

# Auris Medical Reaches Midpoint for Enrollment in AM-201 Phase 1b Proof-of-Concept Study in Antipsychotic-Induced Weight Gain

Hamilton, Bermuda, May 7, 2019 – Auris Medical Holding Ltd. (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 that it has reached the midpoint for enrollment in its Phase 1b proof-of-concept trial of AM-201, the Company's investigational drug for the prevention of antipsychotic-induced weight gain and somnolence.

The Phase 1b trial with AM-201 is being conducted at one European site. The trial will enroll in total 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with the antipsychotic drug olanzapine over four weeks. The protocol is based on a dose escalation with five different doses of intranasal betahistine. The first two dose cohorts have been completed and the next ten study participants have been enrolled into the third dose cohort. The primary efficacy outcome for the study will be the reduction in weight gain; the secondary outcome will be the reduction in somnolence.

"We are pleased with the rapid progress of our AM-201 development program, which builds on previous preclinical and clinical work with oral betahistine in the attenuation of antipsychoticinduced weight gain and somnolence," commented Thomas Meyer, Auris Medical's founder, Chairman and CEO. "We are on track to report top-line data from the Phase 1b trial during the third quarter of 2019, and thus to obtain swiftly the first proof-of-concept data with AM-201."

## About Betahistine

Betahistine is a small molecule structural analog of histamine, which acts as an agonist at the H1 and as an antagonist at the H3 histamine receptors. Unlike histamine, it crosses the blood-brainbarrier. It is known to enhance inner ear and cerebral blood flow, increase histamine turnover and enhance histamine release in the brain, increase release of acetylcholine, dopamine and norepinephrine in the brain and to result in general brain arousal. Betahistine for oral administration is approved in about 115 countries, with the US being a notable exception, for the treatment of vertigo and Meniere's disease. The compound has a very good safety profile, yet it is also known that its clinical utility is held back by poor bioavailability. Intranasal administration of betahistine has been shown to result in 4 to 26 times higher bioavailability.

## About AM-201

Intranasal betahistine is being developed under project code AM-201 for the prevention of antipsychotic-induced weight gain and somnolence. Many antipsychotic drugs are known to block the H1 histamine receptor, which is involved in the control of appetite and wakefulness, resulting in weight gain and somnolence as side effects. As an H1 receptor agonist, betahistine is thought to counteract the antipsychotics' inhibitory effects; in addition, betahistine blocks presynaptic H3 histamine autoreceptors, thus increasing histamine release and in turn augmenting betahistine's direct agonistic effects on H1 receptors.

#### About Auris Medical

Auris Medical is a 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 (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 Hamilton, Bermuda with its main operations in Basel, Switzerland. The shares of Auris Medical Holding Ltd. 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, 2018, 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.

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