

# Auris Medical Announces Publication of AM-111 Phase 3 Results in Peer-Reviewed Scientific Journal

Zug, Switzerland, March 11, 2019 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology and central nervous system disorders, today announced the publication of an article that presents and discusses in detail the outcomes from the HEALOS Phase 3 trial with AM-111, Auris Medical's investigational treatment for acute inner ear hearing loss. The peer-reviewed article "Efficacy and Safety of AM-111 in the Treatment of Acute Unilateral Sudden Deafness – A Double-Blind, Randomized, Placebo-Controlled Phase 3 Study" was published in *Otology & Neurotology*, one of the leading journals in the field of scientific and clinical inner ear research.

"The HEALOS trial demonstrated that effective hearing protection is possible with a drug-based approach even in the case of profound acute hearing loss, a condition with very poor prognosis for recovery and high risk for life-long auditory and cognitive disability," commented Hinrich Staecker, MD, PhD, Professor, Department of Otolaryngology Head and Neck Surgery, University of Kansas Medical Center, Kansas City, lead author on the publication. "In the trial, treatment with a single dose of AM-111 resulted in a clinically meaningful hearing recovery and a marked reduction in the risk of no improvement. These outcomes are very promising as there are still no effective drug treatments available to protect hearing."

The HEALOS trial was conducted in several European and Asian countries as a randomized, doubleblind, placebo-controlled study evaluating the efficacy, safety and tolerability of AM-111. It enrolled 256 patients suffering from severe to profound sudden deafness within 72 hours from onset. Patients were randomized in a 1:1:1 ratio to receive a single dose of either AM-111 0.4 mg/mL, AM-111 0.8 mg/mL or placebo, administered into the middle ear. While the HEALOS trial did not meet the primary efficacy endpoint in the overall study population, post-hoc analyses revealed a statistically significant hearing improvement with AM-111 from baseline to Day 28 in the subpopulation of patients with profound hearing loss (n=98). The AM-111 0.4 mg/mL treatment group showed a mean improvement of 42.7 dB vs. 26.8 dB in the placebo group (p=0.0176). AM-111 was well-tolerated and the primary safety endpoint was met.

### About AM-111

AM-111 is being developed in a biocompatible gel formulation for the treatment of sudden sensorineural hearing loss with a single-dose administration into the middle ear. Its active substance is brimapitide (also known as D-JNKI-1, D-stereoisomer of c-Jun N-terminal Kinase Inhibitor 1), a cell-penetrating peptide which inhibits the JNK stress kinase. JNK is activated following various types of cochlear insults (stress) that cause acute inner ear hearing loss and plays a key role in apoptosis of sensory cells as well as in inflammatory responses. By blocking JNK, AM-111 protects stress-injured cochlear cells and helps to prevent or reduce chronic hearing loss. AM-111's otoprotective effects have 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 and the European Medicines Agency, and it was granted Fast Track status by the FDA.

### About Auris Medical

Auris Medical is a Swiss biopharmaceutical company dedicated to developing therapeutics that address important unmet medical needs in neurotology and mental health supportive care. The company is focused on the development of intranasal betahistine for the treatment of vertigo

Auris Medical Holding AG, Bahnhofstrasse 21, 6300 Zug (Switzerland) +41 41 729 71 94 www.aurismedical.com

(AM-125) and for the prevention of antipsychotic-induced weight gain and somnolence (AM-201). These projects have gone through two Phase 1 trials and will move into proof-of-concept studies in 2019. In addition Auris Medical has two Phase 3 programs under development: Sonsuvi<sup>®</sup> (AM-111) for acute inner ear hearing loss and Keyzilen<sup>®</sup> (AM-101) for acute inner ear tinnitus. The Company was founded in 2003 and is headquartered in Zug, Switzerland. The shares of Auris Medical Holding AG trade on the NASDAQ Capital 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 facts 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 forwardlooking words such as "may", "might", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "projects", "potential", "outlook" or "continue", or the negative of these terms or 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, Auris Medical's need for and ability to raise substantial additional funding to continue the development of its product candidates, the ability to pursue strategic partnering and non-dilutive funding for its Phase *3 programs, the results of Auris Medical's review of strategic options and the outcome of any action* taken as a result of such review, 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 Annual Report on Form 20-F for the year ended December 31, 2017, and in Auris Medical's other filings with the SEC, which are available free of charge on the Securities Exchange Commission's website at: www.sec.gov. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those indicated. All forward-looking statements and all subsequent written and oral forward-looking statements attributable to Auris Medical or to persons acting on behalf of Auris Medical are expressly qualified in their entirety by reference to these risks and uncertainties. You should not place undue reliance on forward-looking statements. 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.

### Investor contact:

Joseph Green / Andrew Gibson Edison Advisors for Auris Medical 646-653-7030 / 7719 jgreen@edisongroup.com / agibson@edisongroup.com

0r

investors@aurismedical.com