

Press Release

Sudden hearing loss study reaches milestone: AudioCure Pharma enrolls more than half of the patients in AC102 study

- To date, more than 50% of the patients in the study have been enrolled in seven European countries.
- The study is testing AC102 as a novel, more effective treatment for sudden hearing loss with fewer side effects.

Berlin – Berlin-based start-up AudioCure Pharma has enrolled more than 50% of the planned patients in its ongoing Phase 2 clinical trial. The aim of the study is to test the efficacy of the new compound AC102 for the treatment of sudden hearing loss. As sudden hearing loss is usually treated with non-specific corticoids that are not approved for this indication or for which there is no clear evidence of efficacy, there is an urgent need for new therapies.

This enrollment milestone is an important step in the development of AC102 and in addressing the unmet medical need for sudden hearing loss. The safety and tolerability of AC102 has already been successfully tested in healthy volunteers. "Recruitment for the trial is challenging because the compound can only be effective in the first few days after the onset of the sudden hearing loss and we can therefore only enroll patients in the study during this short window. I am therefore very pleased with this recruitment success, which underscores the high level of interest in new, more effective treatment options for patients with sudden hearing loss", explains the coordinating investigator, Prof. Dr. Stefan Plontke of Martin-Luther-University Halle-Wittenberg. AC102 is considered a promising alternative to corticoid therapy for sudden hearing loss, as it was able to restore hearing almost completely in an acoustic trauma model after a single application in a preclinical study¹ This work also revealed the mechanism of action of AC102. Unlike the nonspecific, anti-inflammatory effects of corticoids, AC102 specifically targets the sensory cells and synaptic connections in the inner ear that are responsible for hearing loss. "Our goal is to achieve a paradigm shift in the treatment of sudden hearing loss with the specific effect of AC102 and to contribute to better help sudden hearing loss patients in the future," said Dr. Reimar Schlingensiepen, CEO of AudioCure Pharma.

The Phase 2 trial is expected to continue enrolling patients until end of 2025.

References:

¹Rommelspacher H, et al., PNAS. 2024 Apr 9;121(15)



About AudioCure

AudioCure is a pioneering clinical-stage pharmaceutical company based in Berlin, Germany. Specializing in hearing disorders with a high unmet medical need, AudioCure has developed a unique proprietary portfolio of small molecules which both protect and restore the delicate inner ear structures affected in otic conditions. After a Phase 1 trial demonstrated the safety and tolerability of their lead compound AC102 in healthy subjects, the compound is currently being investigated in patients with idiopathic SSNHL in a Phase 2 clinical trial. Projects for treatments of tinnitus and to support residual hearing in cochlear implant patients are also in development.

About hearing disorders

Hearing disorders are a global problem. According to the Centers of Disease Control and Prevention (CDC), hearing loss is the third most common chronic physical condition in the United States and twice as prevalent as diabetes or cancer. Moreover, the WHO estimates that approximately 1.5 billion people worldwide suffer from a hearing disorder. This number is expected to rise to 2.5 billion by 2050. Hearing disorders have consequences not only for those affected, but also for their families. In addition to the well-established link between hearing loss and depression, hearing loss is also known to be the number one modifiable risk factor for dementia and cognitive decline. In sudden hearing loss, the hearing impairment occurs very quickly, usually within a few hours or days. Triggers can include a loud bang or by stress, but in most cases the trigger is unknown. Hearing loss is caused by damage to the sensory cells and the connections between the nerve cells in the inner ear. The standard of care for the treatment of SSNHL are corticosteroids but there is only weak evidence for its effectives for this condition. Therefore, to date, no medications have been approved to treat this condition, leaving many patients with permanently impaired hearing.

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