

REGAIN Consortium announces positive Ph I Results for hearing loss

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The REGAIN consortium, led by Audion Therapeutics BV, a company dedicated to the development of therapeutics for hearing loss, reports positive results from its Phase I multiple ascending dose, open-label safety study of the Notch Inhibitor LY3056480 in 15 patients with mild to moderate sensorineural hearing loss (SNHL). LY3056480 mediated Notch inhibition is aimed at regeneration of inner ear sensory hair cells that are lost with advancing age. The study was conducted at University College London and University College London Hospitals and focused on the safety and tolerability of LY3056480 in patients with adult onset mild to moderate SNHL. Dose escalation within the Phase I clinical trial demonstrated that trans-tympanic injection (3 administrations, one week apart) at the highest dose of 250 micrograms of LY3056480 was safe and well tolerated. No safety issues were reported.

The Phase I data support the advancement of LY3056480 to a multi-centre efficacy study in 40 adult patients with mild to moderate adult onset SNHL recruited in the UK, Germany and Greece. Pure tone hearing levels and speech in noise performance are the main efficacy parameters. Recruitment for this Phase II study started in January 2019.

Audion Therapeutics' CEO Rolf Jan Rutten commented: "These positive Phase I results are an important milestone for Audion's lead program addressing the growing, global need for treatment options for hearing loss. This achievement would not have been possible without our excellent academic and industrial partners with whom we form the REGAIN consortium under the EU Horizon 2020 program".

Professor Anne Schilder, director of the NIHR UCLH Biomedical Research Center's Hearing Theme at the UCL Ear Institute, who led the design and delivery of the clinical trial, said: "We are proud to be part of the REGAIN consortium and to be leading on translating this scientific breakthrough into a treatment that may improve people's hearing health and lives".

Professor Shakeel Saeed, Professor of Otology and Clinical Director of the Royal National Throat, Nose and Ear Hospital and lead clinician on the REGAIN clinical trial added: "We are very excited by this research and are thankful to all the participants in the study without whom we could not have delivered on this trial."