Autifony Therapeutics initiates QuicK^{+}fire, a pilot study of AUT00063 in adult cochlear implant users

London, UK - 6th July 2016 - Autifony Therapeutics Limited ("Autifony"), which is pioneering the development of novel pharmaceutical treatments for hearing loss, today announced the start of a pilot study (called QuicK^{+}fire) to evaluate its lead compound, AUT00063, in adult cochlear implant (CI) users. The study, which will be conducted in the UK, is aimed at helping to improve the hearing of adult CI users, particularly in challenging environments such as with background noise. AUT0063 is currently being tested in a Phase IIa clinical trial in age related hearing loss in the United States.

Cochlear implants have transformed the lives of people with profound hearing loss, but not all outcomes are optimal. There are many who still struggle to understand speech, particularly in noisy environments, where the rapid sounds that make up speech can be difficult to pick-up and discriminate. Hearing loss and age are associated with deterioration of the neural circuits that underpin central auditory processing, which leads to a reduction in the auditory system's ability to resolve rapid sounds, such as elements of speech.

Autifony's AUT00063 is a drug that modulates voltage-gated Kv3 potassium channels, which are critical to the function of neural circuits involved in central auditory processing**.** It is thought that by increasing the precision and timing of neural firing, AUT00063 will enhance people's hearing performance with their cochlear implant.

Adult CI users will be recruited from four clinical trial sites in the UK: London, Cambridge, Birmingham and Manchester, recruiting around 20 subjects in total. The study has a crossover design, so each subject will act as their own control. AUT00063 is an orally active drug that will be taken during the clinical trial once daily for 28 days. A variety of endpoints will be investigated, including responses to direct stimulation of the auditory nerve via the implant, and a range of different speech-in-noise tests. The study is expected to complete within one year.

Dr Charles Large, Chief Executive Officer of Autifony Therapeutics, commented: "Based on the unique and novel mechanism of action of our drug and strong preclinical data, we believe this pilot study has the potential to help users of cochlear implants to attain greater improvements in their hearing, particularly in noisy situations. This is a further example of Autifony's plans to develop drugs to help people with a range of different challenges to their hearing."

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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 other serious diseases of the central nervous system. It is funded by SV Life Sciences, Imperial Innovations plc, Pfizer Venture Investments, International Biotechnology Trust PLC, and UCL Business plc. www.autifony.com

About AUT00063

AUT00063 is a novel, orally active small molecule designed to selectively modulate Kv3 potassium channels. These channels are important for the function of neurons in auditory circuits in the brain, allowing them to fire rapidly and precisely in response to rapid sounds, such as speech. Preclinical studies in rodents have shown that AUT00063 can improve the timing of firing of neurons in auditory brainstem circuits in hearing impaired mice, and can improve the detection of transient sounds in aged rats. These findings predict that AUT00063 will improve central auditory processing in humans which should be reflected in improved speech understanding.

Preclinical studies, Phase I clinical data, and a growing safety database in humans from Autifony's ongoing Phase IIa clinical trial for age-related hearing loss, confirm the excellent safety and tolerability profile of AUT00063.

About Cochlear Implants

A cochlear implant is a surgically implanted electronic device that provides a sense of sound to a person who has a severe or profound hearing loss. A cochlear implant does not cure deafness or hearing impairment, but is a prosthetic substitute which directly stimulates the cochlea. Cochlear implants bypass the normal hearing process; they have a microphone and some electronics that reside outside the skin, generally behind the ear, which transmit a signal to an array of electrodes placed in the cochlea, which stimulates the cochlear nerve. As of December 2012, approximately 324,000 people worldwide had cochlear implants surgically implanted, with roughly 58,000 adults and 38,000 children in the US. There are over 12,000 in the UK.

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