# Auris Medical News Release

## Auris Medical and Cochlear to Collaborate on Clinical Trial with AM-111 for Otoprotection during Cochlear Implant Surgery

**Zug, Switzerland, and Sydney, Australia, June 25, 2015** – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing injectable therapeutics for inner ear disorders, and Cochlear Ltd. (ASX: COH), the global leader in implantable hearing solutions, today announced they will collaborate on a planned randomized placebo-controlled clinical trial in the United States (the REACH trial). As previously announced, REACH shall evaluate Auris Medical's cell penetrating otoprotectant AM-111 in patients with residual hearing who are undergoing cochlear implant (CI) surgery. Under the collaboration, Cochlear will support preparations for REACH and provide expertise in cochlear implants and hearing preservation.

Drug-based otoprotection during cochlear implantation has attracted growing interest in recent years. Under the concept of Electro-Acoustic Stimulation, also known as "Hybrid Hearing", electrical stimulation is delivered through a cochlear implant alongside acoustic stimulation provided via hearing aid functionality built into the CI sound processor. The hearing aid functionality acoustically amplifies low frequencies while the CI electrically stimulates middle and high frequencies. Hybrid Hearing assists patients with severe to profound high-frequency hearing loss and some degree of low frequency residual hearing, who would otherwise receive only limited benefits from a traditional hearing aid alone and may suffer from inadequate speech understanding, especially under noisy conditions. It is expected that more effective otoprotection during CI surgery (in particular during cochlear electrode insertion) will support further adoption of Hybrid Hearing. In a pre-clinical model of cochlear implant surgery trauma, local application of AM-111 30 minutes prior to electrode insertion provided significant protection against surgery-induced hearing loss, loss of hair cells and damage to neural elements.[1]

"Protection of at-risk cochlear sensory structures during CI surgery represents an interesting potential application for AM-111 and could provide important benefits for future CI users", commented Thomas Meyer, Auris Medical's founder, Chairman and CEO. "We are very excited by the opportunity to collaborate with Cochlear, whose Nucleus Hybrid L24 device is the only CI that has been approved by the FDA specifically for Electro-Acoustic Stimulation, and we look forward to progressing further with our preparations for REACH."

Chris Roberts, CEO and President of Cochlear, said Cochlear Nucleus implants had a proven track record for great hearing outcomes, particularly for the new Hybrid Hearing indication. "We are pleased to see an increased adoption of this technology, and keen to support Auris Medical in the clinical investigation of the use of AM-111 during CI surgery," he said.

[1] Eshraghi AA, Gupta C, Van De Water TR, Bohorquez JE, Garnham C, Bas E, Talamo VM (2013): Molecular mechanisms involved in cochlear implantation trauma and the protection of hearing and auditory sensory cells by inhibition of c-Jun-N-terminal kinase signaling, Laryngoscope 123 (Suppl 1), S1-S14.

Auris Medical plans to seek grant funding in support of the REACH trial and expects enrollment to start in the third quarter of 2016.

**About AM-111**

AM-111 contains the synthetic peptide D-JNKI-1 (D-stereoisomer of c-Jun N-terminal Kinase Inhibitor 1), 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. Auris Medical is currently preparing two pivotal clinical trials (HEALOS and ASSENT) 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. In addition, Auris Medical is preparing a Phase 2 trial with AM-111 in the treatment of surgery-induced hearing loss (REACH).

**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".

**About Cochlear**

Cochlear is the global leader in implantable hearing solutions. The company has a global workforce of 2,700 people and invests more than AUS$100 million a year in research and development. Products include hearing systems for cochlear, bone conduction and acoustic implants. Over 400,000 people of all ages, across more than 100 countries, now hear because of Cochlear implants. Nucleus® and Hybrid™ are trademarks of Cochlear Ltd.

**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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