



Autifony Therapeutics initiates recruitment into schizophrenia clinical trial for first-in-class drug

Stevenage, UK – 18 May 2017- Autofony Therapeutics Limited (“Autifony”), which is pioneering the development of novel pharmaceutical treatments for serious disorders of the central nervous system, today announced the start of a Phase Ib biomarker study of the effect of AUT00206, a first-in-class Kv3 ion channel modulator, on patients with schizophrenia.

The clinical trial is being conducted in collaboration with King’s College London, with Professor Oliver Howes as Principal Investigator. It is designed to test the safety, tolerability and pharmacokinetics of AUT00206 in patients with schizophrenia, and also explores the effects of AUT00206 on relevant central biomarkers.

Twenty-four patients, diagnosed with schizophrenia within the last five years, will receive AUT00206 or placebo for 28 days. During that period, electrophysiological measures of central nervous function known to be impaired in schizophrenia will be investigated for signs of improvement. The subjects will also undergo brain imaging, tests of cognition and tests of auditory function, in addition to routine safety monitoring. Because of the pioneering and novel mechanism of action of this drug, a key objective is to characterise this range of biomarkers which will inform the future development of the drug.

This project has been underpinned by a four-year collaboration with the Universities of Manchester and Newcastle, who have explored the effects of AUT00206 in preclinical models of brain pathophysiology relevant to schizophrenia. As previously reported, another Phase Ib study of AUT00206 is already underway in healthy volunteers employing a ketamine challenge, in collaboration with Professor Bill Deakin at the University of Manchester.

This successful collaboration between academia and industry to explore the Kv3 modulation mechanism of action has been made possible by Innovate UK and Medical Research Council funding contributed through the Biomedical Catalyst.

Dr Charles Large, CEO of Autofony, commented: “The commencement of our study of AUT00206 in people suffering from schizophrenia is an important milestone for the company and for our efforts to develop a better treatment for this devastating illness. Our work so far has indicated that AUT00206, which has a completely novel mechanism of action, has the potential to improve the cognitive and negative symptoms of schizophrenia, which current drugs fail to do. AUT00206 may also treat positive symptoms without the typical side effects seen with current medicines. We believe the results of this first study in schizophrenia patients will bring important insights that will help us to plan the next stages of development for this pioneering drug.”

Professor Oliver Howes of King’s College London commented: “Schizophrenia affects 1 in 100 people and sufferers die on average 20 years early. There is a desperate need for new approaches to treat schizophrenia. Today we take a critical step in testing this promising 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 serious diseases of the central nervous system. It is funded by SV Health Investors, Touchstone 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 using models relevant to the pathophysiology of schizophrenia suggest that AUT00206 has the potential to treat cognitive and negative symptoms of schizophrenia, as well as positive symptoms with fewer side effects than current anti-psychotic drugs. Cognitive and negative symptoms are poorly treated by antipsychotic drugs and are associated with significant functional impairment and reduced quality of life for patients.

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 in up to a third of people with schizophrenia, the illness shows a poor response to these drugs. Particularly debilitating are cognitive symptoms of schizophrenia, 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. Side effects of the currently approved antipsychotic drugs are also problematic, including weight gain, diabetes, heart disease, movement disorders and sexual dysfunction. There is a clear need for more effective drugs with fewer side effects.

There is increasing interest in the use of central biomarkers, based on electroencephalographic (EEG) responses to auditory stimuli, in the assessment of new mechanisms of treating schizophrenia, used alongside cognitive function testing and brain imaging (functional MRI, and positron emission tomography).

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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