Acousia Announces Completion of Patient Enrollment in Phase 2 PROHEAR Study Evaluating ACOU085 (INN: Bimokalner) for the Prevention of Cisplatin-Induced Ototoxicity

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Tübingen, Germany, January 8, 2026

Acousia Therapeutics GmbH, a clinical-stage biotechnology company developing treatments for acute and chronic inner ear hearing loss, announced the completion of patient enrollment in its Phase 2 PROHEAR clinical study. ACOU085 (INN: Bimokalner) 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 PROHEAR Study is a double-blind, randomized, placebo-controlled, split-body, multicenter Phase 2 trial. It enrolled young male patients with metastatic testicular cancer who are scheduled to receive cisplatin-based chemotherapy. While cisplatin is a highly effective chemotherapeutic agent, cumulative doses of ?300 mg/m² lead to clinically meaningful, permanent hearing loss in the majority of patients.

Fifteen leading university hospitals in Germany are participating in this interdisciplinary study. Patients are randomized to receive either ACOU085 or placebo administered prior to each cisplatin cycle in a split-body trial design, with a battery of audiometric tests performed at baseline and at the end of each cisplatin cycle.

Primary Objective

The PROHEAR Study aims to assess whether Bimokalner can prevent ototoxic hearing loss induced by cisplatin. The study uses within-patient, placebo-controlled comparisons of functional hearing metrics and is designed to provide translational target validation for Acousia Therapeutics' Kv7.4 activator programs and clinical proof of principle for Bimokalner in hearing loss patients.

Management Commentary

"Today marks an important development milestone for Bimokalner," said Tim Boelke, M.D., CEO & CMO of Acousia Therapeutics. "This drug candidate has the potential to prevent the permanent inner ear damage frequently observed following cisplatin-based chemotherapy. As we reach full enrollment in the PROHEAR Study, I want to express gratitude to all participating patients and clinical teams for their trust and commitment. The blinded preliminary results are promising, and we look forward to reviewing the full unblinded dataset in Q2–Q3 2026."

Tim Boelke (CEO & CMO) and Jonas Dyhrfjeld-Johnsen (CSO & CDO) will attend JPM Week in San Francisco (January 12–15, 2026) and welcome the opportunity to engage with investors and strategic partners during the Biotech Showcase (company presentation: Tuesday, January 13, 2:15 PM PT) and BIO Partnering @ JPM Week.

About ACOU085 (Bimokalner)

ACOU085 is a first-in-class, etiology-agnostic otoprotective small molecule delivered via standard transtympanic administration in a proprietary slow-release gel formulation. Cisplatin-induced hearing loss is a severe and permanent side effect resulting from irreversible damage to the cochlea's outer hair cells (OHCs). ACOU085 modulates the biologically validated KCNQ4-encoded Kv7.4 potassium channel expressed in OHCs and has shown significant potential to reduce cisplatin-induced hearing loss and preserve OHC integrity in preclinical models.

Contact

Tim Boelke, M.D.

boelke@acousia.com

www.acousia.com

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