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Hearing Loss Company Acousia Therapeutics Green Lighted for Game-Changing Phase 2 Trial

Tübingen, Germany (ots/PRNewswire) -

Acousia Therapeutics, a pioneer clinical-stage biotech company focused on the development of novel drug therapies for the prevention and treatment of acute and chronic forms of hearing loss, received approval from the German regulatory authorities (BfArM) for its groundbreaking Phase 2 clinical trial of the etiology-agnostic otoprotectant ACOU085 in patients with cisplatin-induced hearing loss.

Cisplatin-based chemotherapy, a lifeline for countless cancer patients, often delivers an unwanted side effect: irreversible hearing loss, i.e. ototoxicity, which occurs in 60% or more of cancer survivors. This makes the prevention of cisplatin-induced ototoxicity a significant unmet medical need for patients with a large potential market for a new therapeutic regimen. In a recently concluded Phase 1b clinical trial, ACOU085 demonstrated excellent safety and tolerability as well as long local residence time of the proprietary, sustained-release formulation, which is essential for providing extended otoprotection in acute hearing loss conditions such as cisplatin-induced ototoxicity.

The Phase 2a multicentric, randomized, placebo-controlled, split-body trial will evaluate the efficacy of ACOU085 for preventing cisplatin-induced ototoxicity in young male patients diagnosed with testicular cancer. The clinical study will assess several efficacy outcomes for ACOU085, including changes in high-frequency, pure-tone audiometry, speech comprehension in quiet and noisy environments, and otoacoustic emissions. The enrolment of the first patients is expected in late 2023.

Tim Boelke, CEO and Chief Medical Officer of Acousia, said: "Cisplatin is a lifeline for cancer patients, yet the heartache of hearing loss it brings is devastating. We are thrilled by the swift regulatory approval of our ACOU085 trial, which validates our development approach and offers the promise of hearing protection as patients battle cancer."

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. For example, the unique dual mode of action of its small-molecule Kv7.4 agonists, the acute functional OHC enhancement, and the sustained OHC protection aim to both enhance and preserve a patient's natural hearing. Acousia Therapeutics develops drugs for both local and systemic administration.

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