



## Press Release

### AudioCure Pharma enters clinical development phase with lead molecule AC102

- Phase I trial to assess safety, tolerability and pharmacokinetics of AC102-suspension after application into the middle ear of healthy volunteers
- Milestone achievement for AudioCure Pharma on its way to combating hearing loss disorders with unmet medical need

**Berlin, 30 September 2020** – AudioCure Pharma GmbH, a pharmaceutical company based in Berlin, Germany, announced today that the first healthy volunteers have been included into the Phase I trial with the first-in-class molecule AC102. Main primary endpoints of the open-label study are safety and tolerability of AC102-suspension after injection into the middle ear. The trial is conducted at Radboud University Medical Center (Radboudumc) in The Netherlands. “This trial is very important, since safety data in humans are a prerequisite for clinical research of efficacy in patients with sudden hearing loss,” said Dr. Ronald Pennings, MD, PhD and principal investigator of the study. “Each study participant will receive a single dose of either AC102-suspension or vehicle without active ingredient into the middle ear. This method of application has become routine in otic practice to deliver drugs directly to where they are needed,” Pennings explained. Dose escalation will be performed under review by an independent safety board.

Dr. Reimar Schlingensiepen, CEO of AudioCure commented: “Entering the clinical development phase with our front-runner molecule AC102 is a milestone achievement for AudioCure. This is a very important step for us in our endeavor to offer causal treatment at an early stage to patients suffering from hearing disorders.” The mode of action of AC102 is unique in addressing multiple pathological processes that underlie hearing loss leading to strong and consistent efficacy in preclinical models of hearing loss.

AC102 is being developed for the treatment of sudden hearing loss. This is a debilitating disorder of the inner ear caused by damage to the hair cells, the sensory cells of the cochlea, and/or the neurons of the auditory nerve. Loss of these cells can be due, for example, to acoustic trauma (e.g. a very loud noise) or stress but in most cases, the cause remains unknown.

“Hearing loss affects a patients’ life on many levels, from difficulties understanding conversations in meetings at work to socializing with friends. It also affects safety, especially when travelling and commuting. Very often sufferers feel insecure, disconnected or even isolated while for some people it can lead to depression. Overall, hearing loss may substantially affect quality of life,” explained Professor Rommelspacher, CSO and founder of AudioCure.

While many can be affected by hearing loss, to date there are no approved drugs available for patients with sudden hearing loss. Through the development of novel pharmacotherapies, it is AudioCure’s mission to change this. AC102 received orphan drug designation (status of a drug candidate for rare diseases) from the European Medicines Agency (EMA) for the treatment of sudden hearing loss.



## **Notes to Editor**

### **About AudioCure**

AudioCure Pharma GmbH is a pharmaceutical R&D company headquartered in Germany with a focus on hearing impairments. AudioCure was founded by Professor Hans Rommelspacher, a clinician and academic, who has dedicated his career at the Charité in Berlin to the discovery and preclinical development of drug candidates. He is joined by Dr. Reimar Schlingensiepen, CEO, who brings to AudioCure 30 years' experience in medicine and the biopharmaceutical industry in both managerial roles and as an investigator. Highly skilled scientists and executives complete the growing team. AudioCure's mission is to turn incurable hearing loss into a treatable event.

### **About AC102**

AC102 is a disease modifying novel molecule. Preclinical models have demonstrated the unique potential of AC102 to act beneficially upon three cell types of the inner ear which are critical for the hearing process: the sensory inner hair cells, the sensory outer hair cells and the acoustic nerve<sup>1</sup>. AC102 acts as an antagonist to the multitude of pathological processes leading to hearing loss. Therefore, treatment with AC102 almost completely reverses the reduction of hearing in an *in vivo* model of hearing loss. Furthermore, the compound is effective when given over an extended therapeutic window. AC102 has received orphan drug designation from the EMA for the treatment of sudden hearing loss.

### **About hearing disorders**

Hearing disorders are a global problem with an estimated 466 million people suffering from disabling hearing loss worldwide in 2018<sup>2</sup>. This has immense consequences for both the patients and their families. The loss of communication can lead to social withdrawal, isolation and depression as well as limiting job opportunities.<sup>3</sup> Hearing loss also presents a significant economic burden, reflected by an estimated loss in gross domestic product of up to 2% in developed countries.<sup>4</sup>

Nevertheless, to date there is no approved drug for sudden hearing loss. This is an alarming condition in which hearing loss occurs rapidly over hours or noticed upon waking, prompting patients to visit a doctor or the emergency clinic. In a number of patients hearing loss can be permanent.

### **References**

<sup>1</sup>AudioCure, data on file

<sup>2</sup>WHO Global estimates on prevalence of hearing loss, 2018

<sup>3</sup>Mortality and Burden of Diseases and Prevention of Blindness and Deafness. WHO, 2012

<sup>4</sup>Prevention of noise-induced hearing loss. WHO report, Geneva 1997

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