



## **AudioCure Pharma announces completion of Phase 1 trial of lead molecule AC102 for the treatment of sudden hearing loss**

- Phase I study confirms safety and tolerability of AC102 in patients with sudden hearing loss
- This is another important milestone that clears the way for a Phase 2 study evaluating AC102 in patients with sudden hearing loss

Berlin, 7 September 2021 - AudioCure Pharma GmbH, a pharmaceutical company based in Berlin, Germany, today announced the completion of the First-in-Human Phase 1 trial of their lead compound AC102. The open-label study was aimed to investigate safety and tolerability of AC102 after injection into the middle ear. The trial was conducted at Radboud University Medical Center (Radboudumc) in The Netherlands and the Medical University, Vienna in Austria. "We are more than pleased to confirm the safety of AC102 in healthy human subjects. This paves the way for a clinical investigation of efficacy in patients with sudden sensorineural hearing loss," said the principal investigator of the study Dr. Ronald Pennings, MD, PhD.

The study, conducted in 42 male and female healthy volunteers between 18 and 40 years, compared AC102 to a placebo delivered as a gel into one ear. The study showed that both AC102 and placebo gel were well tolerated. Adverse effects were mild and occurred almost equally in both groups. Most of these events were due to the injection or presence of the gel in the ear. Furthermore, there were no significant changes in the inner ear structures related to hearing. Because of the local application of the compound, the levels of AC102 in the body were low and decreased after 24 hours.

These positive results from the Phase 1 trial provide an encouraging foundation for further investigations into the efficacy and clinical potential of AC102. "This is an important milestone for AudioCure and the hearing loss community. The first patients will soon be able to receive a treatment with AC102 in our Phase 2 clinical study," said Dr. Reimar Schlingensiepen, CEO of AudioCure. The initiation of a Phase 2 clinical trial underway in several European countries to examine the efficacy of AC102 in patients with sudden sensorineural hearing loss.

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