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Innovative Treatments for Inner Ear Disorders

Keyzilen™ Program Update

October 11, 2016

NASDAQ: EARS

Forward-looking Statements

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This presentation and the accompanying oral commentary contain “forward-looking” statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this presentation and the accompanying oral commentary, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “might,” “approximately,” “expect,” “predict,” “could,” “potentially” or the negative of these terms or other similar expressions. Forward-looking statements appear in a number of places throughout this presentation and the accompanying oral commentary and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates AM-101 and AM-111, our intellectual property position, our ability to develop commercial functions, expectations regarding clinical trial data, our results of operations, cash needs, financial condition, liquidity, prospects, growth and strategies, the industry in which we operate and the trends that may affect the industry or us.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These include, but are not limited to, the timing and conduct of clinical trials of our product candidates, the clinical utility of our product candidates, including the likelihood that the TACTT3 trial may not meet its endpoints, the timing or likelihood of regulatory filings and approvals, the timing or likelihood of regulatory filings and approvals, our intellectual property position and our financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to our capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption “Risk Factors” in our Annual Report on Form 20-F and future filings with the Securities and Exchange Commission. Forward-looking statements represent our management’s beliefs and assumptions only as of the date of this presentation. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons why actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

Keyzilen™ Development Plan Update

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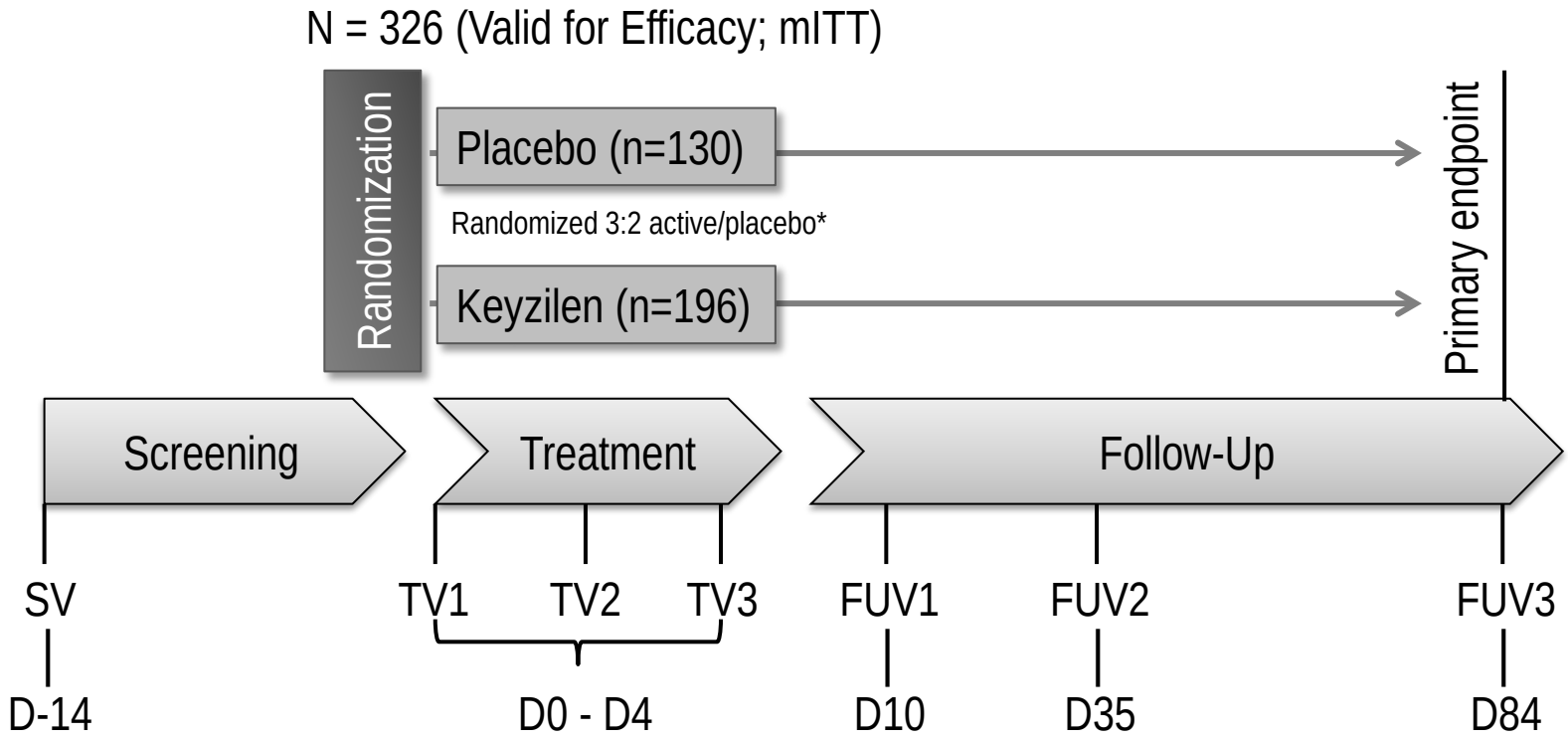
Today's Agenda

- TACTT2 trial: Additional results and learnings
- TACTT3 trial: Protocol amendment
- Planned discussions with FDA regarding US regulatory pathway

TACTT2 Trial Design Overview



** Stratified for etiology (traumatic cochlear injury / otitis media) and laterality (unilateral, bilateral)*

- Acute peripheral tinnitus following traumatic cochlear insult or otitis media
  - Traumatic cochlear insult includes acute noise trauma, barotrauma, surgery trauma
- Up to 3 months from onset
- Conducted primarily in North America

TACTT2 Trial – Baseline and Demographics

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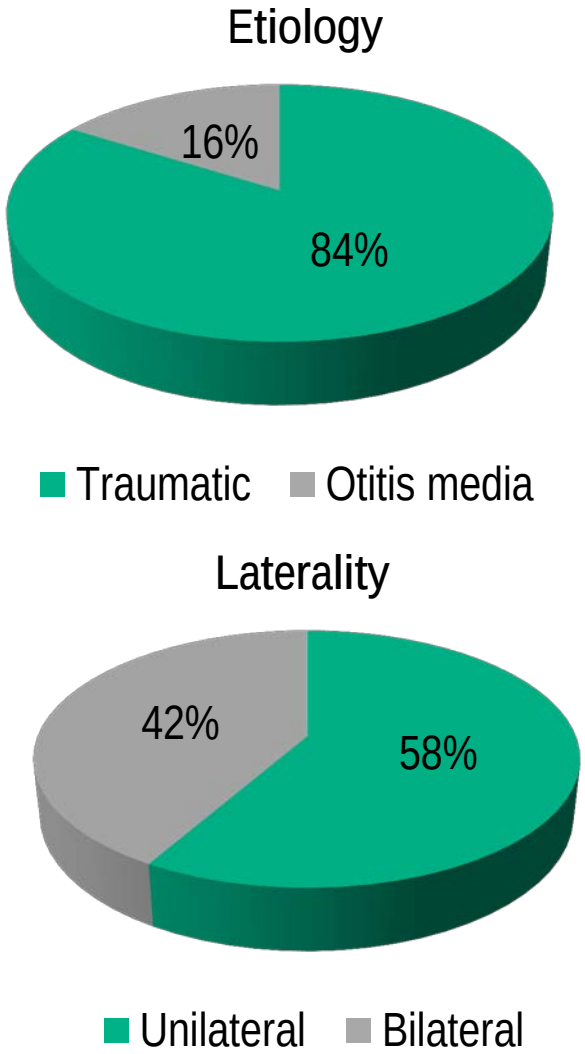
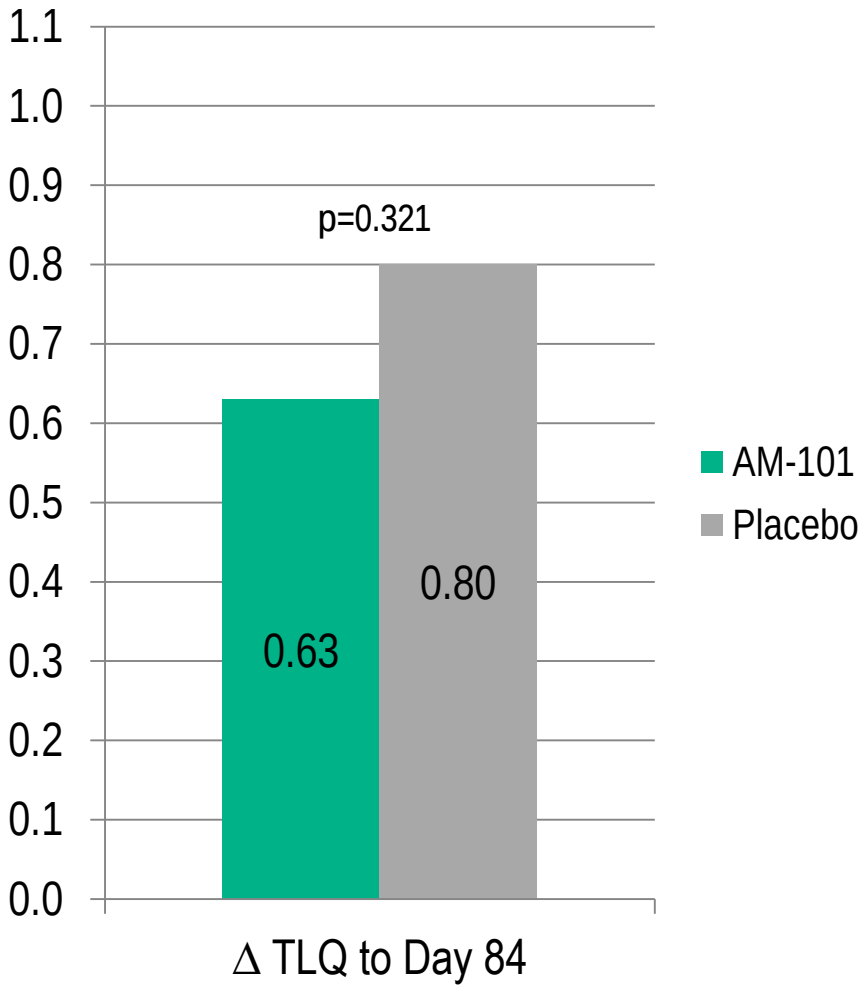
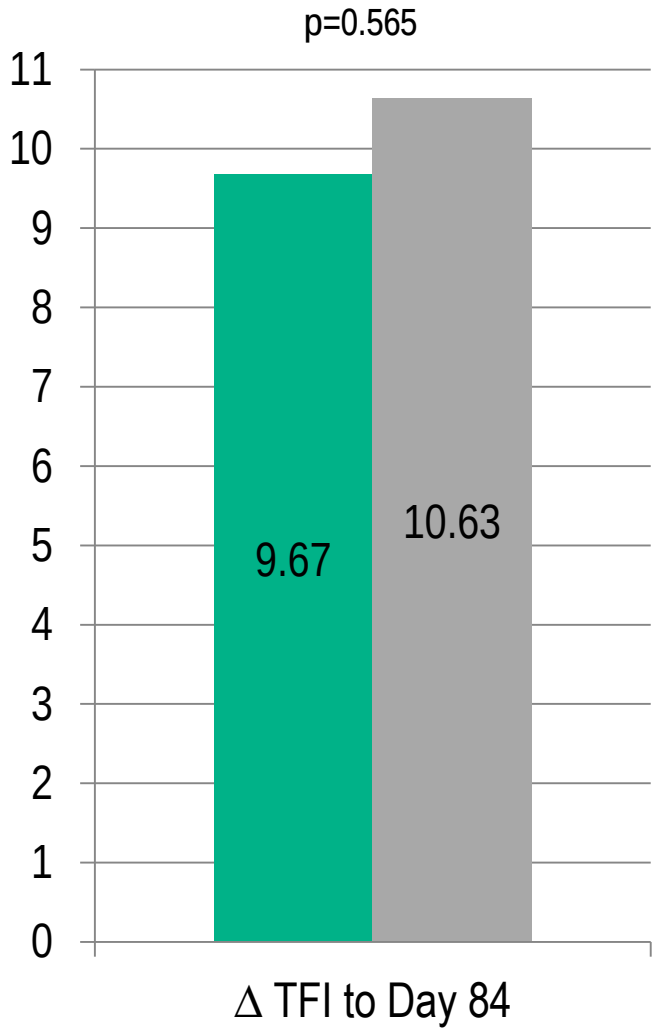
Co-primary endpoints, measured from baseline to Day 84:

- Change in subjective tinnitus loudness (TLQ; 0-10)
  - Baseline values: 6.44 points for Keyzilen, 6.47 points for placebo
- Change in tinnitus burden (TFI; 0-100)
  - Baseline values: 52.4 points for Keyzilen, 50.2 points for placebo



Co-Primary Efficacy Endpoints





TACTT2 Trial – Outcome Analysis

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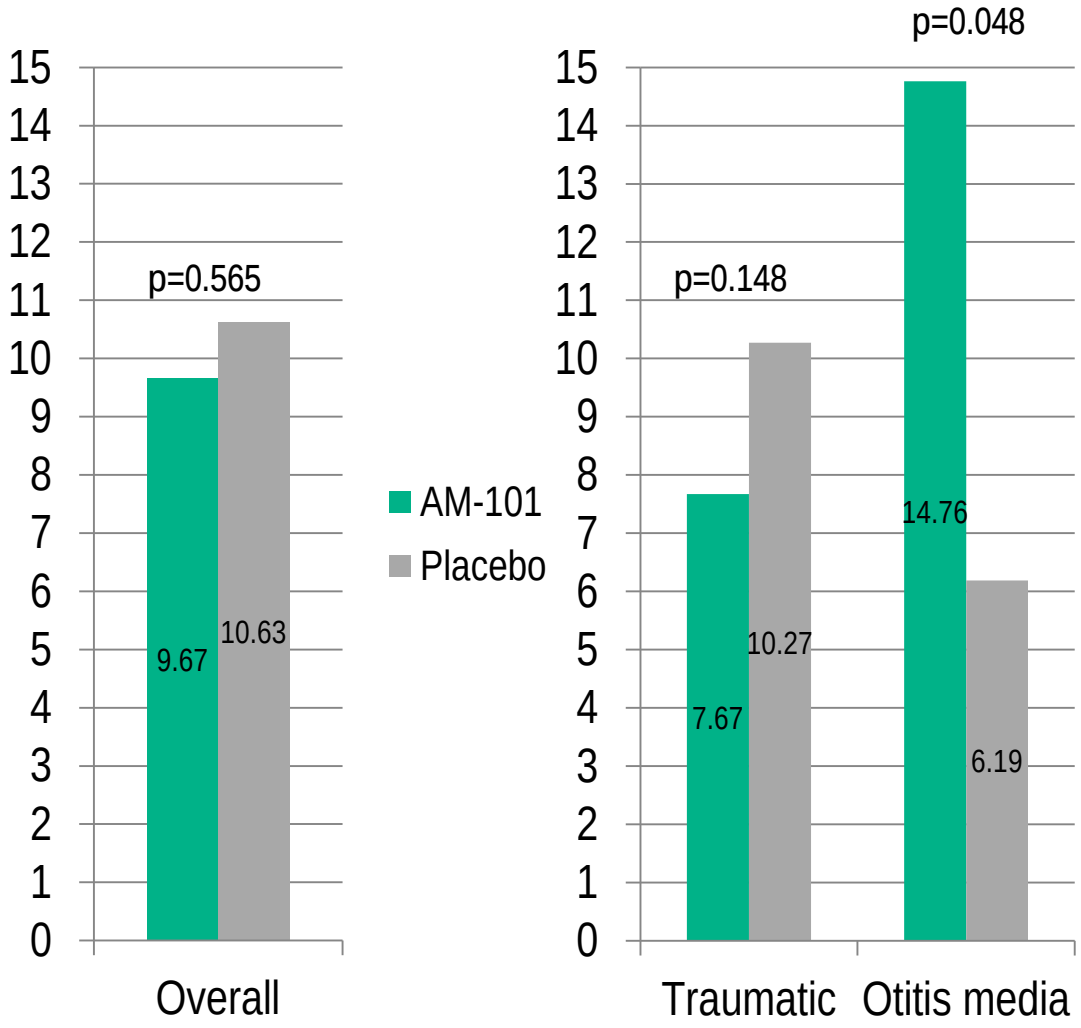
Two principal sources for disappointing outcome:

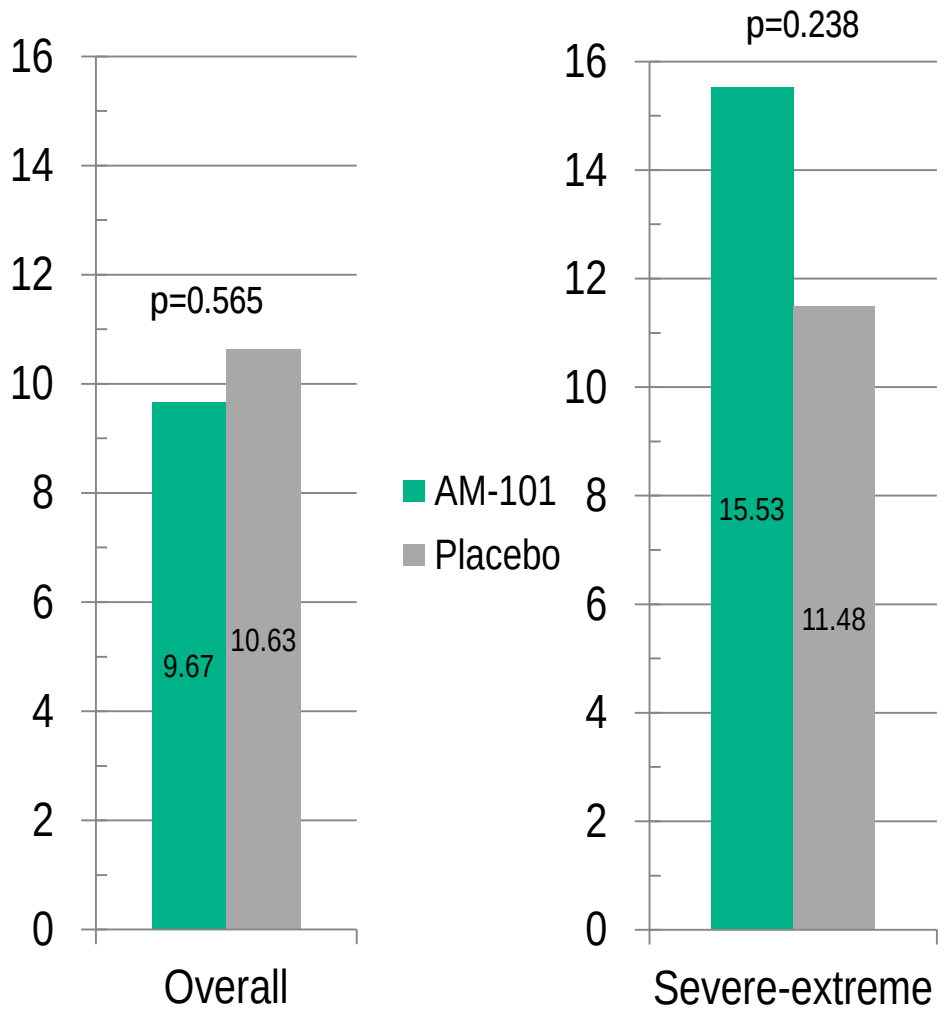
- **Trial design**
  - High frequency (daily) of tinnitus loudness ratings over extended time period
  - TLQ showed lower sensitivity to change than the TFI
- **Trial administration**
  - High variability in outcomes between study sites
  - Positive outcomes at numerous sites, including many high enrollment centers

Subgroup – Otitis Media-Related Tinnitus



- Clinically meaningful and statistically significant TFI results in subgroup with otitis media-related tinnitus
- Δ TFI ≥ 13 defined as clinically meaningful by TFI developers
- Pre-specified subgroup

Subgroup – Severe or Extreme Tinnitus



- Post-hoc analysis showing trend for improvement in subgroup with severe or extreme tinnitus at baseline
- Based on self-rated global severity and TFI definition
- Clinically meaningful improvement in TFI for severe or extreme tinnnitus subgroup

TACTT2 Trial – Safety Outcomes

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- Data show that Keyzilen was well tolerated and confirm favorable safety profile
- Low incidence of clinically meaningful hearing deterioration
  - Primary safety endpoint did not show a significant difference between treatment groups (p=0.82)
- No drug- or procedure-related SAEs observed and rates of drug- or procedure-related AEs were similar
- Occurrence of procedure-related effects low and mostly transient
  - Approximately 1,000 intratympanic administrations performed
- Safety data recently presented at AAO-HNSF meeting

TACTT2 Trial – Summary

- TACTT2 failure to confirm efficacy of Keyzilen in overall trial population clearly disappointing
- Clinically meaningful reductions in tinnitus burden in relevant subgroups very encouraging
- New knowledge gained from TACTT2 allows appropriate adjustments to TACTT3 while outcomes remain fully blinded

TACTT3 Development Plan Update

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Original TACTT3 Trial Design / Enrollment

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	TACTT3 – A	TACTT3 – B
Patients	Acute inner ear tinnitus, within 3 months from onset	Post-acute inner ear tinnitus, 3-6 months from onset
Dosing	Single treatment cycle of three intratympanic injections over 3-5 days, randomized 3:2 to 0.87 mg/mL or placebo	
Enrollment	~300 enrolled • 38% of patients suffering from tinnitus following otitis media as compared to 16% in TACTT2 • Last patient completed last study visit in late September 2016	~330 enrolled
Primary endpoint	Δ Tinnitus Loudness to Day 84	
Key secondary endpoint	Δ Tinnitus Functional Index to Day 84	

TACTT3 Trial – Protocol Amendments

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1. TFI elevated from key secondary endpoint to alternate primary efficacy endpoint
   - TFI has ability to directly measure the clinically relevant tinnitus burden
   - TFI showed higher sensitivity than TLQ in TACTT2
   - Study can be considered successful if one of the two endpoints is achieved
   - Alpha level for significance testing will be 4% for TFI and 1% for TLQ

2. Otitis media and severity subgroups included in confirmatory statistical testing along with overall study population
   - Allows for further corroboration of TACTT2 findings
   - Testing performed according to Hochberg procedure, which avoids need for pre-specification of hierarchy and enhances chance of achieving subgroup success

3. Enhance statistical power by enrolling 120 additional patients
   - 60 additional patients in each of Stratum A and Stratum B

TLQ: Endpoint unchanged but reduced rating frequency between study visits

TACTT3 Trial – Statistical Powering

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Amended TACTT3 trial, including additional patients, to have statistical power of:

- 87% to show significance for the TFI on at least one of the three patient populations: overall, otitis media tinnitus, severe tinnitus
  - Assumptions:
    - Standard deviations equivalent to 80% confidence level in TACTT2
    - Treatment effect of 5-7 points for change in TFI for Keyzilen group compared to placebo
- Overall, at least 87% and up to 94% to show significance for either the TFI or the TLQ on at least one of the three patient populations
  - Assumptions:
    - As above, plus treatment effect of 0.5 for change in TLQ for Keyzilen group compared to placebo

TACTT3 Trial – Summary

- Favorable differences in patient demographics and trial conduct compared to TACTT2
- Measures implemented under amendment will enhance assay sensitivity and shift focus to the TFI
- Increased likelihood of positive trial that successfully detects true treatment effects of Keyzilen

Keyzilen™ Regulatory Update

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Keyzilen Regulatory Update

- TACTT3 protocol amendment to be submitted to regulatory agencies and ethics committees in Europe
- Anticipate approvals around the end of 2016
- Plan to resume trial enrollment in January 2017
- Expect top-line results from expanded TACTT3 trial in early 2018

Keyzilen Regulatory Update

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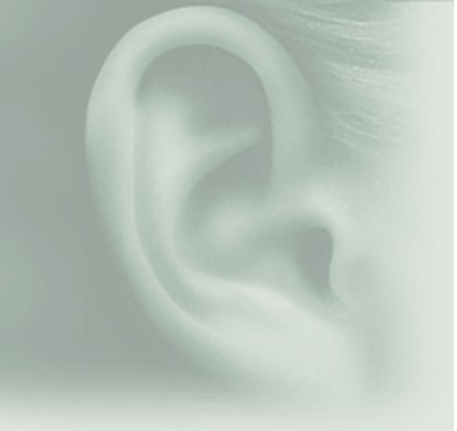
- Type C meeting with FDA scheduled for early December
- Written responses
- Plan to seek feedback on:
  - TACTT2 outcomes
  - TACTT3 protocol modifications
  - US regulatory path forward



Corporate Overview

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AM-111 for Acute Inner Ear Hearing Loss

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- Potential to become first specific therapeutic for acute inner ear hearing loss
- Launched HEALOS in November 2015: Over 50% of patients enrolled
- Launched ASSENT in June 2016: Trial ramping up
- Top-line results expected in second half of 2017
- Objective outcomes based on audiometry
- Orphan drug designation from both FDA and EMA

Keyzilen Program Update

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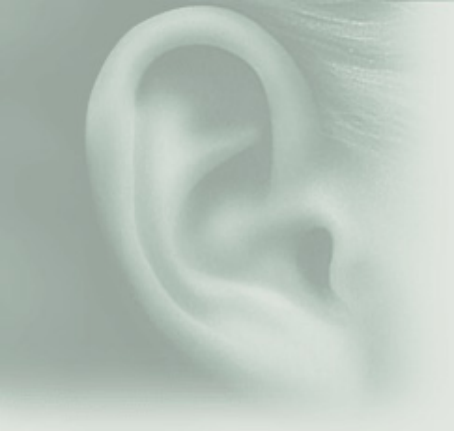
- Positive signals in three previous randomized and controlled trials
- Corroborated positive results in two specific subgroups in TACTT2
- TACTT3 provides solid and timely opportunity to apply learnings from TACTT2
- TACTT3 protocol amendments increase probability of success
- Every reason to continue to believe in Keyzilen, its mechanism of action and the therapeutic concept



Questions & Answers

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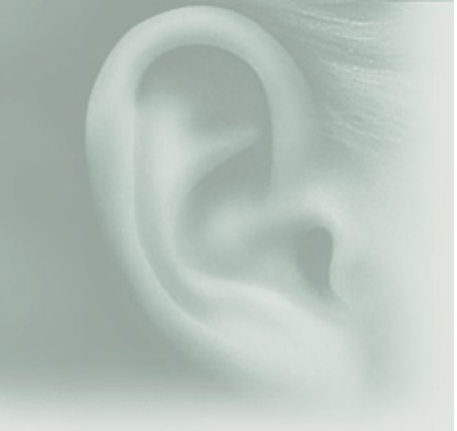

Take care of your ears!

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