

# SPI-1005 for the Treatment of Meniere's Disease (Open Label)

NCT06859788

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3
<b>Sponsor</b>	Sound Pharmaceuticals, Incorporated
<b>Enrollment</b>	200 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Adult males/females, 18-75 years of age at the time of enrollment.
- Diagnosis of probable or definite Meniere's Disease by AAO-HNS Amended 2015 Criteria.
- At least two of three active symptoms (fluctuating hearing; tinnitus; aural fullness; vertigo or dizziness) of Meniere's disease, within 3 months of study enrollment.
- Type A tympanogram at screening.
- Air conduction thresholds  $\leq 90$  dB at all tested frequencies (250-8000 Hz) in both ears.

... and 2 more (see full listing online)

### Exclusion (11)

- Current, or within 60 days prior to study enrollment, use of IV or intratympanic ototoxic medications such as chemotherapy including cisplatin, carboplatin, or oxaliplatin; aminoglycoside antibiotics including gentamicin, amikacin, tobramycin, kanamycin, or streptomycin; or loop diuretics including furosemide.
- History of otosclerosis or vestibular schwannoma.
- History of significant middle ear or inner ear surgery in the affected ear.
- Conductive hearing loss with air-bone gap  $\geq 15$  dB, otitis media, or mixed hearing loss.
- Significant cardiovascular, pulmonary, hepatic, renal, hematologic, gastrointestinal, endocrine, immunologic, neurological, or psychiatric disease.

... and 6 more (see full listing online)

## Locations (8 total)

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The House Institute, Los Angeles, California, United States  
ENT and Allergy Associates of Florida, Boca Raton, Florida, United States  
University of Miami, Miami, Florida, United States  
... and 5 more locations

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<https://clinicaltrials.gov/study/NCT06859788>

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