



## **Autifony Announces Results from Completed CLARITY-1, Phase IIa Trial of AUT00063 in Age-related Hearing Loss**

- CLARITY-1 Phase IIa Trial of AUT00063 did not show a beneficial effect on age related hearing loss
- AUT00063 was safe and well tolerated
- Quick<sup>+</sup>fire study in adult cochlear implant users, with different hearing difficulties and endpoints, continues

**London, UK – 09 August 2016** - Autofony Therapeutics Limited, which is pioneering the development of novel pharmaceutical treatments for hearing disorders and other serious disorders of the central nervous system, today released the results of its CLARITY-1 clinical trial of AUT00063 conducted in subjects with age-related hearing loss.

The trial was a randomised double-blind, placebo-controlled, parallel group study examining the effects of AUT00063 (600 mg orally administered once daily for 28 days) on measures of hearing performance. Eleven clinical investigational sites in the US enrolled 78 subjects to treatment, of which 76 completed with evaluable data. Subjects enrolled to both active and placebo treatment groups were well balanced for age, sex and other baseline characteristics, including baseline scores for the primary outcome measure.

The primary outcome assessment was a comparison between treatment groups of speech in noise performance (QSIN test – Quick Speech-in-Noise) from baseline to Day 28. Both active and placebo treatments showed a significant improvement in performance in QSIN scores at Day 28 compared to baseline. However the difference between drug and placebo was not statistically significant.

A wide range of secondary outcome measures were included, which explored different aspects of the subjects hearing. However, none of these secondary endpoints showed a difference between active and placebo treatments, hence supporting the results of the primary analysis.

AUT00063 was safe and well tolerated by subjects during the trial. Plasma levels of AUT00063 were measured at the end of the trial period and showed drug exposures within the expected range, and in line with previous data from healthy volunteers.

Dr Charles Large, Chief Executive Officer of Autofony Therapeutics, said: “While it is disappointing to all who were involved in this groundbreaking clinical trial that the results did not show a beneficial effect of AUT00063 on age related hearing loss, credit should go to the participants, the Investigators and their teams, and the staff responsible for monitoring, analysing and reporting the data.

“The trial was of high quality and has delivered a clear and unequivocal outcome. The Autofony team would like to thank all those who worked tirelessly to complete this challenging study to such a high standard. The full data will be published in due course.

“In the meantime, our Quick<sup>+</sup>fire study, in adult cochlear implant users, has been initiated in the UK and will test AUT00063 in a population of patients with different hearing difficulties, and with different endpoints.”

-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 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, including 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 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 serious disorders of the central nervous system, such as schizophrenia. Autifony Therapeutics is funded by SV Life Sciences, Imperial Innovations, Pfizer Venture Investments, International Biotechnology Trust PLC and UCL Business. [www.autifony.com](http://www.autifony.com)

### **For more information, please contact:**

#### **Autifony Therapeutics Limited**

Dr Barbara Domayne-Hayman, Chief Business Officer

E: [barbara.domayne-hayman@autifony.com](mailto:barbara.domayne-hayman@autifony.com)

#### **Instinctif Partners**

Sue Charles, Tim Watson, Alex Bannister

T: +44 (0) 20 7866 7860

E: [Autifony@instinctif.com](mailto:Autifony@instinctif.com)