



Update from Autofony Therapeutics' QUIET-1 clinical trial

- QUIET-1 Phase II Trial of AUT00063 in tinnitus terminated due to lack of efficacy
- AUT00063 was safe and well tolerated
- Trial of AUT00063 in age-related hearing loss continuing

London, UK - 13th OCTOBER 2015 - Autofony Therapeutics has now completed a planned interim analysis on the QUIET-1 tinnitus clinical trial with AUT00063. This analysis was conducted to check for evidence of treatment efficacy and to ensure that there were no safety or tolerability signals. Following its review of the results from 58 subjects who have completed the QUIET-1 trial, the Independent Data Monitoring Committee recommended that Autofony terminate recruitment due to lack of efficacy. The Committee compared the outcome of the AUT00063-treated subjects with those that received placebo, and concluded that on a statistical basis it would not be possible to reach the magnitude of positive outcome needed to show improvement over the control.

Importantly, there were no safety or tolerability issues identified with AUT00063.

Over the coming weeks, Autofony will be conducting a full review and analysis of the data from all of the subjects that have completed the study and aims to understand the drivers of this outcome as well as to explore if any subgroups may have benefited from treatment.

This result of the QUIET-1 study in tinnitus does not impact Autofony's clinical trial for Age-Related Hearing Loss, the 'CLARITY' study, which is ongoing in the US, and which will continue as planned.

Dr Charles Large, CEO of Autofony commented: "The lack of efficacy of AUT00063 in the QUIET-1 study is clearly disappointing news for tinnitus sufferers, and indeed for everyone who has supported Autofony in its work on this trial. Autofony is very grateful for all the help it has received in carrying out this study, from Innovate UK in terms of funding, from the charities and patient groups who are supportive of the Company's efforts, from the Principal Investigators and Research Nurses and most of all, from the people with tinnitus who volunteered to participate in the QUIET-1 trial."

Treating tinnitus is a difficult challenge, with a high unmet need, and Autofony is keen to ensure that it learns as much as possible from the results of the QUIET-1 trial. Once the data have been analysed, the key findings will be published in order to support future research in this area.

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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 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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