

Auris Medical News Release

Auris Medical Holding AG Provides Update on Clinical Development Plan for AM-111

Zug, Switzerland, May 4, 2015 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in otolaryngology, today provided an update on the clinical development of its AM-111 product candidate. AM-111 is being developed for the treatment of acute sensorineural hearing loss (ASNHL), an indication for which Auris Medical received Orphan Drug designation.

Auris Medical is currently preparing two pivotal clinical trials with AM-111 in the treatment of idiopathic sudden sensorineural hearing loss (ISSNHL), which the Company estimates to be the most frequent type of ASNHL. The Company expects to start enrollment in the HEALOS trial in the third quarter of 2015 and in the ASSENT trial in the first quarter of 2016. In addition, Auris Medical is preparing a Phase 2 trial with AM-111 in the treatment of surgery-induced hearing loss called REACH. The Company expects to start enrollment in REACH in the third quarter of 2016.

As previously announced, the Company plans to conduct HEALOS in Europe and Asia with approximately 255 patients. A single dose of either 0.4 mg/mL or 0.8 mg/mL of AM-111 will be compared to placebo in patients suffering from acute severe to profound hearing loss within 72 hours from ISSNHL onset. The FDA held a pre-IND meeting with the Company in September 2014 and provided feedback and guidance on HEALOS. In response to this feedback and further Protocol Assistance from the EMA, the design of HEALOS was finalized.

In addition, the Company plans to conduct ASSENT in the U.S. in order to test AM-111 in a second ISSNHL trial with a similar number of patients as for HEALOS. The principal enrollment criteria will be identical to HEALOS, and patients will also be randomized to receive a single dose of either AM-111 0.4 mg/mL, AM-111 0.8 mg/mL or placebo by intratympanic injection. Unlike HEALOS, patients in ASSENT may receive a course of oral cortico-steroid as background therapy. The Company plans to discuss certain aspects of the study protocol with the FDA.

In the REACH trial the Company plans to administer AM-111 intraoperatively in patients with residual hearing who are undergoing cochlear implant surgery and who are at risk of losing residual hearing. The Company submitted an IND for REACH that has become effective, and plans to seek grant funding in support of the trial.

About AM-111

AM-111 contains the synthetic peptide D-JNKI-1 (<u>D</u>-stereoisomer of c-Jun <u>N</u>-terminal <u>K</u>inase Inhibitor <u>1</u>), an inhibitor of the JNK stress kinase coupled to an intracellular transporter. D-JNKI-1 is formulated in a biocompatible and fully biodegradable gel. It is administered by a single dose intratympanic injection into the middle ear. From there the drug diffuses through the round window membrane into the cochlea.

JNK is a signal transmitting enzyme that regulates a number of important cellular activities, including activation of genes encoding inflammatory molecules or promoting cell death (apoptosis). JNK is activated following various types of cochlear insults (stress) that may lead to acute inner ear hearing loss. AM-111 enters cells and binds to JNK, thereby inhibiting activation of transcription factors such as c-jun and c-fos. This in turn prevents JNK mediated apoptosis and inflammatory response, which could otherwise result in irreversible loss of hair cells and cochlear neurons. AM-111 supports natural recovery processes and helps to prevent or reduce chronic hearing loss.

AM-111's otoprotective effect has been demonstrated in various animal models of cochlear stress, including acute acoustic trauma, acute labyrinthitis (inflammation), drug ototoxicity (aminoglycosides), bacterial infection, cochlear ischemia and cochlear implantation trauma.

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, Switzer-land. 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 forward-looking statements are qualified in their entirety by this cautionary statement.

Contact:

Bettina M. Stubinski, Chief Medical Officer, +41 41 729 71 94 Investors: Matthew P. Duffy, Managing Director, LifeSci Advisors, 212-915-0685, <u>matthew@lifesciadvisors.com</u>