



## **AudioCure Pharma initiates Phase 2 clinical trial of lead molecule AC102 for the treatment of hearing loss**

- International Phase 2 study investigates efficacy, safety and tolerability of AC102 in patients with sudden hearing loss at up to 45 European centers
- This is another important milestone on the way to a causal treatment of spontaneous hearing loss, which has a high unmet medical need

Berlin, 16 October 2022 - The pharmaceutical company *AudioCure Pharma* today reports the start of the multinational clinical trial Phase 2 of the new compound AC102 for the treatment of acute hearing loss. This marks the first time AC102 will be used in patients. "Sudden hearing loss is a medical emergency that can still not be treated with an approved and effective medication. We need and want to change that. The start of the Phase 2 study is an important milestone on this path," said company CEO Reimar Schlingensiepen, MD.

The study is conducted in up to 45 study centers in 7 European countries. Approximately 200 adult patients with sudden sensorineural hearing loss in one ear will be enrolled. In the two-arm, randomized, blinded study, the patient group receives AC102, while the comparison group is treated with a steroid medication, the current, but unapproved, standard therapy. This also ensures that all patients receive treatment. Important endpoints of the study are hearing function and speech comprehension. The active substance is applied once into the patient's middle ear. The Coordinating Investigator, Prof. Dr. Stefan Plontke from Martin Luther University Halle-Wittenberg in Germany, explains, "Hearing loss and the associated difficulties in communication often makes my patients feel insecure, disconnected or even isolated. This can substantially affect patients' quality of life, even leading to depression and as we now know increases the risk for cognitive decline and dementia later in life. We therefore urgently need effective medications."

In a preclinical model of hearing loss, the use of AC102 restored hearing almost completely. AudioCure Pharma founder Prof. Hans Rommelspacher, MD, explains, "AC102 simultaneously acts on three key pathological processes that lead to hearing loss. We have shown that the drug protects the cells of the inner ear, restores their functionality, and prevents death of outer hair cells. It also activates repair processes of the contact sites between inner hair cells and the auditory nerve. Now is the time to investigate the efficacy of the compound in patients with sudden hearing loss"



More details on the study:

**ClinicalTrials.gov:** <https://clinicaltrials.gov/ct2/show/NCT05776459>

**Link2Trial:** <https://www.link2trials.de/probandenstudien/sie-haben-plotzlich-ihr-gehor-verloren/trial/944>

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