Update from Autifony Therapeutics' QUIET-1 tinnitus clinical trial

- **Headline data from QUIET-1 confirm lack of efficacy of AUT00063 in the treatment of people with mild-to-moderate tinnitus**
- **AUT00063 was safe and well tolerated**
- **Trial of AUT00063 in age-related hearing loss continuing**

London, UK – 28th April 2016- Autifony, along with Innovate UK, sponsored a Phase IIa tinnitus clinical trial in the UK. Professor Jaydip Ray, ENT Surgeon at Sheffield Teaching Hospitals & Sheffield Children's Hospital, was the national Coordinating Investigator for this clinical trial. Our lead academic collaborator was the University of Nottingham (Professor Deborah Hall). This "proof-of-concept" study explored the potential of Autifony's lead Kv3 modulator, AUT00063, to reduce the symptoms in people with subjective tinnitus.

18 Investigational Centres across the UK enrolled patients to this tinnitus clinical trial. Following a planned interim analysis in October 2015, the Independent Data Monitoring Committee recommended that Autifony terminate recruitment due to lack of efficacy. The Committee compared the levels of tinnitus experienced by the AUT00063-treated subjects with those that received placebo, and concluded that on a statistical basis it would not be possible to reach a positive outcome. Importantly, there were no safety or tolerability issues identified with AUT00063.

A full analysis has now been completed. A total of 91 subjects were randomised into the trial, with 76 providing data for the final analysis, and 71 of these providing a complete dataset. Tinnitus severity on entry, on average, was in the moderate range (group mean Tinnitus Functional Index (TFI) score 44), the placebo group started slightly higher than the active group (46 vs 42, respectively). At Day 28 this difference had disappeared and both groups finished at a TFI score of 40, thus little or no reduction in mean score in the active group. These values were maintained through to the 2 week follow up. Statistical analysis, controlling for covariates of age, tinnitus severity, duration and noise exposure history, found no significant change from baseline in either group, and no difference between groups (p=0.98). Thus these final group level data closely reflect the analysis on the interim population last October. Inspection of the TFI sub-scales found no notable changes in either group on any of the subscales.

A similar picture emerged for the secondary endpoint, Loudness Matching. Active and placebo groups started at a similar mean level, with small changes in both groups at Day 28 relative to Day 1 (-1.28 dB improvement and +0.21dB worsening, respectively). Neither change was significant (p=0.51 and 0.29, respectively) and there was no significant difference between the two groups (p=0.53). In general, AUT00063 was well tolerated in the study, with most side effects being mild and self-limiting.

In conclusion, the headline data from QUIET-1 confirm lack of efficacy of 28 days treatment with AUT00063 (800mg) in people with mild-to-moderate tinnitus. Baseline severity, the stability of TFI and Loudness Matching scores, and the absence of a notable placebo response suggest that the study was adequately designed to detect a drug effect.

Once all analyses are complete, the results will be written up for publication, such that any learnings may be of benefit to future research in tinnitus.

This result of the QUIET-1 study in tinnitus does not impact Autifony's clinical trial for age- related hearing loss, the 'CLARITY' study, which is ongoing in the US, and which will continue as planned.

-ENDS-

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. It is funded by SV Life Sciences, Imperial Innovations plc, Pfizer Venture Investments, International Biotechnology Trust PLC, and UCL Business plc. Autifony 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.

For more information, please contact:

Autifony Therapeutics

Dr Charles Large, Chief Executive Officer

E: charles.large@autifony.com

Instinctif Partners

Sue Charles, Tim Watson, Alex Bannister

T: +44 (0)20 7866 2825

E: Autifony@instinctif.com