Acousia Therapeutics Reaches 50% Patient Enrollment Milestone in Phase 2 PROHEAR Study

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Acousia Therapeutics GmbH announced that it has successfully enrolled 50% of patients in its ongoing Phase 2 clinical trial, the **PROHEAR Study**, evaluating **ACOU085 (INN: bimokalner)** for the prevention of **cisplatin-induced hearing loss** in patients with **testicular cancer** undergoing chemotherapy.

Cisplatin is a cornerstone in modern oncology and is used annually in more than 500,000 cancer patients worldwide. Its introduction in the late 1970s revolutionized testicular cancer treatment, improving the 5-year survival rate (from just 5% to 98%). However, its life-saving efficacy is often overshadowed by severe side effects, with **permanent, bilateral hearing loss** among the most debilitating. Studies indicate that up to **80% of patients** treated with cisplatin may experience clinically-relevant hearing loss.

The **PROHEAR Study** is a **placebo-controlled, randomized, double-blind, split-body trial** in which participants receive **ACOU085**, a Kv7.4 channel activator, in one ear and a **placebo** in the contralateral ear. The study is currently being conducted at **13 leading German ENT university clinics** and is still actively recruiting.

“This marks a significant milestone on Acousia’s journey to offer a treatment for the prevention of permanent hearing loss caused by cisplatin,” said **Professor Hubert Löwenheim**, Chair of the Department of Otolaryngology - Head & Neck Surgery at Tuebingen University and Scientific Supervisor of the study. “Preventing this often overlooked side effect is critical for cancer patients. Notably, all PROHEAR participants who have received ?300 mg/m² of cisplatin to date have developed ototoxicity. This is higher than reported in most, if not all, previous studies.”

The PROHEAR Study is on track to complete enrollment by the end of the **second half of 2025**. For more information, visit clinicaltrials.gov.

ACOU085 (INN: bimokalner) is a first-in-class, small-molecule, etiology-agnostic otoprotective drug-candidate delivered using standard transtympanic administration of a proprietary, slow-release gel formulation. Ototoxic hearing loss is a typical, severe, and permanent side effect of cisplatin treatment and is a consequence of irreversible damage to the sensory cells in the inner ear, the so-called outer hair cells (OHCs). ACOU085 modulates a biologically validated target, the KCNQ4-encoded Kv7.4 potassium channel of the OHCs, and has demonstrated significant potential to reduce cisplatin-induced hearing loss and preserve outer hair cells from ototoxicity in preclinical models.

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