Auris Medical News Release

May 17, 2013 – Safety results from Auris Medical's clinical development of AM-101 presented at international conference

Key safety outcomes from Auris Medical's clinical development of AM-101, a novel intratympanic (i.t.) treatment for acute inner ear tinnitus, were presented at the 7th International TRI Tinnitus Conference in Valencia, Spain. The accumulated data demonstrate that the treatment and the administration procedure are well tolerated and safe even when repeated several times. The outcomes were presented by Guido Muehlmeier, MD, Head of ENT Diagnostics at the Clinic and Policlinic for Otorhinolaryngology, Head and Neck Surgery of the Federal Armed Hospital of Ulm, Germany.

The clinical development programme with AM-101 so far comprises a total of three double-blind, randomized, placebo-controlled, clinical trials, of which two have been completed, and one is approaching completion. In the first of the three trials, a Phase I/II study involving 24 patients, the safety of a single dose administration of AM-101 was demonstrated in a dose escalation up to 0.81 mg/mL. It also revealed minimal systemic exposure from the treatment. These results have been published previously.[1]

At the TRI Tinnitus Conference, key safety outcomes from the second study, a Phase IIb clinical trial, were presented for the first time. The study enrolled a total of 248 patients who were treated 3 times over 3 consecutive days either with AM-101 at 0.27 or 0.81 mg/mL or placebo. Study participants were monitored over 90 days. The primary safety endpoint was the occurrence of clinically relevant hearing deterioration from baseline to Day 30, defined as increase in the pure tone hearing threshold ≥15 dB in any two contiguous test frequencies.

The Phase IIb study confirmed the previous results from the Phase I/II trial and provided a wealth of additional safety and local tolerance data. As expected, the occurrence of clinically significant hearing loss was low, and there were no statistically significant differences between treatment groups, neither for the primary endpoint at D30, nor at any of the other study visits or overall. On average, hearing thresholds improved slightly over the 90 day observation period.

There were no statistically significant and/or clinically significant differences in the frequency, intensity or relationship of adverse events between treatment groups in the Phase IIb study. Most adverse events were mild or moderate in intensity, and local rather than systemic. As expected, the majority of them were reported for a transient deterioration in hearing and tinnitus perception, which was mostly related to the tympanotomy performed prior to the injection. They usually resolved upon full closure of the eardrum. At D7, just 7% of eardrums were not fully closed, yet. Other procedure-related transient adverse events like vertigo, ear pain or inflammation were observed only rarely. Serious adverse events were also low in numbers and all considered unrelated or unlikely related.

Overall, more than 900 i.t. injections of AM-101 at concentrations of up to 0.81 mg/mL or placebo have been performed on patients suffering from acute inner ear tinnitus to date. "The accumulated data and

[1] Muehlmeier G, Biesinger E, Maier H (2011): Safety of intratympanic injection of AM-101 in patients with acute inner ear tinnitus, Audiology & Neurotology 16, 388-397.

experiences from the clinical trials reveal and confirm an attractive safety profile for AM-101," stated Dr. Mühlmeier, who has been involved in the entire clinical development programme with AM-101 as a Principal Investigator. "They also demonstrate excellent tolerance of the AM-101 formulation in the middle ear and, importantly, also show high acceptance of intratympanic injections by patients."

Detailed results on the Phase IIb clinical trial with AM-101 will be published in a scientific journal later this year. Preliminary outcomes from the ongoing third study (Phase II trial), will be released in summer.

About acute inner ear tinnitus

Tinnitus, the perception of sound without external acoustic stimulation, is a symptom common to various ear or other diseases. Inner ear tinnitus may be provoked by various injuries to the cochlea, the organ of hearing, such as overexposure to noise or disruptions in its blood supply. It may be short and just transitory; however, it may also become permanent. Tinnitus of less than three months of duration is considered acute, while tinnitus that is older than one year is considered chronic.

Inner ear tinnitus may be only a slight nuisance, but often it has a serious impact on the ability to sleep, relax, or concentrate, or it may lead to tiredness, irritation, nervousness, despair, frustration, or even depression. As of today, there exists neither a universal standard of care for acute inner ear tinnitus, nor a truly proven, effective treatment method.

About AM-101

AM-101 contains a small molecule that selectively blocks N-methyl-D-aspartate (NMDA) receptors. Emerging evidence suggests that NMDA receptors in the cochlea play a major role in the occurrence of tinnitus following inner ear excitotoxicity, which is characterized by excessive synaptic release of glutamate, the principal neurotransmitter in the auditory system. Cochlear excitotoxicity may be triggered by, for example, trauma (e.g. exposure to excessive noise), neuroinflammation, disturbances in inner ear blood supply (anoxia/ischemia), or the administration of certain ototoxic drugs. It has been hypothesized that the upregulation of NMDA receptors induced by cochlear excitotoxicity is responsible for aberrant excitation of auditory nerve fibres, which is perceived as tinnitus.

The development of AM-101 is based on research conducted at the INSERM Institute for Neurosciences of Montpellier, France. The clinical development of AM-101 was initiated by Auris Medical in 2007. Following proof of concept, confirmatory Phase III clinical trials are currently under preparation. Patents have been granted in more than 30 countries worldwide to date.

About Auris Medical

Auris Medical is a biotechnology company developing specific pharmaceutical compounds for the prevention or treatment of inner ear disorders, an area of great unmet medical need. The Company is currently focusing on the development of treatments for acute inner ear tinnitus (AM-101) and for acute inner ear hearing loss (AM-111) by way of intratympanic injection with biocompatible gel formulations. In addition, Auris Medical is pursuing early-stage research and development projects. The Company was founded in 2003 and is headquartered in Basel, Switzerland.

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