



Autifony Therapeutics Initiates Phase I Study for Lead Product, AUT00063, for the Treatment of Hearing Loss and Tinnitus and Tops Up Series A Financing with Further £5.5 million Investment

London, UK, - 4 June 2013 - Autofony Therapeutics Limited (“Autifony”), which is pioneering the development of novel pharmaceutical treatments for hearing disorders, today announced the start of a Phase I clinical study of the novel, first-in-class Kv3 potassium channel modulator, AUT00063.

This is a randomized, placebo controlled Phase I study, conducted in the UK, to investigate the safety, tolerability and pharmacokinetics of orally administered single and multiple dose regimens of AUT00063 in around 60 young and elderly volunteers. The study, which is also exploring a variety of novel pharmacodynamic endpoints and interactions, is expected to be completed in Q1 2014.

AUT00063 is being developed as a treatment for age-related hearing loss and tinnitus. Despite the fact that 50% of those aged over 60 suffer from age-related hearing loss and 10% of the population suffer from some form of tinnitus, there are currently no effective treatments for either condition. AUT00063 is a novel pharmaceutical that targets auditory processing in the brain. Deficits in these central mechanisms are believed to contribute to hearing difficulties in the elderly as well as the emergence of tinnitus.

To fund this lead programme through to clinical Proof-of-Concept for at least one hearing disorder indication, Autofony has also announced that Pfizer Venture Investments, the venture capital arm of Pfizer Inc., has invested £5 million to join existing investors SV Life Sciences, Imperial Innovations plc and UCL Business plc (UCL-B) in the Series A financing round. Dr Elaine Jones from Pfizer has joined the Autofony board. The International Biotechnology Trust PLC (IBT) has also invested, bringing the total funds raised to date to £15.75 million.

Dr Charles Large, Chief Scientific Officer of Autofony Therapeutics, commented: “We are delighted by the progress that has been made to bring AUT00063 into clinical development. Hearing loss and tinnitus affect the lives of a vast proportion of the population, yet there are no effective treatments available. AUT00063 has the potential to change that.

“We welcome the financial commitment from Pfizer and IBT, in addition to SV Life Sciences, Imperial Innovations, and UCL-B, which will allow us to explore the therapeutic potential of this first-in-class medicine. Our current intent is to partner the programme, for which we hold unencumbered global rights, once we have achieved clinical proof of concept and we are encouraged by the interest shown to date by pharmaceutical companies.”

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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. It is funded by SV Life Sciences, Imperial Innovations plc, Pfizer Venture Investments, International Biotechnology Trust PLC, and UCL Business plc. Autofony works closely with hearing research experts at University College London's Ear Institute, Yale University and other academic collaborators around the world to progress its pioneering research. www.autifony.com

About AUT00063

AUT00063 is a novel, orally active small molecule designed to selectively modulate Kv3 potassium channels, which are important in central auditory processing. Preclinical studies have shown that AUT00063 has the potential to reduce symptoms of age-related hearing loss and tinnitus, and may also help to prevent hearing loss caused by noise trauma. Safety and toxicology studies support the clinical development of AUT00063, and suggest that the drug will be safe and well tolerated in humans.

About age-related hearing loss

Age-related hearing loss affects more than half of people over the age of 60. The onset of hearing loss for some can occur before the age of 60, which can affect the ability to work, leading to higher rates of unemployment. With our society's aging demographics, age-related hearing loss is set to become an increasing problem that causes social isolation and depression. Furthermore, with so many young people now listening to personal stereos for extended periods at high volume, the problem is likely to increase, and this generation is likely to suffer significant hearing loss even earlier as they age. Consequently, the healthcare economic impact of hearing loss amongst those still in work is increasing and is beginning to be studied more widely.

The key complaint for those suffering from age-related hearing loss is difficulty understanding speech, in particular in noisy environments or where several people are talking at the same time, such as at a social gathering. Understanding speech requires both that the speech is heard, but also importantly that the different components of speech can be distinguished (for example, the difference between a "b" and "p" sound). These speech components can be very fast and rely on optimal functioning of auditory processing mechanisms in the brain as well as on reception by hair cells in the cochlea.

With aging, hair cells are lost and the signal reaching the brain reduces. Combined with this, a deterioration of central auditory processing and the decline of cognitive capacity can add to the problem. Evidence that age-related hearing loss is due as much to problems in the brain as to loss of hair cells in the cochlea comes from the finding that some people who have perfect audiograms still struggle to understand speech in environments where there is a lot of background noise.

There are no current treatment options. Hearing aids or cochlear implants can help some sufferers, although often interpreting speech remains a challenge.



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 as much as 10% of the population, although many cope well with the symptoms. However, for around 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.

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