



Autifony Therapeutics successfully completes Phase I study of AUT00206, a first-in-class Kv3 modulator for schizophrenia

London, UK - 01 August 2016 - Autofony Therapeutics Limited ("Autifony"), which is pioneering the development of novel pharmaceutical treatments for hearing disorders and other serious disorders of the central nervous system, today announced successful completion of a Phase I clinical evaluation of its Kv3 modulator, AUT00206.

There have been few new approaches to treating schizophrenia in recent years, and with existing treatments often not delivering the desired efficacy and safety, there is strong interest in new mechanisms from both industry and academia. Modulation of Kv3 channels has the potential to treat schizophrenia patients early in the course of the disorder, with a much improved safety profile compared to current antipsychotic treatments. Evidence from preclinical models suggests that this novel approach may have the potential to treat cognitive and negative symptoms, as well as positive symptoms, which would represent a major breakthrough for patients. AUT00206 is a first-in-class Kv3 modulator that Autofony is progressing specifically for schizophrenia.

The Phase I study assessed the safety, tolerability and pharmacokinetics of AUT00206 in relation to dose in over 60 healthy volunteers. Double blind, randomised, placebo controlled single ascending dose and multiple ascending dose studies in fed and fasted states were conducted in the UK. AUT00206 was shown to be safe and very well tolerated, with pharmacokinetics confirming drug concentrations at levels required to generate a clinical effect, as predicted by preclinical models.

The next steps are two important Phase Ib clinical trials: a ketamine challenge study to be carried out by Professor Bill Deakin at the University of Manchester, which will translate an approach that demonstrated positive results in a preclinical model; and a study in schizophrenia patients investigating clinical biomarkers of efficacy, to be conducted in collaboration with Dr Oliver Howes at the Institute of Psychiatry, Psychology and Neuroscience (IoPPN) Kings College London. The programme is supported by the Biomedical Catalyst, jointly funded by Innovate UK and the Medical Research Council, who also contributed important enabling funding towards the preclinical stages of the programme, in collaboration with the Universities of Manchester and Newcastle.

Dr Charles Large, Chief Executive Officer of Autofony Therapeutics, commented: "We are delighted that AUT00206 is showing such a promising profile. It's widely recognized that there is a huge unmet need for new, more efficacious and safer treatments for schizophrenia. We believe AUT00206 has the potential to be a breakthrough for patients, and we will therefore continue to seek collaborative ways to expedite development of this exciting new drug."

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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 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 AUT00206

AUT00206 is a novel, orally active small molecule designed to selectively modulate Kv3 potassium channels.

Preclinical studies relevant to aspects of schizophrenia have shown that AUT00206 may have the potential to treat positive symptoms with fewer side effects than current anti-psychotic drugs, as well as cognitive and perhaps also negative symptoms of the disease. These latter domains are poorly treated by antipsychotics and are associated with significant functional deficits and lower quality of life for patients.

Safety and toxicology studies support the clinical development of AUT00206, and suggest that the drug will be safe and well tolerated in humans, and this is supported by the Phase I data in healthy volunteers.

About Schizophrenia

Schizophrenia remains a major healthcare challenge throughout the world. Patients with the condition have a poor quality of life and prognosis. Antipsychotics are the main treatment but it is generally asserted that in up to a third of people with schizophrenia, the illness shows a poor response to antipsychotic medication. Side effects of current approved drugs are problematic, including weight gain, diabetes, heart disease, movement disorders and sexual dysfunction. Particularly debilitating are the cognitive symptoms such as poor decision making, attention and memory; and negative symptoms, such as social withdrawal and anhedonia, which make work and relationships difficult to sustain. There is a clear need for more effective drugs with fewer side effects.

See 'The Abandoned Illness', a report by the Schizophrenia Commission, November 2012.

About Innovate UK

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About Biomedical Catalyst

Catalysts are run jointly by Innovate UK and the Research Councils. A Catalyst is a form of research and development funding which focuses on a specific priority area and aims to help take projects from research to as close to commercial viability as possible. The Catalyst model supports projects in priority



areas where the UK research base has a leading position and where there is clear commercial potential. Current Catalysts include: Biomedical Catalyst, Agri-tech Catalyst and the Industrial Biotechnology Catalyst.

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