

# **Auris Medical News Release**

# Auris Medical Holding AG Achieves 50% Enrolment Milestone in Post-Acute Tinnitus Stratum of TACTT3 Clinical Trial

**Zug, Switzerland, January 14, 2015** – Auris Medical Holding AG (NASDAQ: EARS) today announced that it has enrolled the first 150 patients with post-acute tinnitus in Stratum B of the Company's ongoing TACTT3 clinical trial, representing fifty percent of the target enrolment in this Stratum. TACTT3 is a randomized, place-bo-controlled double-blind trial conducted in several European countries to evaluate AM-101 in the treatment of inner ear tinnitus following traumatic cochlear injury or otitis media. Participants in the TACTT3 trial receive three intratympanic injections of AM-101 0.87 mg/mL or placebo over three to five days and are followed for 84 days.

Stratum B of the TACTT3 trial is enrolling patients in the post-acute tinnitus stage (between 3 and 12 months from onset), whereas Stratum A is recruiting patients with acute tinnitus (up to 3 months from onset). While previous clinical trials with AM-101 had focused on acute tinnitus only, data from a Phase 2 trial suggested that AM-101 might be effective also beyond the three month acute stage. Stratum B is seeking to explore if and to what extent AM-101 could be effective in the treatment of post-acute tinnitus. A planned interim analysis for futility will be performed once the enrolled 150 Stratum B participants will have completed their second follow-up visit on Day 35.

"We are very pleased to have reached the halfway point in the enrollment of our post-acute tinnitus stratum," said Thomas Meyer, the Company's founder, Chairman and CEO. "Although the clinical development of AM-101 remains focused on the treatment of acute tinnitus at this point, we expect Stratum B to provide important further insights into the potential scope of AM-101's therapeutic use." As previously indicated, no interim analysis is planned for Stratum A, and enrollment is expected to be completed in fall 2015.

#### 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 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.

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 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, exposure to excessive noise, 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 three completed clinical trials to date. Currently, two pivotal trials with AM-101 are ongoing in North America and Europe (TACTT2 and TACTT3). 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 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 Zug, Switzerland. The shares of Auris Medical Holding AG trade on the NASDAQ Global Market under the symbol "EARS".

## Forward-looking Statements

This press release may contain statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forwardlooking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or Auris Medical's strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "outlook" or "continue," and other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include, but are not limited to, the timing and conduct of clinical trials of Auris Medical's product candidates, the clinical utility of Auris Medical's product candidates, the timing or likelihood of regulatory filings and approvals, Auris Medical's intellectual property position and Auris Medical's financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to Auris Medical's capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption "Risk Factors" in Auris Medical's prospectus relating to its Registration Statement on Form F-1, as amended, and future filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and Auris Medical does not undertake any obligation to update them in light of new information, future developments or otherwise, except as may be required under applicable law. All forwardlooking statements are qualified in their entirety by this cautionary statement.

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