



Autifony Therapeutics recruits first patient into Phase IIa trial for first-in-class drug to treat Age Related Hearing Loss

Study follows acceptance of Autofony's first IND by the FDA

London, UK – 27th April 2015- Autofony Therapeutics Limited (“Autifony”), which is pioneering the development of novel pharmaceutical treatments for hearing disorders, today announced that it has recruited the first subject in a Phase IIa study for treatment of Age Related Hearing Loss. This proof of concept study (called CLARITY-1) will explore the potential of AUT00063, Autofony’s first-in-class Kv3 potassium channel modulator, to improve hearing in the elderly by focusing on the discrimination of speech from background noise, which is an area of significant unmet medical need.

The study will be conducted in around 14 key sites across the USA, with Dr Robert Frisina Jr, University of South Florida and director of the USF Global Center for Hearing & Speech Research, as Principal Investigator. The initiation of the trial also highlights the acceptance of Autofony’s first IND (Investigational New Drug) by the FDA, an important milestone for the company.

In a Phase I study, AUT00063 showed a good safety and tolerability profile, and pharmacokinetics compatible with once daily oral dosing. In the Phase IIa study, one hundred subjects will undergo four weeks of once daily dosing, during which their hearing will be assessed using a speech-in-noise test, as well as other tests to probe central auditory processing.

AUT00063 is also in development for the treatment of tinnitus, with a Phase IIa clinical trial in this indication already underway in the UK.

Dr Charles Large, Chief Executive Officer of Autofony, commented: “Hearing loss has unjustly attracted very little attention from the medical community, but has significant implications for society. The UK charity Action on Hearing Loss estimates more than 70% of over 70 year olds and 40% of over 50 year olds have some form of hearing loss, so this is as much a problem for people still working as for the elderly where it contributes to social isolation and depression.

“Hearing aids can help improve audibility, but do little to help with the central problem of understanding speech, particularly in noisy environments. CLARITY-1 is a pioneering trial, and the concept of a pharmaceutical treatment to improve hearing is completely novel. Anyone wishing to learn more about where our trial is taking place, and how to enrol, should regularly check our website for details.”

Dr Ralph Holme, Head of Biomedical Research at Action on Hearing Loss, the UK charity dedicated to hearing loss research, commented: “Significant progress in hearing research over recent years has brought us to a point where new medicines are being tested clinically, and heralding the start of a new era of treatment options for people confronting hearing loss. We are delighted that Autofony have begun the next phase of clinical testing of potentially the first drug treatment to help people with age-related hearing loss.”

- ENDS -



About Age Related Hearing Loss

Age-related hearing loss affects up to half of people over the age of 65, and the onset of hearing loss for some occurs well before this, affecting their ability to work, leading to higher rates of unemployment. With our society's aging demographics, age-related hearing loss is an increasing problem that can cause social isolation, depression, and even an acceleration of dementia. Furthermore, with so many young people now listening to personal listening devices for extended periods at high volume, the problem is likely to increase; this generation is likely to suffer significant hearing loss even earlier as they age. Consequently, the impact of hearing loss, even 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 social gatherings. Understanding speech requires not only 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 components can be very fast and rely on optimal function 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 near perfect audiograms may 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 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 Action on Hearing Loss

Action on Hearing Loss (formerly RNID) is the charity working for a world where hearing loss doesn't limit or label people, where tinnitus is silenced – and where people value and look after their hearing. Our vision is



to find a cure for hearing loss and tinnitus. For more information about Action on Hearing Loss's Biomedical Research programme, go to www.actiononhearingloss.org.uk/biomedicalresearch

For more information, please contact:

Autifony

Dr Charles Large, Chief Executive Officer

E: charles.large@autifony.com

Instinctif Partners

Sue Charles, Tim Watson, Gemma Howe

T: +44 (0) 20 7866 7860

E: Autifony@instinctif.com