Auris Medical News Release

Auris Medical announces enrollment of first patient in European Phase 3 study of AM-101 in treatment of acute peripheral tinnitus

Basel, Switzerland, February 21, 2014 – Auris Medical today announced enrollment of the first patient into in the TACTT3[1] clinical trial - a phase 3 study designed to evaluate the efficacy, safety and tolerability of intratympanic injections of AM-101 in the treatment of acute peripheral tinnitus following traumatic cochlear injury or otitis media. The TACTT3 study will enroll 600 patients at more than 60 European sites: 300 during the acute tinnitus stage (up to 3 months from onset) and 300 during the post-acute tinnitus stage (4 to 12 months from onset).

It is one of two pivotal double-blind, placebo-controlled trials in Auris Medical's phase 3 development program with AM-101. The second study, TACTT2, is expected to start enrollment in the United States and Canada shortly. All participants completing one of the TACTT studies and continuing to meet certain criteria will be eligible to enter an open label safety study (AMPACT1, respectively AMPACT2)[2] and receive up to 3 treatment cycles with AM-101 over up to 9 months.

Thomas Meyer, Auris Medical's founder and CEO, commented: "Acute peripheral tinnitus seriously affects the wellbeing and quality of life of many people around the world and represents a significant unmet medical need. TACTT3 will be a major milestone on our way towards the development of the first specific therapeutic for this condition," he added. Results from TACTT3 are expected in late 2015.

About acute peripheral tinnitus

Tinnitus, the perception of sound without external acoustic stimulation, is a symptom common to various ear or other diseases. Peripheral (inner ear) tinnitus may be provoked by various injuries to the cochlea, the organ of hearing, such as overexposure to noise or inflammation. 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 older tinnitus is considered chronic.

Peripheral 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 is a small molecule N-methyl-D-aspartate (NMDA) receptor antagonist formulated in a biocompatible gel for intratympanic injection. 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),

[1] Efficacy and Safety of AM-101 in the Treatment of Acute Peripheral Tinnitus
[2] **AM**-101 in the **P**ost-**Ac**ute Treatment of Peripheral **T**innitus

neuroinflammation, disturbances in inner ear blood supply (anoxia/ischemia), or the administration of certain ototoxic drugs. It has been proposed that the upregulation of NMDA receptors induced by cochlear excitotoxicity is responsible for aberrant excitation of auditory nerve fibers, 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 and comprises 3 clinical trials to date. In 2013, Auris Medical reached agreement with the US Food and Drug Administration (FDA) under a Special Protocol Assessment (SPA) for its pivotal TACTT2 study. Patents have been granted in more than 30 countries worldwide so far.

About Auris Medical

Auris Medical is a Swiss biopharmaceutical company dedicated to developing therapeutics that address important unmet medical needs in otolaryngology. The Company is currently focusing on the development of treatments for acute peripheral 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.

Contact:
Dr. Thomas Meyer, CEO, ear@aurismedical.com
Gretchen Schweitzer, MacDougall Biomedical Communications, +49 172 861 8540
gschweitzer@macbiocom.com