Auris Medical News Release

February 13, 2013 – Auris Medical completes enrolment in TACTT1 study with AM-101 for the treatment of acute peripheral tinnitus

Auris Medical announced today that enrolment has been completed for its TACTT1[1] study, a phase II clinical trial with AM-101 for the treatment of acute peripheral tinnitus. A total of 85 patients were enrolled in the study to receive either AM-101 at 0.81 mg/mL or placebo. In Stage 1 of the trial, a single dose intratympanic injection was administered, while in Stage 2 each study subject received a total of 3 intratympanic injections over 2 weeks. The study recruited patients suffering from tinnitus following acute noise trauma, inner ear barotrauma, middle ear surgery or otitis media up to 3 months after onset. Results from the TACTT1 study, which is being conducted in the USA, Belgium, Germany and Poland, are expected to become available in summer 2013.

About acute peripheral tinnitus

Tinnitus, the perception of sound without external acoustic stimulation, is a symptom common to various ear or other diseases. Peripheral tinnitus may be provoked by various injuries to the peripheral auditory system. The cochlea, the organ of hearing, may e.g. be injured by overexposure to noise or disruptions in its blood supply. The tinnitus 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.

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 peripheral 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, 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. Patents have been granted in more than 30 countries worldwide to date.

[1] Comparison of Single versus Repeat Doses of AM-101 in the **T**reatment of **Ac**ute Inner Ear **T**inni**t**us

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 peripheral tinnitus (AM-101) and for acute sensorineural hearing loss (AM-111).

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