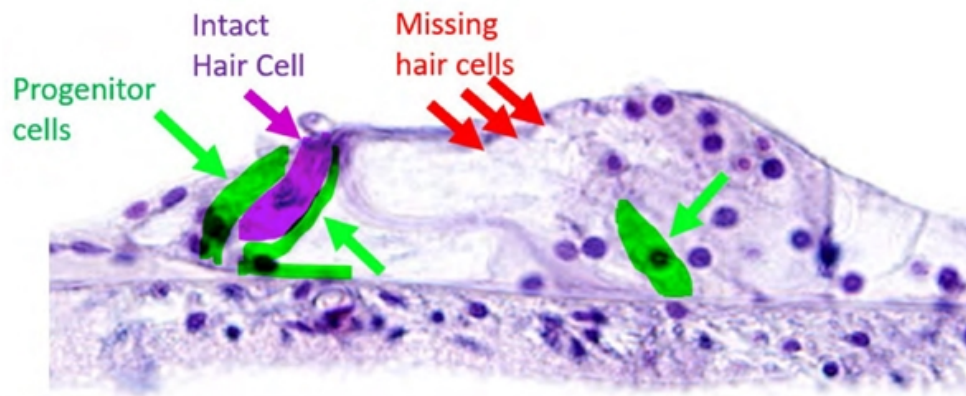
# Uniqueness of Our PCA approach



## Our Approach:

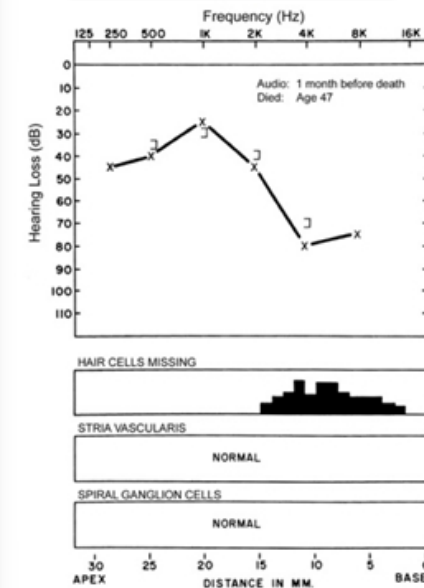
### Activation of Progenitors to Replace Hair Cell Loss

Despite Hair Cell Loss, Progenitor Cells Remain



*Human Cochlea Cross-section*

Audiogram



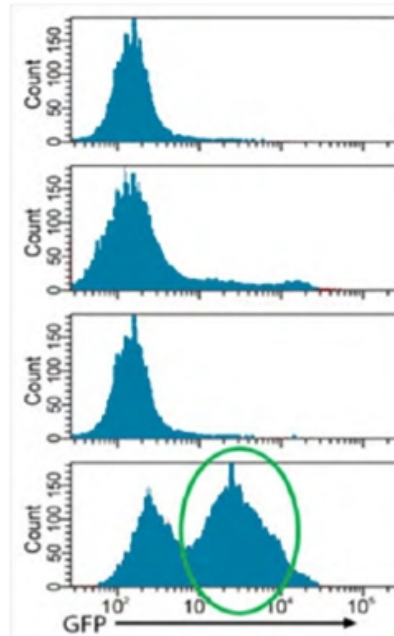
47 Year Old Male with Occupational Noise Deafness



# Profound Synergy Between Pathways to Regenerate Cells

## Cochlear Progenitor Proliferation (Lgr5+ – GFP)

HDAC = Histone deacetylase  
NCE = new chemical entity  
In vitro mouse model testing



Culture Media

Wnt Activation  
(glycogen synthase kinase-3  
(GSK3) Inhibitor; NCE)

HDAC Inhibition  
(sodium valproate)

Wnt Activation + HDAC inhibition

**PROFOUND SYNERGY**

# FX-322 Agents Induce Protein Expression Consistent with Fully Functional Sensory Hair Cells



Sensing Sound  
Generating intricate  
hair bundles



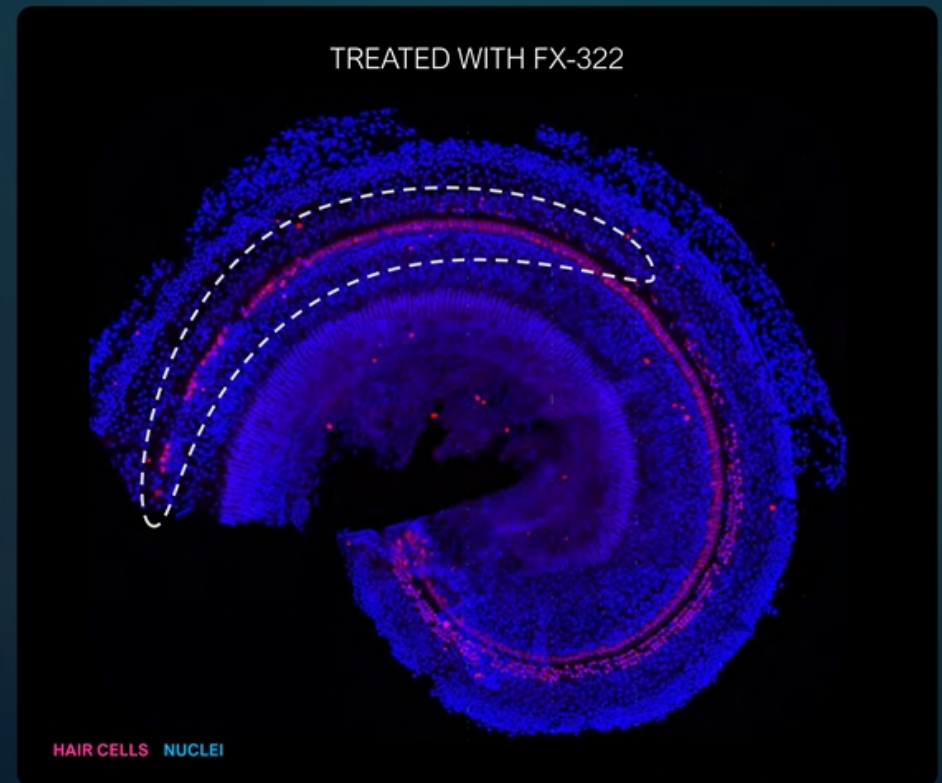
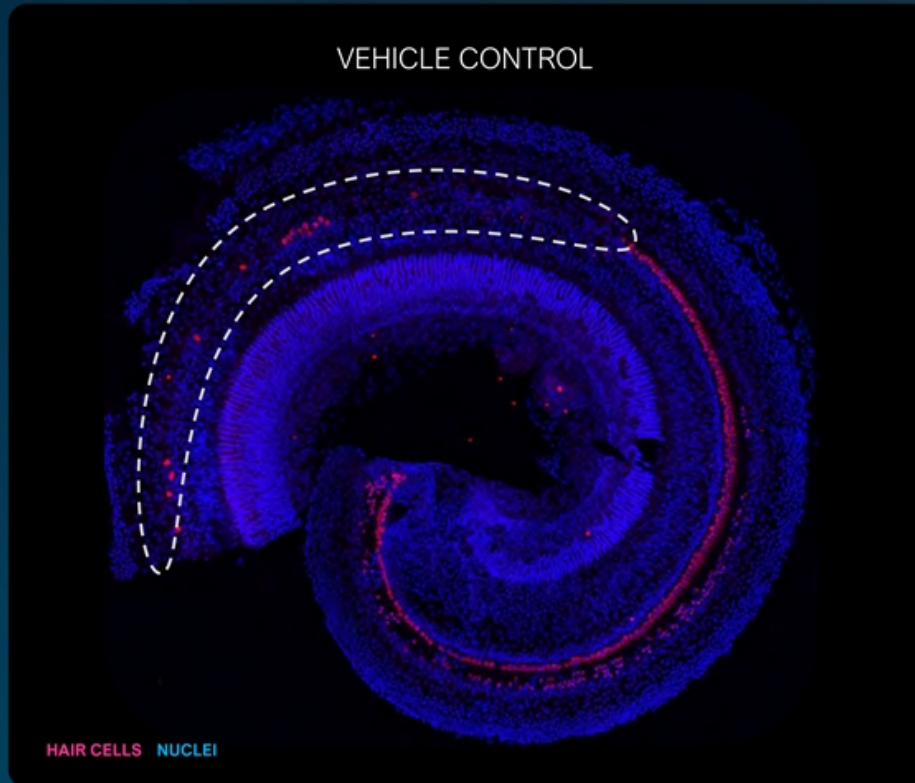
Creating Signal  
Producing functional  
ion channels



Transmitting Signal  
Synaptic proteins to communicate  
with nerve are present

# Images Showing Cellular Regeneration

## *In Vivo* Hearing Loss Model



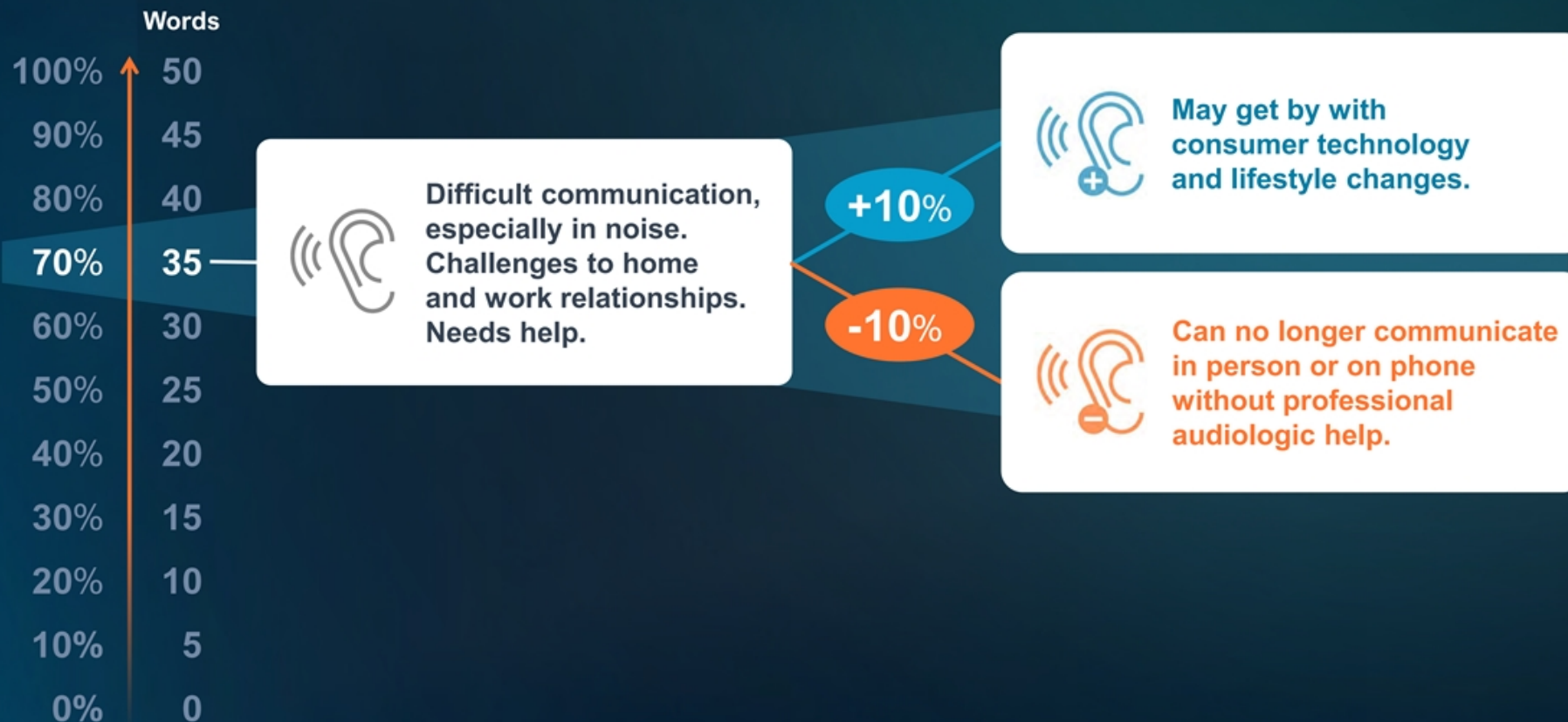
Representative of n=7; Numbers correspond to frequencies; 30 days after treating



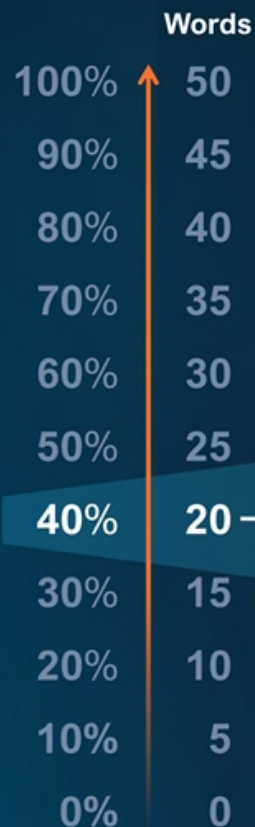
## Strong FX-322 Pre-Clinical Validation

Test	Outcome
In vitro	
Adult human inner ear tissue	Created new hair cells
In vivo	
Adult deafened mice	Restored hair cells and hearing across all frequencies
Therapeutic drug levels	Achieved active levels in the cochlea in multiple species

# Clinically Meaningful: 10% Means Needing Audiologic Help



# Clinically Meaningful: 10% Means Functional Deafness or Need for Implant



Unable to communicate, even with hearing aids. At risk for depression due to impact on home and work.

+10%



Can communicate using hearing aids and accommodations at home and work.

-10%



Cochlear implants or functionally deaf.

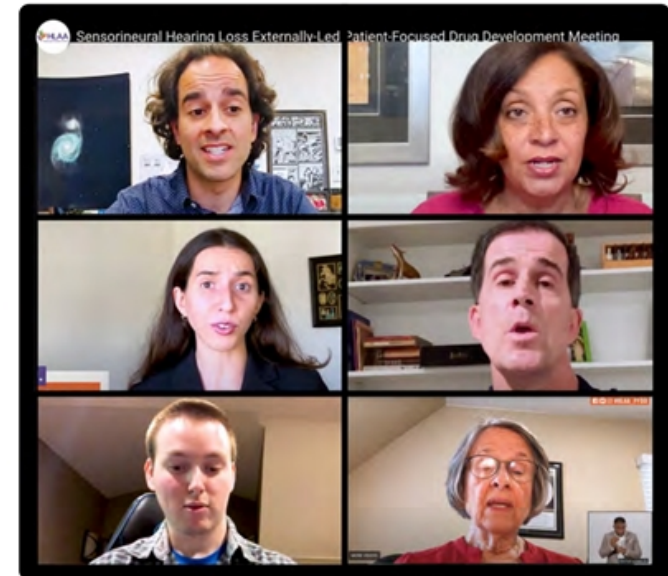


# Externally-Led (HLAA) Patient Focused Drug Development Program on Sensorineural Hearing Loss

## Top two needs for new drug or device



## Top two hearing loss concerns



## Astellas Collaboration:

### Ex-US Development and Commercialization of FX-322

- **Development and commercialization collaboration for FX-322, including lifecycle improvements**
- **Astellas has ex-US rights; Frequency retains US rights to FX-322**
- **Payments of up to \$625mm which included \$80mm upfront**
  - Development milestone payments to Frequency of \$65.0 million and \$25.0 million upon the first dosing of a patient in a Phase 2b clinical trial for SNHL in Europe and Asia, respectively
  - \$100.0 million and \$40.0 million upon the first dosing of a patient in a Phase 3 clinical trial for SNHL in Europe and Asia, respectively
- **Development & commercialization:**  
Astellas responsible for execution and costs of ex-US clinical development and commercialization



Strategic commitment to invest in ENT as a therapeutic area

Research focus in regenerative medicine

Global footprint in major markets and distributorship model in Africa/ME and LATAM

# Proven Leadership Team



**David Lucchino**  
President, CEO  
& Co-Founder

Former CEO of Entrega Bio (PureTech). Co-founder / CEO of Semprus BioSciences (acquired), Polaris Partners. MIT Sloan Fellow.



**Chris Loose, Ph.D.**  
Chief Scientific Officer  
& Co-Founder

Co-founder/CTO of Semprus BioSciences through FDA / CE clearance and acquisition. Princeton, MIT, Hertz Fellow and Yale Faculty.



**Peter Pfreundschuh**  
Chief Financial Officer

CFO of numerous public life sciences companies including UroGen and Sucampo, as well as business development and finance leadership positions at Astra Zeneca and J&J.



**Dana Hilt, M.D.**  
Chief Medical Officer

Neurologist and neuroscientist with two decades in biopharma and CNS drug development. Amgen, Lysosomal, Forum Pharma.



**Carl Lebel, Ph.D.**  
Chief Development Officer

Chief Scientific Officer of Otonomy (2009 to 2016). Executive Director, Amgen. Scientific fellow of the American Academy of Otolaryngology.



**Sue Stewart, J.D., LLM**  
Chief Regulatory Officer

CRO at numerous biopharma companies including Kaleido Biosciences, Candel Therapeutics, and regulatory leadership roles at Tokai Pharma, Transmolar and Genzyme Corp.



**Wendy Arnold**  
Chief People Officer

HR leader with extensive life science experience including senior leadership roles at Kaleido Biosciences, Moderna, Celgene Avilomics Research, and Inotek Pharmaceuticals



**Quentin McCubbin, Ph.D.**  
Chief Manufacturing Officer

Led pharmaceutical sciences and process chemistry at Takeda / Millennium and headed technical operations Cerevel Therapeutics.



## Scientific Advisory Board



**Jeff Karp,  
Ph.D.**

Associate Professor at  
Brigham and Women's  
Hospital, Harvard  
Medical School



**Robert Langer,  
SC.D.**

David H. Koch Institute  
Professor at the  
Massachusetts Institute  
of Technology



**Robin Franklin,  
Ph.D.**

Professor of Stem  
Cell Medicine,  
Wellcome Trust-MRC  
Cambridge  
Stem Cell Institute



**Sheng Ding,  
Ph.D.**

Senior Investigator,  
Gladstone  
Institute of  
Cardiovascular  
Disease



**Sean J.  
Morrison, Ph.D.**

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Center Research  
Institute,  
UT Southwestern



**Siddhartha  
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Columbia University  
Medical Center



**Amy Wagers,  
Ph.D.**

Forst Family Professor  
of Stem Cell and  
Regenerative Biology,  
Harvard University



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Otology and  
Neurology, Mass  
Eye and Ear



**Rene Gifford,  
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Associate Director of  
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Director of Cochlear  
Implant Program,  
Vanderbilt University



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Director, Mass. Eye  
and Ear Balance and  
Vestibular Center



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Communications Sciences  
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University of Wisconsin



**Chris Runge,  
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Chief of the Division  
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Sciences, Medical  
College of Wisconsin



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Keck School of  
Medicine of USC.



**Julie Arenberg,  
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for Research and  
Education, Mass Eye  
and Ear



**David Friedland,  
M.D., Ph.D.**

Vice-Chair of the  
Department of  
Otolaryngology and  
Communications Sciences,  
Medical College of  
Wisconsin

## Clinical Advisory Board



# Pioneering a New Category in Regenerative Medicine

Frequency Therapeutics Corporate Presentation

January 2022

FREQUENCY  
THERAPEUTICS 