

## **Auris Medical News Release**

### **August 10, 2012 – Auris Medical completes enrolment in first stage of AM-101 TACTT1 study**

Auris Medical announced today that enrolment has been completed for the first of two stages in its TACTT1 phase II clinical trial with AM-101 for the treatment of acute inner ear tinnitus. A total of 40 patients were enrolled in the study and received either AM-101 at 0.81 mg/mL or placebo in a single dose intratympanic injection. The study recruited patients suffering from tinnitus following acute noise trauma, otitis media, inner ear barotrauma or middle ear surgery not more than 3 months ago.

The purpose of the TACTT1 study is to further evaluate the optimum dosing regimen for AM-101 as well as to generate additional safety and pharmacokinetic data. It is being conducted in the USA, Belgium, Germany and Poland. In the second stage of the study, a dosing regimen comprising 3 intratympanic injections over 2 weeks will be tested. Enrolment for the TACTT1 study is expected to be concluded before the end of the year.

#### **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, 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.

#### **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](mailto:tm@aurismedical.com)*