



Promising First-in-Patient Results for ACOU085 (INN: Bimokalner) in Cisplatin-Induced Ototoxicity

Descrizione

COMUNICATO STAMPA - CONTENUTO PROMOZIONALE

TÄBINGEN, Germany, June 12, 2026 /PRNewswire/ - Acousia Therapeutics GmbH, a clinical-stage biotechnology company pioneering treatments for acute and chronic inner ear hearing loss, today announced positive top-line efficacy results from its completed Phase 2a PROHEAR Study. ACOU085 is a proprietary, first-in-class small molecule that has demonstrated robust and reproducible efficacy across multiple preclinical hearing loss models, including drug-induced ototoxicity.

The exploratory, placebo-controlled, split-body Phase 2a PROHEAR Study assessed the otoprotective efficacy of a 6 mg transtympanic dose of ACOU085 compared to placebo in testicular cancer patients at risk of cisplatin-induced sensorineural hearing loss.

Among the young, hearing-healthy participants, more than 90% developed ototoxicity in at least one ear, as defined by ASHA criteria, after three cisplatin cycles (300 mg/m²). The hearing loss primarily affected the extended high-frequency range (10-16 kHz), with mild to moderate severity.

Preliminary Top-Line Efficacy Results

In patients who developed ototoxicity, treatment with ACOU085 resulted in a clinically meaningful prevention of pure-tone audiometry (PTA) threshold increases at affected frequencies, compared to placebo, following the final cisplatin cycle. Further analysis of the PROHEAR Study results, including post-hoc evaluations, is ongoing and will be submitted for publication in a peer-reviewed journal.

This is an important and encouraging milestone toward establishing Kv7.4 activation as a novel therapeutic approach for multiple forms of hearing loss. This broad therapeutic potential addresses a significant unmet medical need, which current device-based solutions only partially meet. The clinical results for ACOU085 create a compelling opportunity to advance Kv7.4 modulation into broader patient populations," said Professor Hubert LÄwenheim, Chair of Otorhinolaryngology & Head & Neck Surgery at TÄbingen University Medical Center and Scientific Supervisor of the PROHEAR Study.

Management Commentary

“Today represents an exciting advancement for cancer patients at risk of cisplatin-induced hearing loss,” said Tim Boelke, M.D., CEO & CMO of Acousia Therapeutics GmbH. “Our novel drug candidate has the potential to prevent permanent inner ear damage commonly seen after cisplatin-based chemotherapy.”

The Acousia team will attend the BIO International Convention in San Diego (June 22-25, 2026) to discuss collaboration opportunities with strategic partners for the next phase of clinical development.

ACOU085 (Bimokalner)

ACOU085 is a first-in-class, etiology-agnostic otoprotective agent, administered via a standard transtympanic injection using a proprietary slow-release gel formulation. Cisplatin-induced hearing loss is a severe, permanent side effect caused by irreversible damage to the cochlea's outer hair cells (OHCs). By modulating the biologically validated Kv7.4 potassium channel target (encoded by KCNQ4) in OHCs, ACOU085 has demonstrated significant potential to reduce cisplatin-induced hearing loss and preserve OHC integrity in preclinical studies.

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Data di creazione

Giugno 12, 2026

Autore

redazione

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