

Auris Medical News Release

April 20, 2012 – Auris Medical completes enrolment in phase IIb trial with AM-111 for the treatment of acute sensorineural hearing loss

Auris Medical announced today that enrolment has been completed for its phase IIb clinical trial with AM-111 for the treatment of acute sensorineural hearing loss (ASNHL). A total of 210 patients were enrolled in the study to receive a single dose intratympanic injection of either AM-111 at 0.4 or 2 mg/ml or placebo. The study recruited patients suffering from acute acoustic trauma or sudden deafness with a mean hearing loss of at least 30 dB in 3 contiguous frequencies within the first 48 hours following the incident. Results from the AM-111 trial are expected to become available in fall 2012.

About acute sensorineural hearing loss

Acute sensorineural hearing loss may be the consequence of various insults to the cochlea. It may result e.g. from overexposure to noise, bacterial or viral infections, inflammation, vascular compromise, or a variety of other factors. In ASNHL, sensorineural structures of the inner ear – inner and outer hair cells, neurons – are damaged, as well as other structures such as supporting cells or vascular tissues. The common observation is a temporary increase in hearing thresholds, i.e. hearing loss. Thanks to cellular defences and intrinsic repair mechanisms, a certain amount of such hearing loss is frequently recovered in the subsequent days and weeks. The remaining hearing loss however is irreversible. ASNHL may be accompanied by other disorders of the inner ear such as dizziness or tinnitus.

When ASNHL develops into permanent hearing loss, it may have chronically debilitating consequences. Hearing loss may have serious impacts on professional and personal lives, e.g. through avoidance or withdrawal from social situations, reduced alertness and increased risk to personal safety, impaired memory and ability to learn new tasks, or reduced job performance and earning power. To date, there exists no treatment for ASNHL with proven efficacy.

About AM-111

AM-111 is a cell-permeable peptide that selectively blocks JNK MAPK mediated apoptosis of stress injured hair cells and neurons in the cochlea. Major cochlear stress incidents that may result in irreversible hearing loss include exposure to excessive noise, disturbances of the blood supply, viral or bacterial infections, and exposure to certain ototoxic substances. When administered within a therapeutic time window after the incident, AM-111 can effectively protect cochlear hair cells and neurons that would otherwise undergo apoptosis and be lost forever. AM-111's otoprotective properties have been extensively tested and confirmed in various animal models so far, including acute acoustic trauma, acute labyrinthitis, surgery trauma, aminoglycoside ototoxicity, semicircular canal injury in otitis media and cochlear ischemia. AM-111 has been granted orphan drug status in both the European Union and the USA for the treatment of acute sensorineural hearing loss. The active substance of AM-111 has been in-licensed by Auris Medical from Swiss biotechnology company Xigen S.A.

About Auris Medical

Auris Medical is a Swiss biotechnology company developing specific pharmaceutical compounds for the prevention or treatment of inner ear disorders, an area of great unmet medical need. Around the world, many million people are permanently suffering from severe hearing loss and tinnitus. Truly effective and safe treatments for these disorders are still lacking. Auris Medical is currently focusing on the development of treatments for acute inner ear tinnitus (AM-101) and for acute sensorineural hearing loss (AM-111).

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