

Auris Medical News Release

June 21, 2006 – Auris Medical reporting results of a phase I/II clinical trial with AM-111

Auris Medical, a Swiss-French biotechnology company developing specific treatments for inner ear disorders, reported the results of the first clinical trial with the investigational otoprotective drug AM-111. The double blind, randomised clinical trial involving two sites in Germany was conducted in early 2006 to evaluate the safety of AM-111 in the treatment of acute sensorineural hearing loss (ASNHL). Study results show that AM-111 was well tolerated by all patients and provide first indications of a therapeutic effect of this novel otoprotective drug.

The clinical evaluation of AM-111, an investigational otoprotective drug under development by Auris Medical for the treatment of ASNHL, was launched with a phase I/II study in Germany in the first quarter of 2006. A total of 11 patients suffering from acute acoustic trauma (AAT) due to New Year's firecracker accidents with a hearing loss of at least 30 dB were enrolled in the clinical trial. Enrolment at the two study centres, the Otolaryngology departments of the Ludwig Maximilian University Munich and the Charité Berlin, took place on January 1, 2006 (i.e. for up to 24 hours following AAT). Study participants received a single dose of AM-111 at either 2 mg/ml or 0.4 mg/ml in a 250 microlitre gel formulation by transtympanic injection into the most affected ear. All patients attended a follow-up visit three days later as well as a final examination 30 days after their accident. The primary endpoint of the study was the recovery of hearing thresholds from baseline to day 30 measured by pure tone audiometry (average of 4 and 6 kHz).

Study participants had an average hearing loss at baseline (i.e. at the time of their first examination) of 35.9 dB in their worse affected and thus subsequently treated ear and 20.0 dB in their less or not affected contralateral ear. Hearing thresholds recovered to 24.5 dB in treated ears and to 17.6 dB in untreated ears by day 30. Overall, AM-111 was well tolerated by all study participants, independently of the dose. Adverse events occurred in only small numbers and were either unrelated or considered unlikely related to the treatment. Regarding AM-111's efficacy in hearing protecting following ASNHL, the clinical trial provided some first indications of a therapeutic effect of the drug. Two patients with moderate or severe ASNHL from acute acoustic trauma showed a substantial and relatively quick recovery of hearing thresholds leaving them with only a minor permanent hearing loss or none at all at study end. More details about the study and its results will be published in a scientific / medical publication later this year.

Markus Suckfüll, MD, the study's lead investigator, commented: "AM-111 has shown a good safety profile in this first clinical trial, confirming previous preclinical data. In addition, hearing recovery rates following treatment with AM-111 suggest in a few cases a significant therapeutic benefit based on clinical experience." Thomas Meyer, Auris Medical's founder and Managing Director, added: "We are very encouraged by the positive results from this first clinical evaluation of AM-111. The successful conclusion of the study represents an important milestone for our company and the development of a treatment for ASNHL, an

important unmet medical need." In a next step AM-111's efficacy will be tested more specifically in a phase II clinical study with a larger number of participants.

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 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, surgery induced acoustic trauma (cochlear implant electrode insertion) and aminoglycoside ototoxicity. 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 pharmaceutical ingredient of AM-111 has been in-licensed by Auris Medical from Swiss biotechnology company Xigen S.A. Its otoprotective properties were first discovered by the Institute for Neurosciences of Montpellier, France.

About Auris Medical

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

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