Auris Medical News Release

November 13, 2012 – Auris Medical reporting positive results from phase IIb trial with AM-111 for the treatment of acute sensorineural hearing loss

Auris Medical announced today positive results from a phase IIb clinical trial with AM-111, its investigational drug for the intratympanic (i.t.) treatment of acute sensorineural hearing loss (ASNHL). The study demonstrated that the treatment was well tolerated and showed a statistically significant and clinically relevant treatment effect.

The double-blind, randomized, placebo-controlled phase IIb study with AM-111 was conducted in Germany, Poland and the Czech Republic, involving more than 30 sites. A total of 210 patients suffering from acute acoustic trauma or sudden deafness were enrolled within the first 48 hours following the incident. Their hearing loss, measured against a reference value, had to be at least 30 dB at the average of 3 contiguous audiometric test frequencies. Study participants received one single dose of either AM-111 at 0.4 or 2 mg/ml or placebo by way of i.t. injection and were followed for 90 days. In case of insufficient hearing recovery by Day 7, they were given the option of receiving oral prednisolone as a reserve therapy.

Preliminary results from the phase IIb study show that the local treatment with AM-111 was well tolerated. In addition, the study demonstrated a substantial improvement in hearing threshold and speech discrimination score. In subjects with severe to profound hearing loss who were treated with AM-111 0.4 mg/mL, the primary study endpoint, absolute hearing improvement in the 3 most affected contiguous test frequencies from baseline to Day 7, was met ($p < 0.02$, compared with placebo). The outcome was confirmed by the co-primary endpoint "% of hearing loss recovered at Day 7" ($p < 0.03$); the odds ratio for complete hearing recovery was > 2.2. Importantly, the improvement in the speech discrimination score from baseline to Day 7 showed also a statistically significant difference between AM-111 and placebo treated study subjects ($p < 0.02$). The differences in hearing and speech discrimination recovery between treatment groups appeared as early as on Day 3 and were clinically relevant. Further information on the clinical trial and detailed outcomes shall be presented in a scientific journal.

"The cell penetrating peptide AM-111 represents a novel approach to treating ASNHL", stated Professor Markus Suckfüll, Munich (Germany), coordinating investigator of the study. "The clear and clinically meaningful improvements observed with AM-111 in the treatment of severe to profound hearing loss demonstrate that effective otoprotection is feasible, and they appear very promising. The inclusion of a placebo arm to control for the effects of spontaneous recovery lends particular credibility to the results and will provide also a wealth of important new information for future hearing research." Thomas Meyer, Auris Medical's founder and Managing Director, commented: "We are very pleased with the positive results from the phase IIb trial with AM-111, which were achieved under challenging clinical conditions. The outcomes are in line with the positive results from preclinical studies conducted in various ASHNL conditions, which had demonstrated the strong otoprotective effects of the peptide." In a next step, Auris Medical is planning to discuss the phase IIb results and further clinical development with AM-111 with regulatory agencies.

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).

Contact:
Dr. Thomas Meyer, Managing Director, telephone +41 61 201 13 50, tm@aurismedical.com