Press Release

AudioCure Pharma's AC102 receives FDA orphan drug designation for the treatment of sudden sensorineural hearing loss (SSNHL)

- The FDA has granted orphan drug designation to AC102, concluding that AudioCure's lead compound may become of significant benefit for patients suffering with the rare and chronically debilitating disease of sudden sensorineural hearing loss (SSNHL).
- Comprehensive preclinical proof-of-principle data provide strong evidence of efficacy in a model of acute hearing loss.

Berlin, 23 March 2021 – The German clinical-stage pharmaceutical company AudioCure Pharma GmbH announced today that the US Food and Drug Administration (FDA) has granted orphan drug designation to their first in class molecule AC102 for the treatment of SSNHL. SSNHL is a form of hearing loss with a rapid onset. In most cases the cause is unknown. The prevalence of the disorder is considered rare with less than 200,000 people affected in the U.S.

The FDA exclusively grants orphan drug designation to facilitate the development of medicines intended to treat rare, severely debilitating disorders. Another prerequisite for this status is clear evidence for the potential of the drug to bring significant benefit to affected patients. In this regard, AC102 has been shown to almost completely restore hearing across all tested frequencies in a preclinical model of acute hearing loss. The compound specifically targets the pathological processes that underlie SSNHL: it not only prevents the cell death of sensory cells in the inner ear but also restores their synaptic connections to the auditory nerve. The designation qualifies AudioCure for certain benefits, including up to seven years market exclusivity, tax credits for clinical development and FDA regulatory assistance through to market approval.

Dr. Reimar Schlingensiepen, CEO of AudioCure commented: "The orphan drug designation is a major milestone in the development program of AC102. It will enable a more efficient and cost-effective regulatory pathway and is therefore an important step in pursuing our goal of developing treatments for a condition for which there are currently no approved curative therapies. With our Phase I first-in-human clinical trial with AC102 underway in Europe, we look forward to future interactions with the FDA to advance our lead compound to the market."

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