

Hearing loss company Acousia announces first patient enrolled in its Phase 2 PROHEAR-Study

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Acousia Therapeutics GmbH, a Tübingen-based clinical stage biotech company focused on the enhancement and preservation of natural hearing, just announced the randomization of the first patient for the PROHEAR-Study. The PROHEAR-Study is a placebo-controlled, Phase 2a study with split-body design, which investigates the otoprotective efficacy of ACOU085 in patients with testicular cancer undergoing high-dose cisplatin-based chemotherapy regimens (cis-Pt 300 mg/m²).

Germ-cell testicular cancer is the most common cancer among young men, with incidence rates continuously increasing. With the introduction of cisplatin as a treatment option in the late 1970s, most men with metastatic testicular cancer are cured, with a 30–60 year life expectancy after treatment. Ototoxicity is a typical and severe 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. While ototoxicity may have been an unavoidable trade-off for a cancer cure to date, clinical hearing loss comes with considerable negative impacts for survivors, including communication problems, heightened fatigue, reduced social interaction, and an increased long-term risk of developing dementia. In preclinical models, ACOU085 has demonstrated its significant potential to reduce cisplatin-induced hearing loss and preserve outer hair cells from ototoxicity.

In the double-blind, randomized PROHEAR-Study, patients with testicular cancer receive transtympanic injections of ACOU085 in one ear and a placebo in the contralateral ear prior to each chemotherapy cycle, as such each patient serves as his own control. The PROHEAR-Study is being conducted at major university clinics across Germany and has been formally endorsed by the Study Group of the German Society of Otorhinolaryngology (DSZ-HNO).

“The enrollment of the first patient into our ACOU085 Clinical Phase 2 program marks a further major milestone in our efforts to finally make acute and subacute forms of hearing loss treatable” said Dr. Tim Bölke, CEO and CMO of Acousia Therapeutics.

About Acousia Therapeutics GmbH

Acousia Therapeutics GmbH is a privately held, clinical-stage biotech company based in Tübingen, Germany. The company is dedicated to the identification of small molecules for the effective prevention and treatment of different hearing loss etiologies. Acousia is focused on the development of proprietary drug candidates, which are designed to affect the sensory outer hair cells (OHC) in the cochlea of the inner ear. The unique dual mode of action of its small-molecule Kv7.4 activators combines acute functional OHC enhancement and sustained OHC protection and aims to both enhance and preserve a patient's natural hearing. Acousia Therapeutics develops drugs for both local and systemic administration.

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