Auris Medical News Release

Auris Medical Announces Publications Related to AM-101 in Peer-Reviewed Scientific and Medical Journals

Zug, Switzerland, April 20, 2015 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in otolaryngology, today announced publications related to AM-101, the Company's lead product candidate for the treatment of acute inner ear tinnitus, in two peer-reviewed specialist journals. "We are very pleased to see these important additional pre-clinical and clinical data published on our AM-101 program", commented Thomas Meyer, Auris Medical's founder, Chairman and CEO. "They add further to our understanding of the pathogenesis of inner ear tinnitus as well as AM-101's therapeutic effects and potential clinical use."

The first of the two articles appeared in Audiology & Neurotology and describes the outcomes from TACTT1, the second randomized, placebo-controlled, double-blind phase 2 clinical trial conducted with AM-101 in the treatment of acute inner ear tinnitus.[1] The primary objective for TACTT1 was the evaluation of appropriate dosing regimens by comparing treatment outcomes between a single intratympanic dose of AM-101 or three doses spread over two weeks. The trial showed a consistent trend for superior tinnitus improvement for AM-101 treatments over placebo that was similar for both dose regimens. The primary endpoint, the change in tinnitus loudness from baseline to the last follow-up visit, did not show a statistically significant difference. The comparison of the primary endpoint effect sizes observed in TACTT1 with the corresponding value in the preceding TACTT0 trial revealed that the best results were achieved with repeated injections over a short treatment cycle.

"The TACTT1 trial provided further evidence of AM-101's therapeutic benefits in the treatment of acute inner ear tinnitus and additional support for our choice of dose regimen," commented Bettina Stubinski, Auris Medical's Chief Medical Officer. "The repeated application of AM-101 over a few days is well tolerated and allows for concentrated inhibition of cochlear NMDA receptors, while limiting the procedural impact on the patient." In the currently ongoing phase 3 trials, AM-101 or placebo are administered three times over 3-5 days.

The second article was published in Cellular Physiology and Biochemistry and presents the results of a study of AM-101 in an animal model of tinnitus induced by acute noise trauma.[2] The study was conducted by Prof. Marlies Knipper and colleagues at the Tübingen Hearing Research Center in Germany. The researchers sought to further assess the role of aberrant NMDA receptor activation and related auditory nerve excitation in the generation of tinnitus following traumatic injury to the cochlea. They focused on the damage to inner hair cells (IHCs)

[1] Staecker H, Maxwell KS, Morris JR, van de Heyning P, Morawski K, Reintjes F, Meyer T (2015): Selecting appropriate dose regimens for AM-101 in the intratympanic treatment of acute inner ear tinnitus, Audiology & Neurotology 20(3), 172-182. Open access: www.karger.com/Article/Pdf/369608

[2] Bing D, Lee SC, Campanelli D, Xiong H, Matsumoto M, Panford-Walsh R, Wolpert S, Praetorius M, Zimmermann U, Chu H, Knipper M, Rüttiger L, Singer W (2015): Cochlear NMDA receptors as a therapeutic target of noise-induced tinnitus, Cellular Physiology and Biochemistry 35(5), 1905-1923. Open access: www.karger.com/Article/Pdf/374000

and in particular loss of ribbon synapses as correlate for deafferentation as well as on its impact on auditory brainstem responses (ABRs). Previous studies had shown that a pattern of severe IHC ribbon loss and reduced ABR wave size after acute noise trauma was linked to high-frequency hearing impairment and tinnitus.

In the present study, the researchers administered AM-101 to the inner ear of laboratory rats in single or repeated doses several days after exposure to tinnitus-triggering noise trauma. They found in AM-101 treated animals a significant reduction in trauma-induced loss of IHC ribbons and superior preservation of the centrally generated ABR wave amplitudes. While the IHC ribbon synapses and signal transmission in the auditory nerve were conserved, the treatment had no negative effect on hearing thresholds. The authors concluded that round-window application of AM-101 may be a promising therapeutic intervention for the treatment of synaptopathic tinnitus by counteracting maladaptive auditory patterns in the ascending auditory pathway.

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 40 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 the parent company 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. Forward-looking 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 forward-looking statements are qualified in their entirety by this cautionary statement.

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