



Autifony Therapeutics announces initiation of Phase IIa study for first-in-class drug to treat tinnitus

London, UK – 20 November 2014- Autofony Therapeutics Limited (“Autifony”), which is pioneering the development of novel pharmaceutical treatments for hearing disorders, today announced that it has initiated a Phase IIa study in tinnitus subjects with its lead compound AUT00063. This proof of concept study (called the QUIET-1 study, QUest In Eliminating Tinnitus) will explore the potential of AUT00063, Autofony’s first-in-class Kv3 potassium channel modulator, to reduce the symptoms of tinnitus, which is an area of significant unmet medical need.

The study will be conducted in 12 key hospital sites across the UK. Professor Jaydip Ray, ENT Surgeon at Sheffield Teaching Hospitals and Sheffield Children’s Hospital, will be the national Coordinating Investigator, 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. The study is co-funded by a UK government-backed Biomedical Catalyst award.

In the earlier Phase I study, AUT00063 showed a good safety and tolerability profile, and pharmacokinetics compatible with once daily oral dosing. The Phase IIa study will focus in particular on tinnitus associated with hearing loss following noise exposure or ageing. Subjects will undergo four weeks of once daily dosing.

AUT00063 is also in development for the treatment of age-related hearing loss and a Phase IIa clinical trial in this indication is expected to start soon in the US.

Dr Charles Large, Chief Executive Officer of Autofony, commented: “There are no drugs yet approved for the treatment of tinnitus, and there is a considerable need to treat this surprisingly common and very disturbing condition. Tinnitus affects over 10% of the UK population, and seriously impacts quality of life for up to 1% of people, disrupting sleep and concentration, as well as affecting their hearing and emotional state. Anyone wishing to learn more about where our trial is taking place, and how to enrol, should regularly check our website for details.”

David Stockdale, CEO of the British Tinnitus Association, the UK charity dedicated to tinnitus sufferers, commented: “At the BTA we continue to work towards finding a cure for tinnitus and ways to help reduce the symptoms of this incredibly common condition. We are delighted to support this trial moving into its next phase and will be monitoring progress closely.”

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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 also focus on targets within the brain, and not just the cochlea.

About Autofony 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. Autofony Therapeutics is funded by SV Life Sciences, Imperial Innovations, Pfizer Venture Investments, International Biotechnology Trust PLC and UCL Business. www.autifony.com

About Sheffield Teaching Hospital

The Sheffield Teaching Hospital has a dedicated Neurosciences department including an intensive care unit for patients with head injuries, neurological conditions such as stroke and for patients that have undergone neurosurgery. It also has an award winning Gastroenterology department, a large Tropical Medicine and Infectious Disease Unit as well as a specialist Haematology centre and other medical and surgical services. The Regional Department of Neurology is involved in several translational research projects investigating various inner ear disorders of hearing and balance. The trust is part of one of the earliest Academic Health Science Networks.

About the University of Nottingham

The University of Nottingham 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, in the top 10 for student experience according to the *Times Higher Education* and one of the world's greenest universities. It is ranked in the world's top 1% of 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.

About the National Institute for Health Research (NIHR)

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 the Biomedical Catalyst

Catalysts are run jointly by Innovate UK (previously the Technology Strategy Board) and the Research Councils. The Biomedical Catalyst is delivered jointly by the Medical Research Council and Innovate UK. 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 Innovate UK

Innovate UK (previously known as 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 Innovate UK 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.



About the British Tinnitus Association

The British Tinnitus Association (BTA) is an independent charity which supports over 270,000 people a year who experience tinnitus and advises medical professionals from across the world. The BTA is the primary source of support and information for people with tinnitus in the UK, facilitating an improved quality of life. It aims to encourage prevention through its educational programme and to seek effective treatment for tinnitus through a medical research programme.

The experienced team at the BTA understands the impact that tinnitus can have on the lives of those who experience tinnitus and those who live with them, so seeks to provide the most appropriate and expert advice and information free of charge – via a confidential freephone helpline on 0800 018 0527 and online at www.tinnitus.org.uk.

For more information, please contact:

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