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Cochlear therapies

Innovative Treatments for Inner Ear Disorders

AM-111 Program Update

January 4, 2018

NASDAQ: EARS

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Key Takeaways from HEALOS Trial

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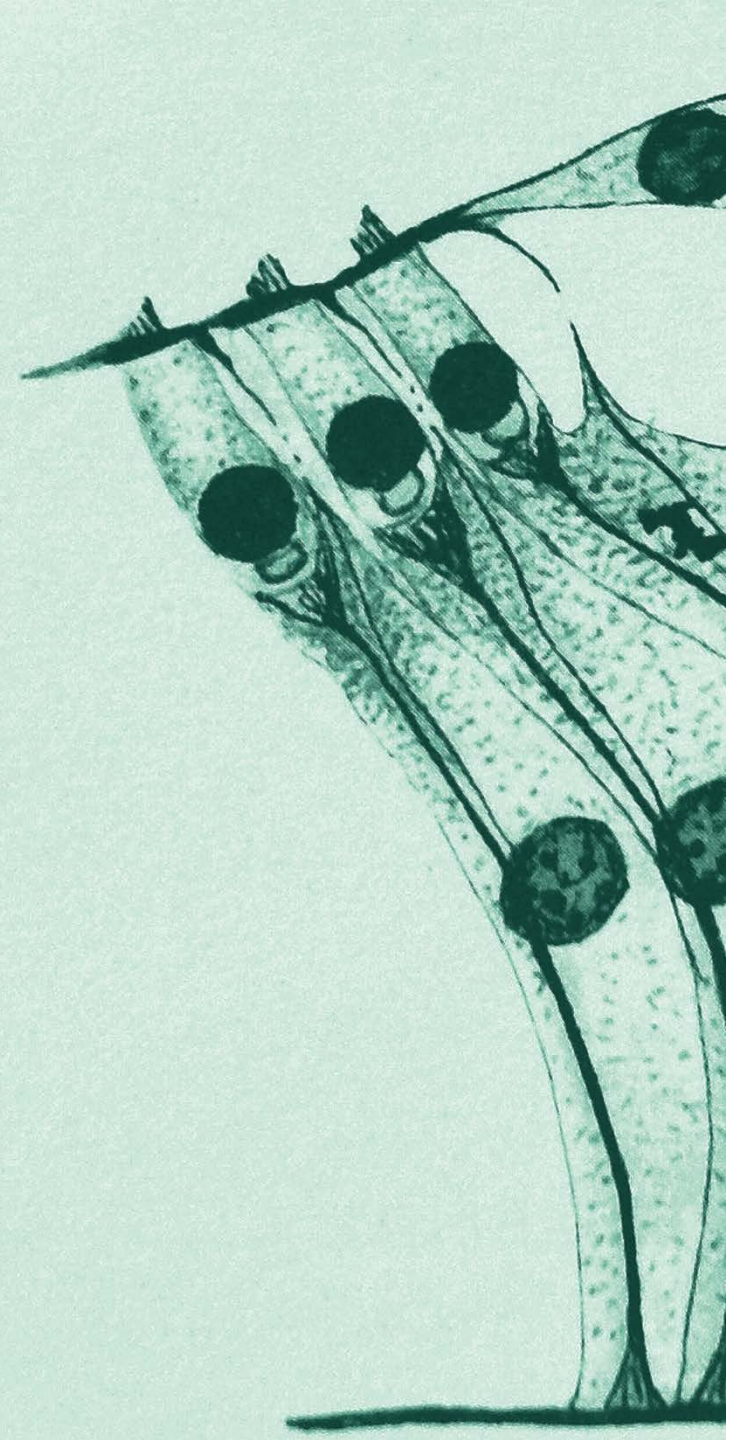
As presented November 28, 2017, based on top-line data

Primary endpoint not met in overall population with *severe to profound* acute hearing loss

But: clinically and statistically significant improvement in patients with *profound* hearing loss

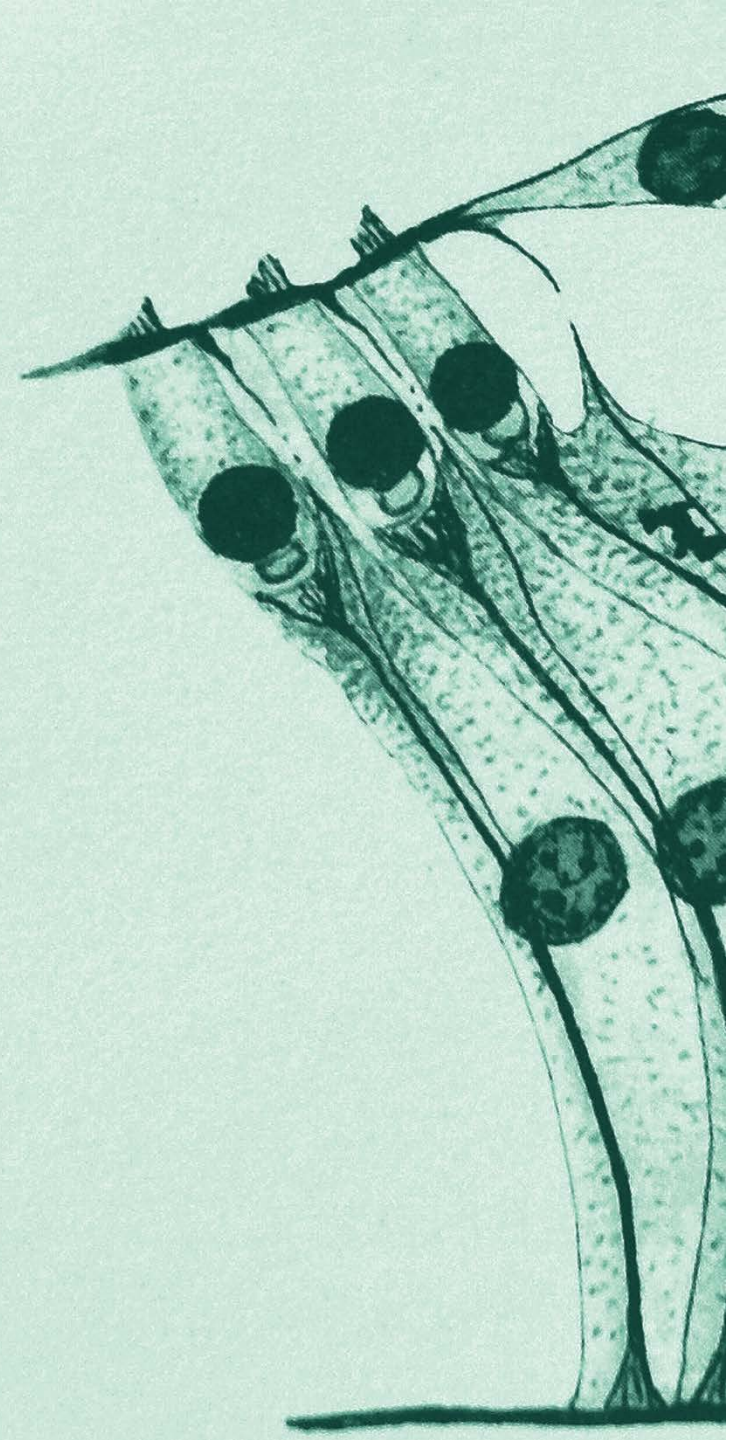
Favorable safety profile of AM-111 confirmed

Worst prognosis, and highest unmet medical need, is in those patients with profound hearing loss



Agenda

- Treating Patients with Sudden Deafness
  Hinrich Staecker
- AM-111 Project Update
  Thomas Meyer
- Regulatory Considerations
  Andrea Braun
- Market Considerations and Conclusions
  Thomas Meyer
- Questions and Answers



Treating Patients with Sudden Deafness

Hinrich Staecker, MD, PhD

David and Mary Zamierowsky Professor

Director Division Otology/Neurotology

Departments of Otolaryngology/Head and Neck Surgery and Speech and Hearing

University of Kansas

Disclosure

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- Principal investigator in several Auris Medical sponsored trials
  - Tinnitus: TACTT1 and TACTT2 trials
  - Hearing loss: ASSENT trial
- Served as medical expert for Auris Medical in regulatory agency meeting
- Hosted scientific symposia sponsored by Auris Medical and participated as speaker
- Principal investigator in several other trials, e.g.
  - Novartis GCF-166 (gene therapy for hearing loss; ongoing)
  - Otonomy OTO-104 (Meniere's disease)
- Member of multiple scientific advisory boards
  - MedEl GmbH (cochlear implants)
  - Quark Pharmaceuticals (siRNA)

The KUMC ENT Department

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- Personal background:
  - Training and residency at Albert Einstein College of Medicine
  - PhD University of Liege, Belgium (developmental biology of the ear)
  - Neurotology Fellowship Mass Eye and Ear Infirmary/Harvard Medical School
- Clinical and research focus: treatment of neural disorders of the inner ear (sensorineural hearing loss, tinnitus, balance disorders)
- Built up integrated basic / clinical research program:
  - 250 hearing / balance outpatient visits per week
  - Largest number of completed and ongoing inner ear drug trials in the country
  - Developed first inner ear gene therapy program in the world
  - Active implantable device program achieving landmarks such as first implantation of a MedEl brainstem implant in the country

A Primer on Sudden Deafness

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- Idiopathic sudden sensorineural hearing loss (ISSNHL, “sudden deafness”):
  - At least 30 dB hearing reduction over at least three contiguous (audiometric test) frequencies
  - Occurring over a period of 72 hours or less
  - No identifiable cause despite adequate investigation
  - Indicating a dysfunction of the cochlea, auditory nerve, or higher aspects of central auditory perception or processing
- Usually affecting only one ear
- Tinnitus and vertigo as frequent comorbidities
- Possible etiologies: vascular, infectious, autoimmune…
- Underdiagnosed and undertreated in US compared to Europe and Japan

Natural History

- Thanks to intrinsic repair mechanisms, the majority of sudden deafness patients experience spontaneous recovery of hearing in the days, weeks and months following the incident
- Factors known to result in higher spontaneous recovery:
  - Low frequency hearing loss
  - Low severity of hearing loss
  - Short damage to sensory cells
- Any hearing loss remaining four weeks after incident is highly likely to become chronic as sensory cells have been irreversibly lost

When There is No or Insufficient Recovery

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- Hearing loss can have significant impact on cognitive and auditory function
- Substantially reduced quality of life
- Some people depend on well-functioning auditory function
  - Musicians, pilots, drivers, soldiers, etc.
- Even if hearing recovers, speech intelligibility may remain reduced
  - “Cocktail party effect”
- Increasing number of studies showing link between hearing loss and cognitive decline

If One Ear Only Is Affected

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- Even if only one ear is affected, speech perception, communication, and social interaction can be substantially impacted[1]
- Binaural hearing where the ear closest to the sound source receives the signal earlier and at a higher intensity provides auditory cues
- Cues are critical for processing of complex auditory signals such as speech perception in noise and localization of sound[2]
- Inability to determine where a sound originates can be frustrating and even disorienting to the listener, and the inability to localize sound may also be very dangerous and put patients at risk for accidents[3]
- Impact amplified if second ear having some deficit, e.g. age-related hearing loss
  - Incidence of sudden deafness highest ≥ 65 years[4]

[1] Wie et al. (2010), Unilateral deafness in adults: effects on communication and social interaction. Ann Otol Rhinol Laryngol. 119(11):772-781.
[2] Snapp et al. (2017), Comparison of speech-in-noise and localization benefits in unilateral hearing loss subjects using contralateral routing of signal hearing aids or bone anchored implants. Otol Neurotol. 38(1):11-18.
[3] Stachler et al. (2012), Clinical practice guideline: sudden hearing loss. Otolaryngol Head Neck Surg 146:S1-35.
[4] Alexander and Harris (2013), Incidence of sudden sensorineural hearing loss. Otol Neurotol. 34(9):1586-9.

Current Treatments

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- Oral corticosteroids are de facto standard of care
  - Typically for 14 days followed by a 5-day taper
  - Prednisone or prednisolone 1 mg/kg/day, at a maximum 60 mg/day
- Intratympanic corticosteroids are used less frequently
  - Mostly as ‘salvage therapy’ in case of insufficient hearing recovery (dexamethasone or methylprednisolone)
- Other treatments include antivirals, thrombolytics, vasodilators, vasoactive substances, or antioxidants

US Clinical Practice Guideline

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Table 3. Summary of Evidence-Based Statements

Management of Patients with Sudden Hearing Loss (Evidence-Based Statement)	Statement Strength
Diagnosis	
Exclusion of conductive hearing loss (Statement 1)	Strong recommendation
Modifying factors (Statement 2)	Recommendation
Computed tomography (Statement 3)	Strong recommendation against
Audiometric confirmation of idiopathic sudden sensorineural hearing loss (Statement 4)	Recommendation
Laboratory testing (Statement 5)	Strong recommendation against
Retrocochlear pathology (Statement 6)	Recommendation
Shared decision making	
Patient education (Statement 7)	Strong recommendation
Treatment	
Initial corticosteroids (Statement 8)	Option
Hyperbaric oxygen therapy (Statement 9)	Option
Other pharmacologic therapy (Statement 10)	Recommendation against *
Salvage therapy (Statement 11)	Recommendation **
Follow-up	
Outcomes assessment (Statement 12)	Recommendation
Rehabilitation (Statement 13)	Strong recommendation

** Clinicians should not routinely prescribe antivirals, thrombolytics, vasodilators, vasoactive substances, or antioxidants to patients with ISSNHL.*

*** Clinicians should offer IT steroid perfusion when patients have incomplete recovery from ISSNHL after failure of initial management.*

Efficacy of Corticosteroids

- Oral steroids as option since “even a small possibility of hearing improvement makes this a reasonable treatment to offer patients, considering the profound impact on QOL [quality of life] a hearing improvement may offer”[1]
- In spite of their widespread use, corticosteroids’ efficacy remains controversial and in some cases is contra-indicated (high blood pressure, diabetes, etc.)
- Meta-analysis showed[2]
  - Route of steroid administration does not seem to significantly affect treatment outcome;
  - Steroids do not appear to have an effect as a primary treatment for ISSNHL;
  - Available data suggest a rather large treatment effect for steroids as salvage treatment, but the quality of available studies appears to be poor.

[1] *Stachler et al. (2012), Clinical practice guideline: sudden hearing loss. Otolaryngol Head Neck Surg 146:S1-35.*
[2] *Crane et al. (2015), Steroids for treatment of sudden sensorineural hearing loss: a meta-analysis of randomized controlled trials. Laryngoscope. 125(1):209-17.*

Where the Unmet Medical Need Is Highest

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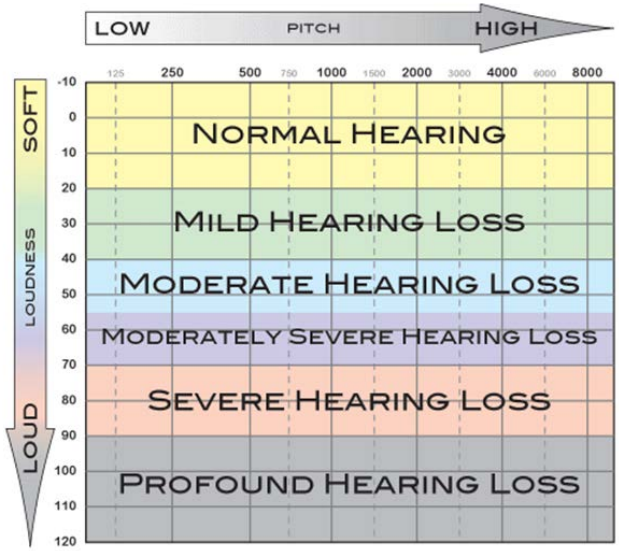
Hearing loss severity classification*



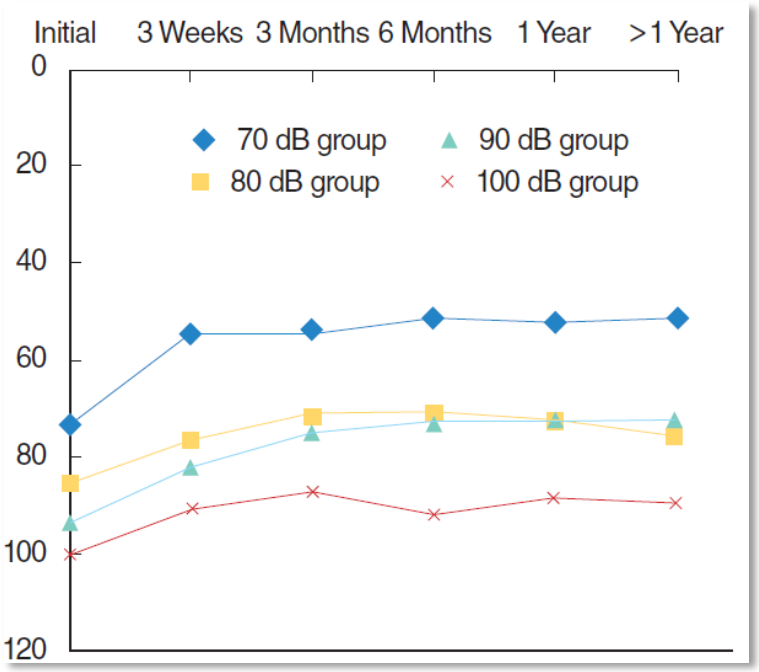
** American Speech Language Hearing Association*

- Severe and especially profound ISSNHL represent major challenges
- In case of profound hearing loss,
  - patients have always trouble understanding conversational speech even when using a hearing aid;
  - without a hearing aid, they are unable to detect even the loudest components of shouting
- Patient clearly aware of problem
- Try to prevent profound hearing loss from becoming chronic
- Preferably improve to hearing aid range (30 to 90 dB)

Severity as Prognostic Factor

- Severity of hearing loss single most important prognostic factor
- Patients with profound hearing loss across all test frequencies, treated with corticosteroids, had lowest rate of complete recovery (11.5 vs. 40.7% all types of sudden deafness)[1]
- Sudden deafness patients receiving intensive treatment protocol had lower magnitude – both relative and absolute – of hearing recovery when their initial hearing loss was 100 dB or more compared to lower severity cases[2]

Hearing level (dB) following sudden deafness[2]



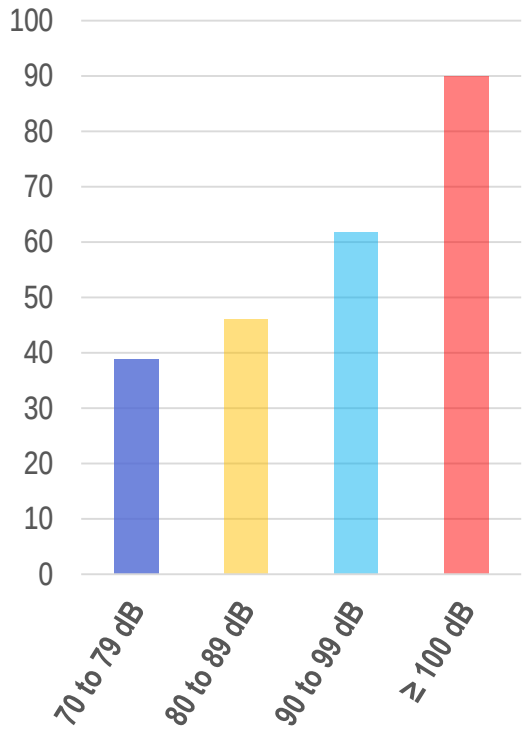
Hearing recovery at average of 0.5, 1, 2 and 4 kHz; n=10, 11, 16, 9. Treatment protocol: methylprednisolone i.m. for 12 days, hydroxyethyl starch and magnesium sulfate for 7 days, prostaglandine E1 for 5 days, concomittantly carbogen b.i.d. In case of lack of improvement: intratympanic dexamethasone every second day for 2 weeks.

[1] Huy and Sauvaget (2005), Idiopathic sudden sensorineural hearing loss is not an otologic emergency. Otol Neurotol. 26(5):896-902.
[2] Jo et al. (2015), Outcomes of severe to profound idiopathic sudden sensorineural hearing loss. Clin Exp Otorhinolaryngol. 8(3):206-10.

Risk of Persisting Profound Hearing Loss

- Several studies using «Siegel's criteria» for assessing hearing recovery[1]
  - Recovery < 15 dB considered «no improvement»
- Substantial risk of no improvement in profound acute hearing loss, in spite of corticosteroid treatment
  - Kang et al.: 30.3% (n=132)[2]
  - Nakashima et al.: 29.2% (n=24)[3]
  - Wen et al.: 70.2% (n=576)[4]

Incidence of no improvement (%) as function of initial acute hearing loss

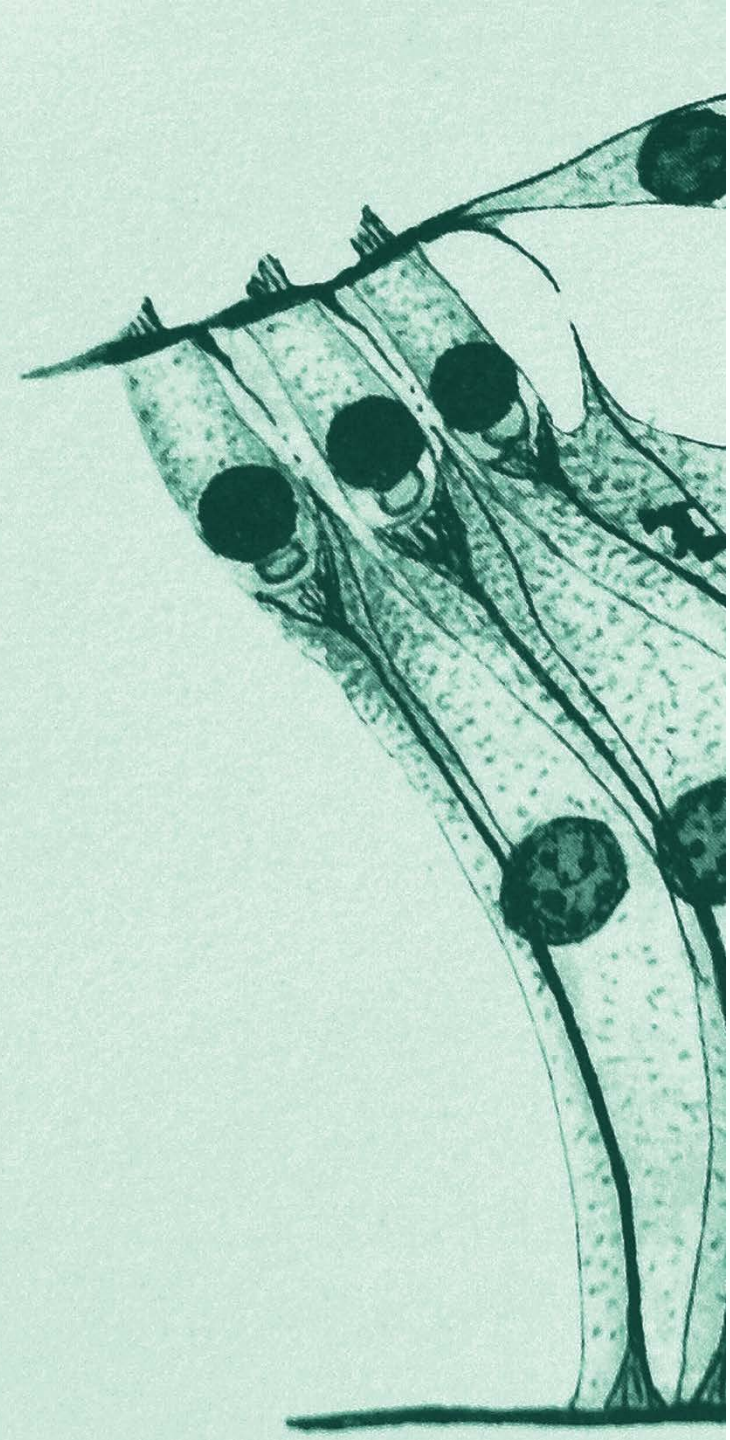


Patients with less than 15 dB hearing recovery after 3 weeks at average of 0.5, 1, 2 and 4 kHz; n=77, 65, 60, 100. From *Jo et al. (2015), Outcomes of severe to profound idiopathic sudden sensorineural hearing loss. Clin Exp Otorhinolaryngol. 8(3):206-10.*

[1] Siegel (1975), The treatment of idiopathic sudden sensorineural hearing loss. Otolaryngol Clin North Am. 8(2):467-73.
[2] Nakashima et al. (2014), Idiopathic sudden sensorineural hearing loss in Japan. Acta Oto-Laryngol. 134:1158–63.
[3] Kang et al. (2017), Prognostic factors for recovery from sudden sensorineural hearing loss: a retrospective study. J Audiol Otol. 21(1):9-15.
[4] Wen et al. (2014), Prognostic factors of profound idiopathic sudden sensorineural hearing loss..Eur Arch Otorhinolaryngol. 271(6):1423-9.

Conclusions

- Idiopathic condition – limited diagnostics
- Dearth of reliable and comprehensive data on natural history
- Marked increase in research activities
  - More reference data becoming available
  - Evidencing
- Severe and especially profound sudden deafness remain challenging condition
- Therapeutic window during acute stage for intervention to protect sensory cells
- Avoid or reduce chronic hearing loss and related impact on quality of life, auditory and cognitive ability
- No effective treatment option available to date
- Any treatment that improves hearing and/or reduces the risk of persisting profound hearing loss will be welcomed by patients and ENT physicians



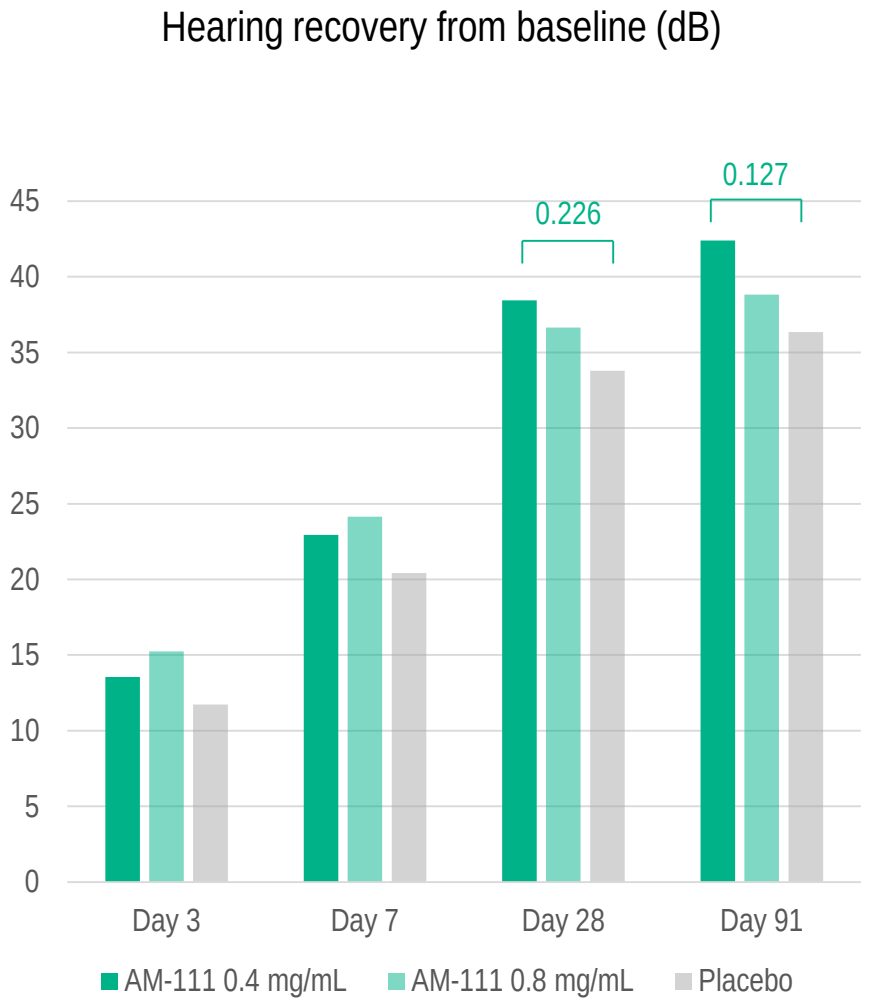
Update on AM-111 Program

Thomas Meyer, PhD

Chief Executive Officer

What Top-Line HEALOS Data Told Us

- Primary efficacy endpoint not met in overall population
- Hearing recovery numerically superior at all time points
- Recovery in placebo group higher than expected
- Statistically and clinically significant treatment effect in subpopulation of patients with profound acute sudden deafness
- Favorable safety profile confirmed



Improvement of hearing threshold at the average of the three worst affected contiguous test frequencies from baseline; repeated mesures ANCOVA (mITT; n=240).

Severe vs. Profound Hearing Loss Outcomes

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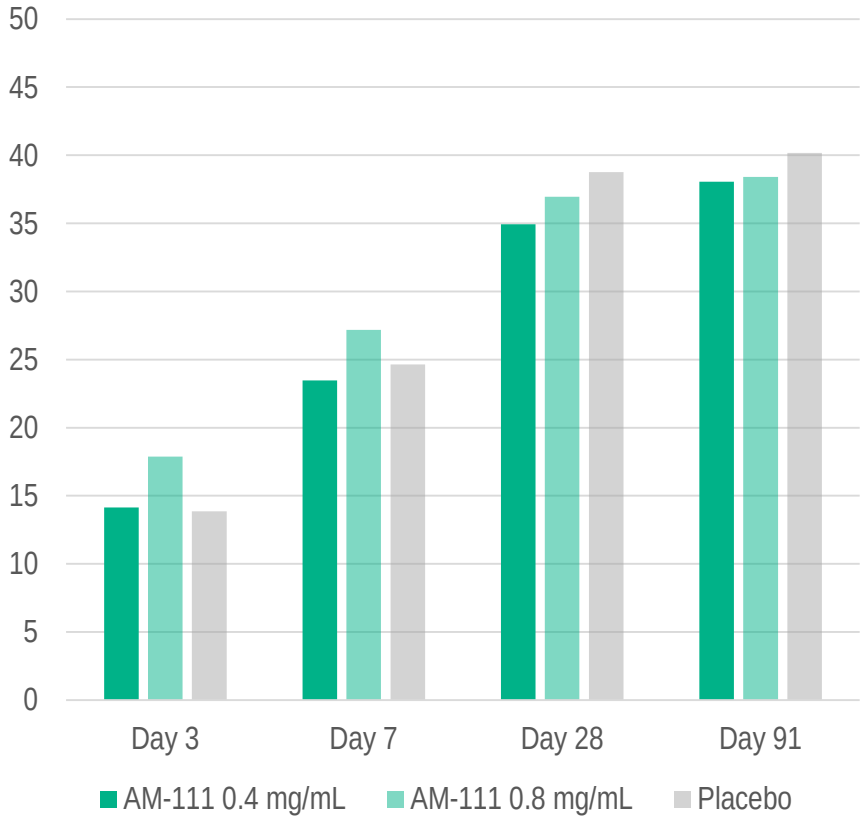
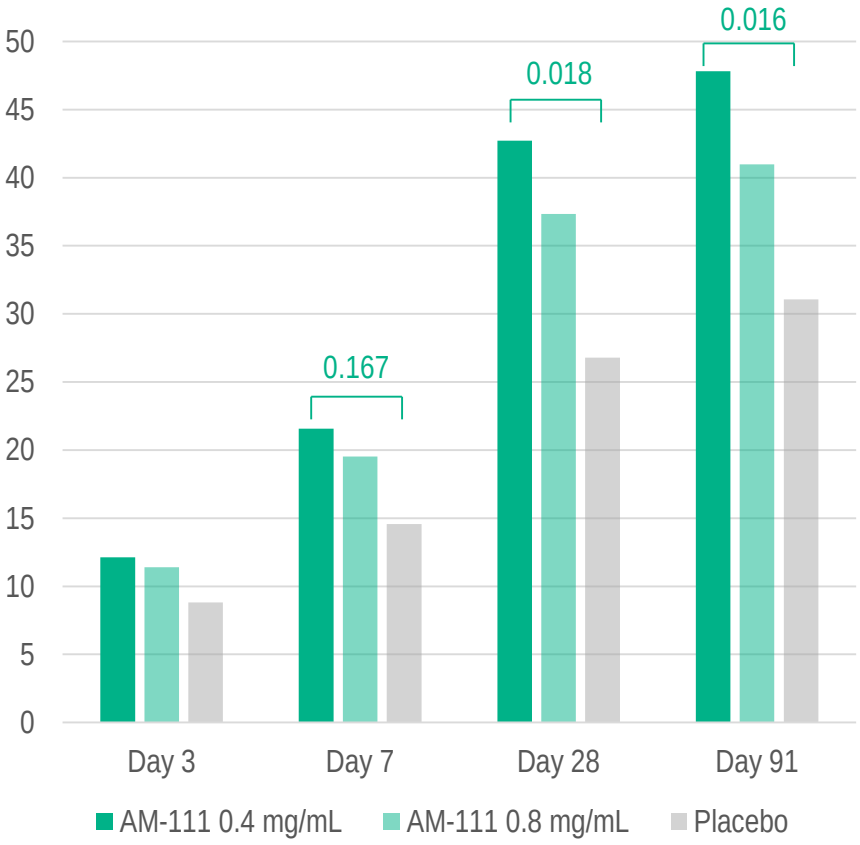
Hearing recovery from baseline (dB)

Severe acute hearing loss (< 90 dB) at baseline



Profound acute hearing loss (≥ 90 dB) at baseline



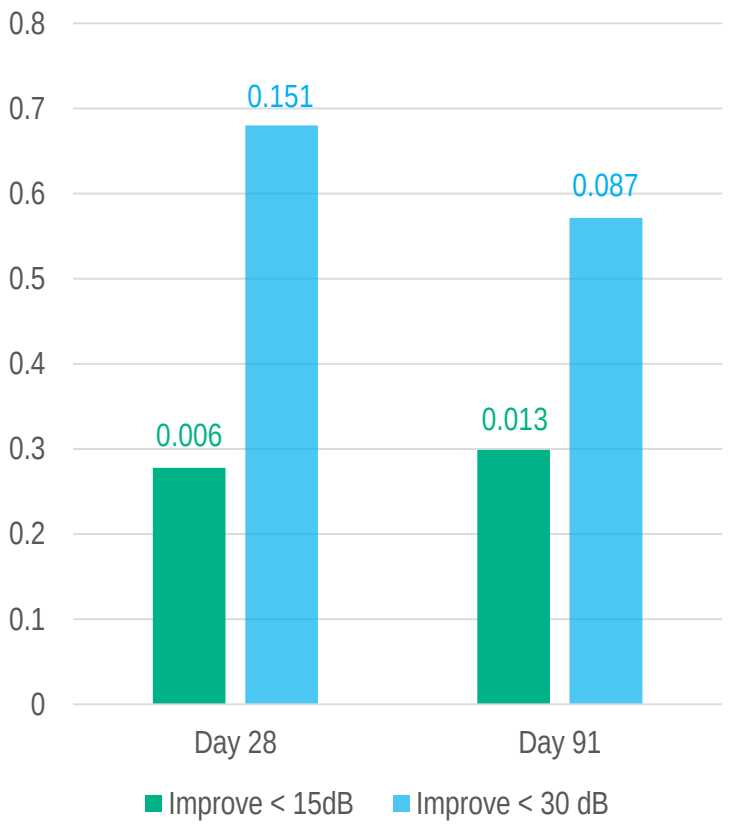
Improvement of hearing threshold at the average of the three worst affected contiguous test frequencies from baseline; post-hoc repeated mesures ANCOVA (mITT; n=142 for severe, n=98 for profound acute hearing loss subpopulation).

Clinical Relevance of Treatment Effects

- The average patient with profound acute hearing loss in the AM-111 0.4 mg/mL group
  - improved from being essentially deaf to a moderately severe hearing loss instead of a severe hearing loss
  - had about 17 dB better hearing
  - had significantly lower risk of no hearing improvement[1] (< 15 dB)
  - had substantially lower risk of no marked improvement[2] (< 30 dB)

  compared to the placebo group

Relative risk ratio AM-111 0.4 mg/mL vs. placebo

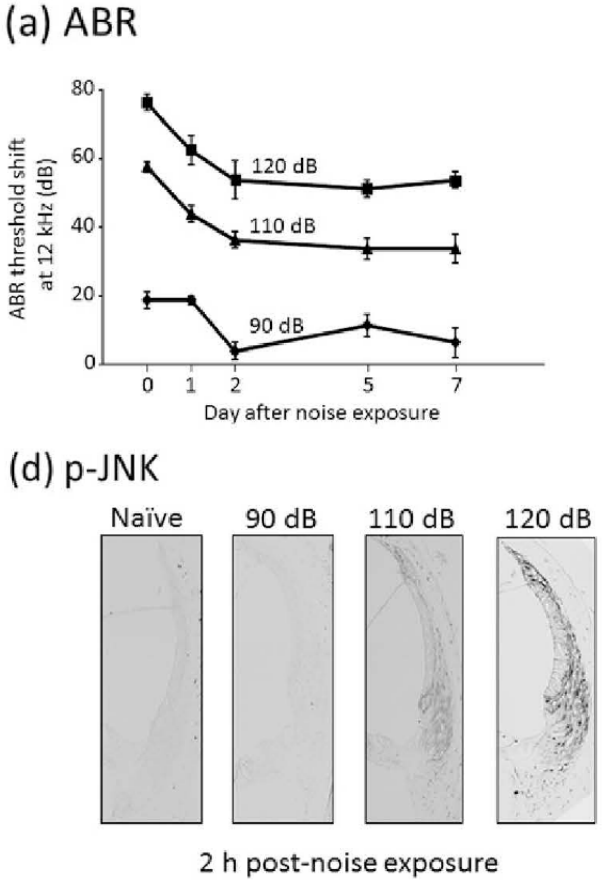


Relative risk ratio for AM-111 0.4 mg/mL patients to recover < 15 dB or < 30 dB in hearing threshold at the average of the three worst affected contiguous test frequencies from baseline compared to placebo; post-hoc Fisher's exact test (mITT; profound acute hearing loss subpopulation, n=35 (active), n=34 (placebo), last observation carried forward).

[1] *Siegel's criteria*
[2] *Proposed by various authors, e.g. Labatut et al., 2013*

Why Does Severity Matter?

- AM-111 can only exert otoprotective effects if acute cochlear injury is severe enough to trigger significant JNK activation
- Exposure of mice to sound at 110 and 120 dB for 2 hours resulted in permanent hearing loss and activation of JNK in the lateral wall structures of the cochlea
- Sound exposure at 90 dB caused only temporary, but not permanent hearing loss and did not result in activation of JNK
- Cochlear JNK activation in mice is believed to mirror the biological activity in humans. It is not practicable to measure this effect in humans → rely on measure of symptom intensity

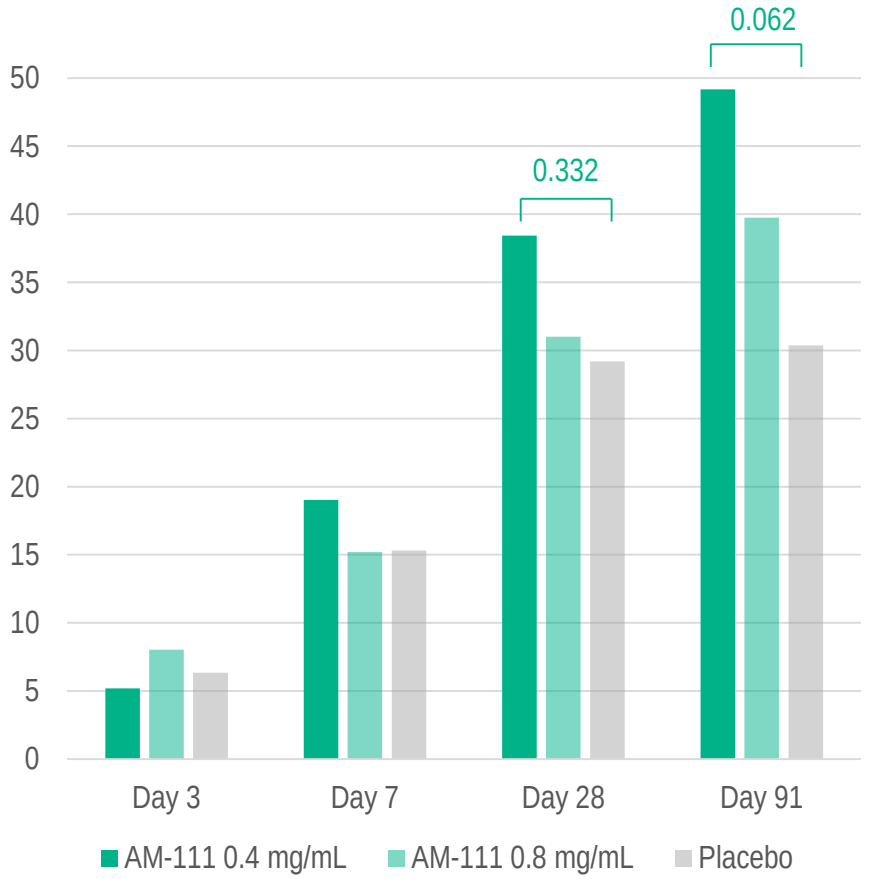


Nagashima et al. (2011), Acoustic overstimulation activates 5' -AMP-activated protein kinase through a temporary decrease in ATP level in the cochlear spiral ligament prior to permanent hearing loss in mice. Neurochem Int 59(6):812-820.

Supported by Improved Word Recognition

- Word recognition consistently tested at 80 dB stimulus level
- As expected, improvement lagging behind improvement in pure tone hearing
- The average patient
  - at baseline understood one word out of ten in the AM-111 0.4 mg/mL group and one word out of 6 in the placebo group
  - at Day 91 understood three out of five words in the AM-111 0.4 mg/mL group and every second word in the placebo group
- Difference at Day 91 of 19 percentage points clinically meaningful[1]

Improvement in word recognition from baseline (% pts.)

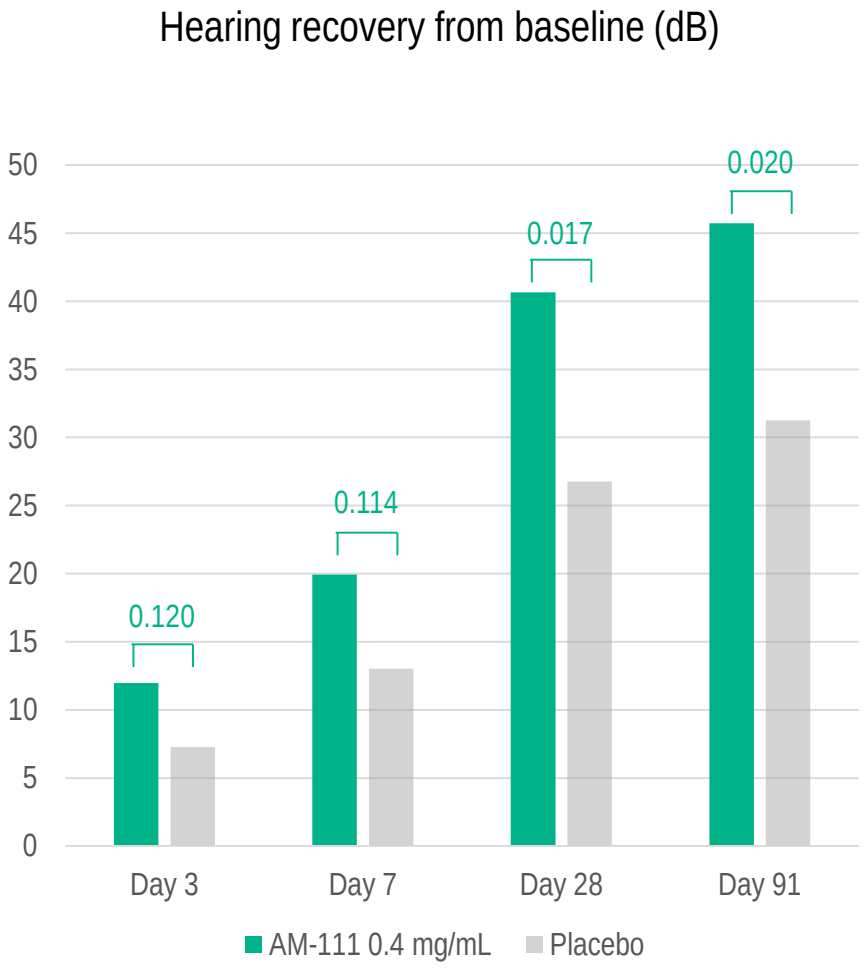


Improvement of word recognition score at 80 dB stimulus level from baseline; post-hoc repeated mesures ANCOVA (mITT; profound acute hearing loss population, n=98).

[1] *Difference of at least 15 percentage points considered clinically meaningful*

How Does HEALOS Compare Against Phase 2?

- Recovery in HEALOS placebo group higher than in Phase 2:
  - 40.2 dB vs. 31.6 dB in severe group
  - 31.1 dB vs. 29.2 dB in profound group
- Studies reporting improvement of 30-32 dB in corticosteroid-treated patients with severe-profound hearing loss[1,2]
- Pooling HEALOS data with Phase 2 data from profound acute hearing loss:
  - Similar pattern and magnitude of recovery
  - No improvement frequency 14.9 vs. 38.6% (relative risk 0.39, p=0.016)



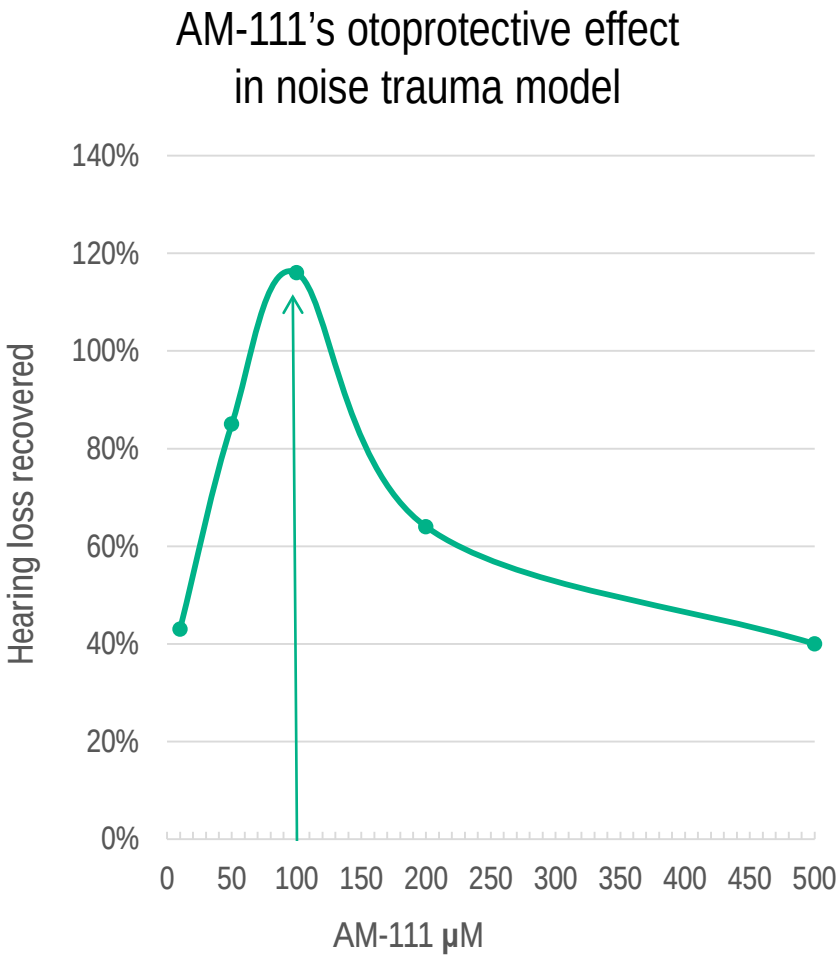
Improvement of hearing threshold at the average of the three worst affected contiguous test frequencies from baseline; post-hoc repeated mesures ANCOVA (mITT; profound acute hearing loss pooled from HEALOS and Phase 2, n=47 (active), n=44 (placebo)).

[1] *Labatut et al. (2013), Intratympanic steroids as primary initial treatment of idiopathic sudden sensorineural hearing loss. Eur Arch Otorhinolaryngol. 270:2823Y32.*

[2] *Rauch et al. (2014), Oral vs intratympanic corticosteroid therapy for idiopathic sudden sensorineural hearing loss: a randomized trial. JAMA 305:2071–9.*

Best Effects Observed at 0.4 mg/mL

- 0.4 mg/mL dose shown as most effective in both HEALOS and Phase 2
- Three animal studies showing upward sloping dose effect relationship up to 0.4 mg/mL(100 µM)
  - Noise trauma[1]
  - Sterile inflammation[2]
  - Ischemia[3]
- Another study showed AM-111's effect peaking at 0.4 mg/mL, then declining
  - Impact of cell permeation by D-TAT



Recovery of compound action potentials at the average of 6, 8 and 10 kHz in guinea pig ears treated with AM-111 4 hours post acute acoustic trauma (130 dB at 6 kHz for 15 minutes) compared with untreated contralateral ears 15 days post trauma

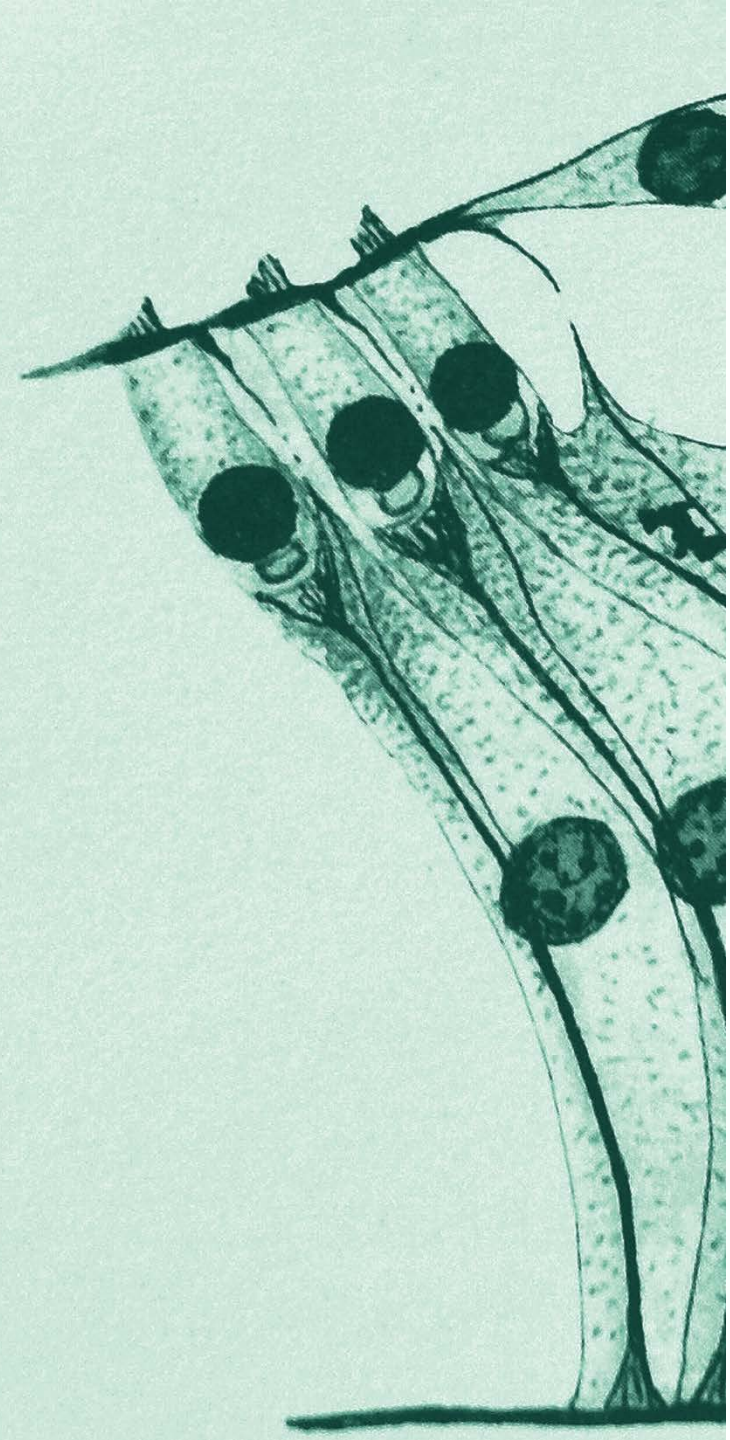
[1] Wang et al. (2007), Inhibition of the JNK-mediated mitochondrial cell death pathway restores auditory function in sound exposed animals. Mol Pharmacol 71:654-66.
[2] Barkdull et al. (2007), AM-111 reduces hearing loss in a guinea pig model of acute labyrinthitis. Laryngoscope 117:2174-82.
[3] Omotehara et al. (2011), Protection against ischemic cochlear damage by intratympanic administration of AM-111.Otol Neurotol. 32(9):1422-27.

ASSENT Trial Update

- Decision to terminate prematurely – based on
  - Enrollment stage
  - Need for substantial changes to protocol (hearing loss severity…)
  - Desire to obtain feedback on regulatory pathway
- 56 patients enrolled – of which 31 with profound acute hearing loss
- Data to become available in March 2018

Conclusions

- HEALOS first Phase 3 study ever to demonstrate effective otoprotection in humans
- Clinically and statistically significant hearing improvement over placebo
- Significant reduction in risk of no improvement
- Pure tone hearing outcomes confirmed by word recognition outcomes
- HEALOS outcomes essentially in line with Phase 2 data
- Demonstration of AM-111's otoprotective effect in HEALOS required high severity of cochlear injury with significant JNK activation
- ASSENT expected to further support current findings



Regulatory Considerations

Andrea Braun, PhD

Head of Regulatory and Quality Affairs

Current Regulatory Status

- Orphan Drug status awarded by EMA and FDA
- Fast Track designation from FDA
- Seriousness of condition and unmet medical need acknowledged
- Thorough discussions with health authorities during development
  - US: Pre-IND Meeting, IND, several Type C Meetings and other interactions
  - EU: several Protocol Assistance procedures
  - Covered all aspects of the development (clinical, non-clinical, CMC and combination product)

What Do FDA and EMA Require?

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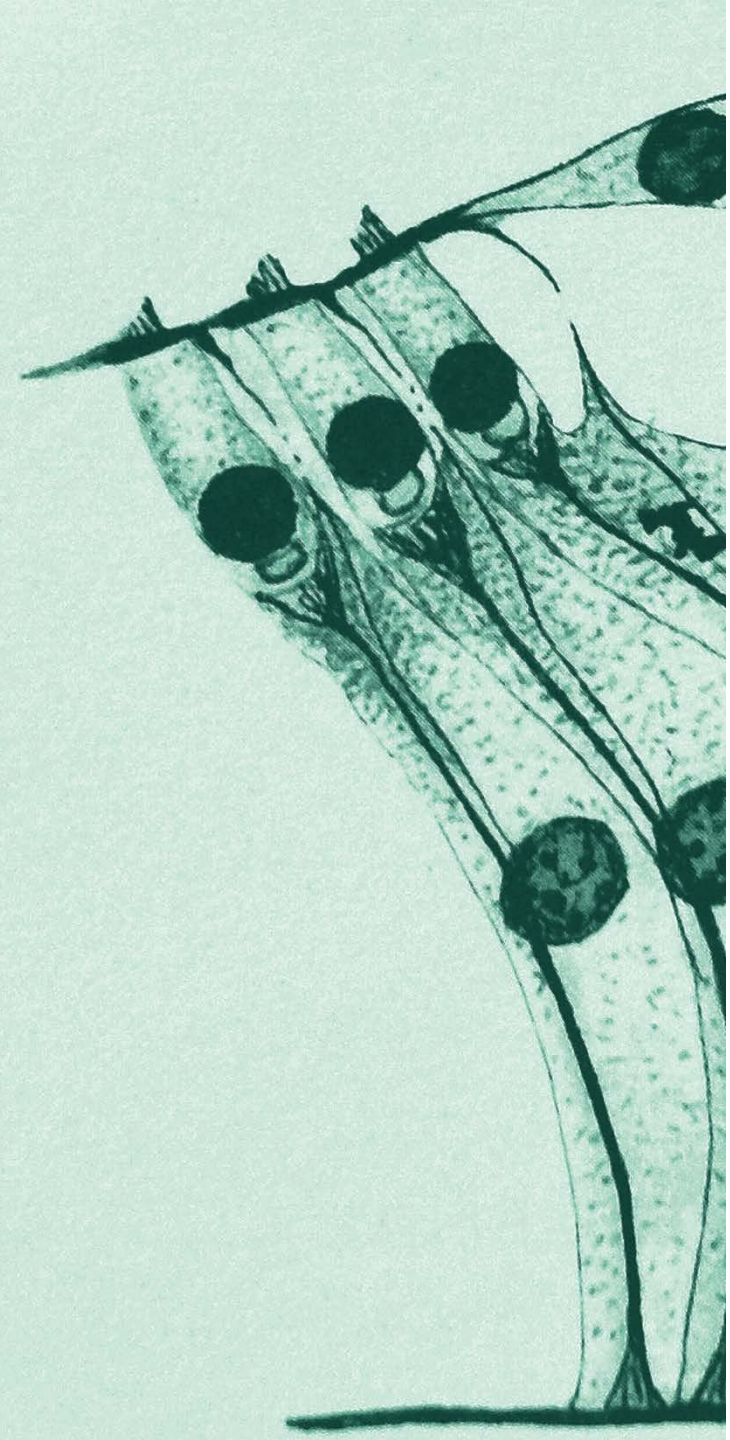
- Provide hearing recovery superior to placebo (spontaneous recovery)
  - Statistically significant and clinically meaningful (Δ at least 10 dB)
- Pure tone hearing thresholds as primary efficacy outcome variable
  - Traditionally used in hearing research
  - Universal use and application around the world
- FDA: primary efficacy endpoint after 91 days (FUV4) requested
- EMA: primary efficacy endpoint after 28 days (FUV3) acceptable
- Speech audiometry clinically important as well, but…
  - Lack of standardization of procedure
  - Language specific
  - Floor and ceiling effects

Planned Regulatory Interactions

- Current data package shows favorable safety profile and efficacy data from two randomized controlled studies in profound acute hearing loss patients
- Objective of Health Authority Meetings
  - Share and discuss HEALOS data
  - Seek guidance on path forward to dossier submission and approval
- Procedure
  - US: Type C Meeting
  - EU: Protocol Assistance with SAWP/CHMP at EMA
  - ASSENT data to be incorporated
  - Feedback from health authorities expected for Q2 2018



Market Considerations

Conclusions

Thomas Meyer, PhD

Chief Executive Officer

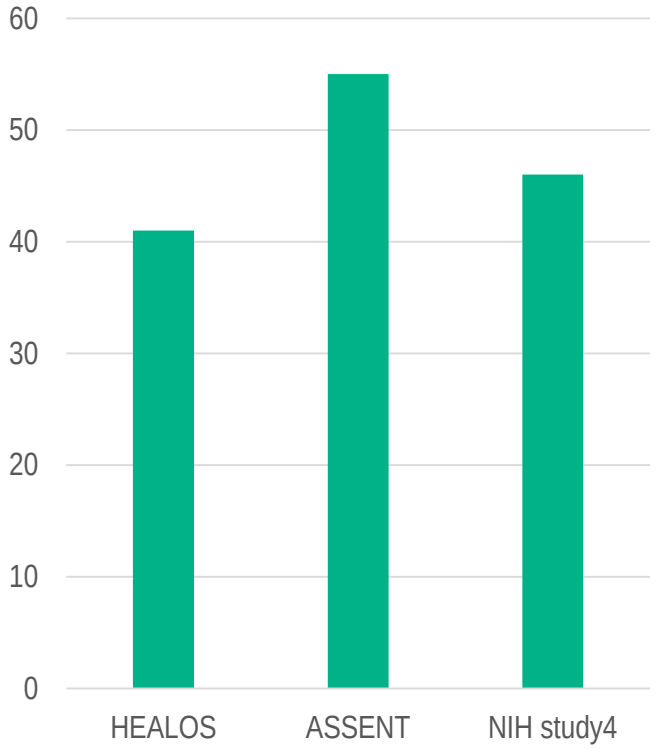
Positioning of AM-111

- Potential to become first treatment specifically indicated for acute inner ear hearing loss
- Target label = treatment of profound acute sensorineural hearing loss
  - Sudden deafness
  - Acute acoustic trauma
  - Surgery trauma / cochlear implants
- Single dose intratympanic administration
- Provides rapid and significant recovery of hearing
- Reduces risk of no improvement / chronic deafness
- Favorable safety profile
- Unlike corticosteroids no contraindications for people with diabetes

Incidence of Profound Sudden Deafness

- Profound category represents 25-30% of treated sudden deafness patients in most studies[1,2,3]
- Profound category represents 41-55% within studies enrolling both severe and profound sudden deafness patients
- High problem awareness and medical need in patients with profound acute hearing loss

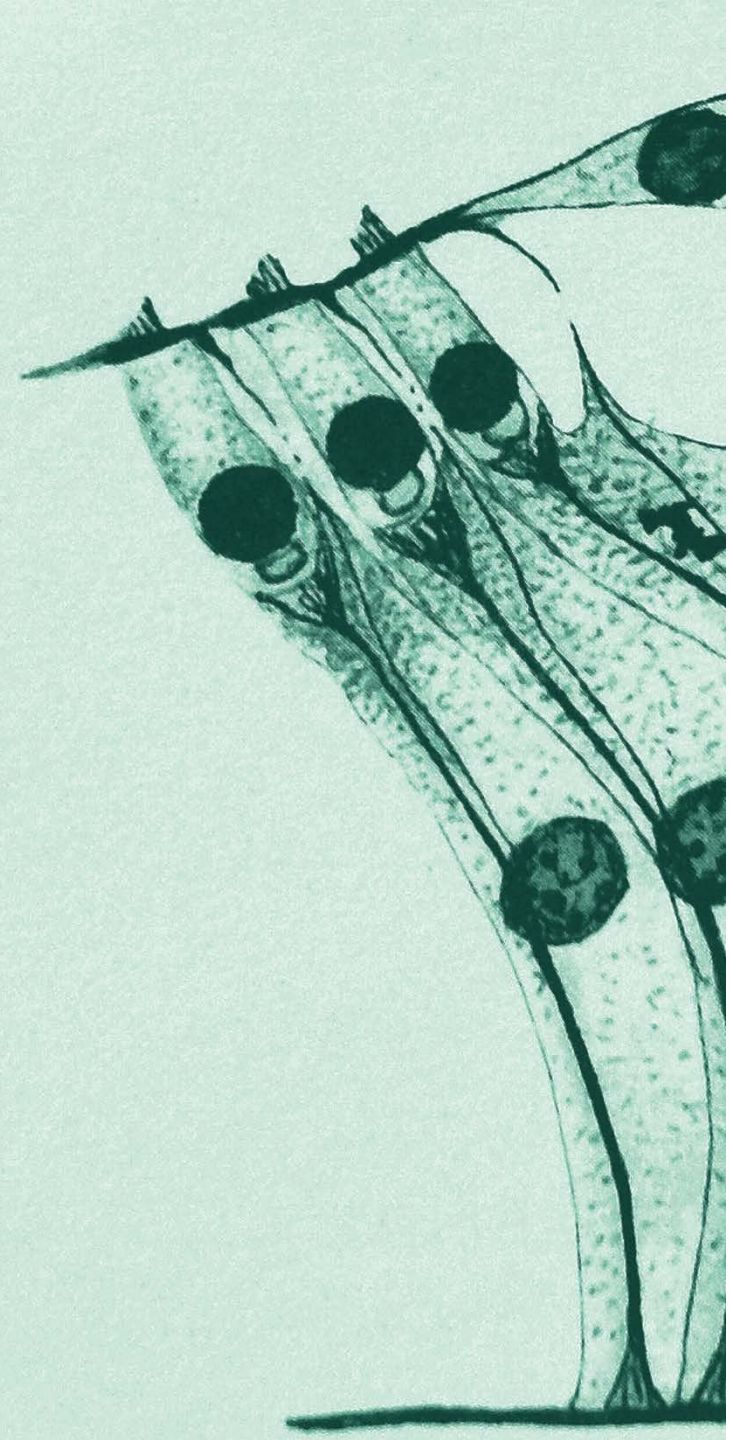
Share of profound sudden deafness patients in trials enrolling severe and profound cases (%)



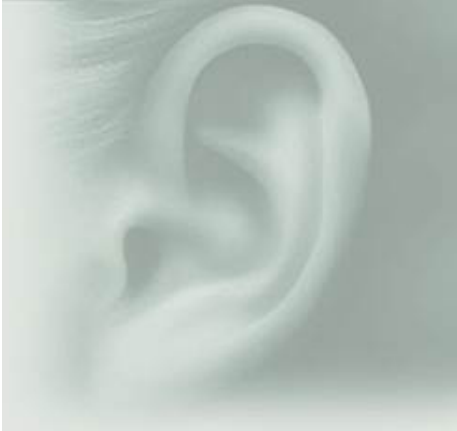
[1] *Edizer et al. (2015), Recovery of Idiopathic Sudden Sensorineural Hearing Loss. J Int Adv Otol. 11(2):122-6.*
[2] *Kang et al. (2017), Prognostic factors for recovery from sudden sensorineural hearing loss: a retrospective study. J Audiol Otol. 21(1):9-15.*
[3] *Huy and Sauvaget (2005), Idiopathic sudden sensorineural hearing loss is not an otologic emergency. Otol Neurotol. 26(5):896-902.*
[4] *Rauch et al. (2014), Oral vs intratympanic corticosteroid therapy for idiopathic sudden sensorineural hearing loss: a randomized trial. JAMA 305:2071–9.*

Conclusions and Outlook

- Apart from off-label use of corticosteroids, treatment of acute inner ear hearing loss has remained largely uncharted territory
- Large body of non-clinical and clinical data demonstrating AM-111's efficacy in protecting acutely injured cochlea
- Sufficient severity reached in profound hearing loss to activate AM-111's target and allow the drug to work
- HEALOS first Phase 3 study ever to demonstrate effective otoprotection in humans
- Compelling set of safety and efficacy data for serious condition / high unmet medical need
- Discussions with FDA and EMA expected to clarify path forward
- More detailed outcomes from HEALOS and ASSENT to be presented in 2018



Questions and Answers



Take care of your ears!

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