

FOR IMMEDIATE RELEASE

Autifony Therapeutics awarded £2.2 million to progress first-in-class drug for tinnitus into Phase IIa study

Award follows successful completion of Phase I

London, UK - 4 June 2014 - Autifony Therapeutics Limited (“Autifony”), which is pioneering the development of novel pharmaceutical treatments for hearing disorders, today announced that it has been awarded funding of £2.2 million towards a Phase IIa clinical trial in tinnitus patients with its lead compound AUT00063, by the UK’s innovation agency, the Technology Strategy Board. Autifony will be sponsor of the clinical study, with Professor Deborah Hall at The University of Nottingham and National Institute for Health Research (NIHR) Nottingham Hearing Biomedical Research Unit (BRU) as lead academic collaborator.

AUT00063 is a first-in-class Kv3 potassium channel modulator in development for the treatment of age-related hearing loss, for which a Phase IIa clinical trial is expected to start later this year. The Technology Strategy Board funding award will now enable Autifony to initiate a randomized, placebo controlled Phase IIa study in patients with tinnitus in the UK, allowing Autifony to test the drug’s efficacy in this poorly served patient group.

The award follows an application to the Biomedical Catalyst, jointly funded by the Technology Strategy Board and the Medical Research Council, and comes after the recent successful completion of a randomized, placebo controlled Phase I study, conducted in the UK, which investigated the safety, tolerability and pharmacokinetics of orally administered single and multiple dose regimens of AUT00063 in more than 60 young and elderly healthy volunteers. In the study the drug appeared safe and well tolerated, and no serious adverse events were recorded. AUT00063 showed excellent pharmacokinetics, compatible with once/daily oral dosing. The Phase I trial also explored a variety of novel pharmacodynamic endpoints and interactions, which confirmed the engagement of the drug with the Kv3 ion channel target, and provided further supporting evidence for dose selection in the Phase II studies.

Dr Charles Large, Chief Executive Officer of Autifony, commented: “There is a huge need for a drug to treat tinnitus, which is surprisingly common, affecting over 10% of the population. Tinnitus seriously impacts quality of life for up to 1% of people, disrupting sleep and concentration, as well as affecting their hearing and emotional state. We are very hopeful that our pioneering Kv3 channel modulator approach may be able to bring some relief to patients with tinnitus, although there is clearly still a long development path ahead of us. The Technology Strategy Board funding will be very helpful in enabling us to test AUT00063 in this additional indication with such high unmet medical need.”

Dr Ralph Holme, Head of Biomedical Research at Action on Hearing Loss, the UK charity dedicated to hearing loss research, commented: “On a daily basis we are contacted by people who struggle to cope with their tinnitus and want to know if there are effective treatments for this condition. We are delighted that Autifony, who we have worked with closely from their inception, has secured funding to continue clinical testing on a potential new drug treatment that we hope will bring relief to tinnitus sufferers.”

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About Autifony Therapeutics Ltd

Autifony Therapeutics is an independent UK based biotechnology company formed in 2011 as a spin-out from GSK, which retains equity in the company. The company is focused on the development of high value, novel medicines to treat hearing disorders and serious disorders of the central nervous system, such as schizophrenia. Autifony Therapeutics is funded by SV Life Sciences, Imperial Innovations, Pfizer Venture Investments, International Biotechnology Trust PLC and UCL Business. www.autifony.com

About the University of Nottingham

The [University of Nottingham](http://www.nottingham.ac.uk) has 43,000 students and is ‘the nearest Britain has to a truly global university, with campuses in [China](#) and [Malaysia](#) modelled on a headquarters that is among the most attractive in Britain’ (*Times Good University Guide 2014*). It is also the most popular university in the UK among [graduate employers](#), one of the [world’s greenest universities](#), and winner of the [Times Higher Education Award](#) for ‘Outstanding Contribution to Sustainable Development’. It is ranked in the World’s Top 75 universities by the QS World University Rankings.

[Impact: The Nottingham Campaign](#), its biggest ever fundraising campaign, will deliver the University’s vision to change lives, tackle global issues and shape the future. [More news...](#)

The National Institute for Health Research (NIHR) is funded by the Department of Health to improve the health and wealth of the nation through research. Since its establishment in April 2006, the NIHR has transformed research in the NHS. It has increased the volume of applied health research for the benefit of patients and the public, driven faster translation of basic science discoveries into tangible benefits for patients and the economy, and developed and supported the people who conduct and contribute to applied health research. The NIHR plays a key role in the Government’s strategy for economic growth, attracting investment by the life-sciences industries through its world-class infrastructure for health research. Together, the NIHR people, programmes, centres of excellence and systems represent the most integrated health research system in the world. For further information, visit the NIHR website (www.hearing.nihr.ac.uk/).

About Tinnitus

The word 'tinnitus' comes from the Latin word for 'ringing'. It is the perception of sound in the absence of any corresponding external sound, which is generated by the sufferer’s own auditory pathways. The location of the sound may be difficult to pinpoint, but it may be heard in one ear, in both ears or inside the head. The noise may be low, medium or high-pitched. There may be a single noise or multiple components. The noise may be continuous or it may come and go. Tinnitus can arise from many possible different causes, and is often accompanied by hearing loss. It is a common condition which affects over 10% of the population, although many cope well with the symptoms. However, for up to 1% of the population, it brings considerable suffering.

Many treatment options are tried, most with limited success. They range from drugs affecting the central nervous system to electrical treatments and auditory and cognitive behavioural therapies.

Research shows that tinnitus arises within the central nervous system, and may be caused by increased neural activity in regions of central auditory pathway. Thus treatments for tinnitus need to focus on targets within the brain, and not the cochlea.

About the Biomedical Catalyst

Catalysts are run jointly by the Technology Strategy Board and the Research Councils. The Biomedical Catalyst is delivered jointly by the Medical Research Council and the Technology Strategy Board. A Catalyst is a form of research and development funding which focuses on a specific priority area and aims to help take projects from research to as close to commercial viability as possible. The Catalyst model supports projects in priority areas where the UK research base has a leading position and where there is clear commercial potential. Current Catalysts include: Biomedical Catalyst, Agri-tech Catalyst and the Industrial Biotechnology Catalyst. For more details please visit: <https://www.innovateuk.org/-/catalysts>

About the Technology Strategy Board

The Technology Strategy Board is the UK government's innovation agency. Its goal is to accelerate economic growth by stimulating and supporting business-led innovation. Sponsored by the Department for Business, Innovation and Skills (BIS), the Technology Strategy Board brings together business, research and the public sector, supporting and accelerating the development of innovative products and services to meet market needs, tackle major societal challenges and help build the future economy. For more information please visit www.innovateuk.org.

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