



Autifony Therapeutics initiates Phase I study of AUT00206, a novel treatment approach for schizophrenia

London, UK - 24th November 2015 - Autofony Therapeutics Limited (“Autifony”), which is pioneering the development of novel pharmaceutical treatments for hearing loss and other serious brain disorders, today announced the start of Phase I clinical evaluation of its second Kv3 modulator, AUT00206. This is the first time that a Kv3 modulation mechanism has been applied to the treatment of schizophrenia. AUT00206 represents a novel class of Kv3 modulator which is being developed specifically for schizophrenia and related indications.

Kv3 ion channels are implicated in brain circuits which are believed to be dysfunctional in schizophrenia. This serious psychiatric illness has seen diminishing investment in research in recent years, and yet remains an area of high unmet need, with existing treatments often not delivering the desired efficacy and safety. The condition continues to impose a major social and economic burden.

The first-in-human Phase I study initiated by Autofony is a randomized, placebo controlled ascending dose group trial that is being conducted in the UK. It will investigate the safety, tolerability and pharmacokinetics of orally administered single and multiple doses of AUT00206 in healthy volunteers in fed and fasted states. A variety of biomarkers will be evaluated to explore pharmacodynamic activity.

The study is expected to complete in Q2 2016 and will be followed by two experimental medicine studies in human volunteers and patients. 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 Autofony now has a second programme in clinical trials. We believe that AUT00206 has the potential to be a real breakthrough in the treatment of schizophrenia. Preclinical results relevant to aspects of the disease strongly support the potential efficacy of AUT00206 in patients with schizophrenia, with fewer side effects than the current standard of care. We aim to progress this new drug as quickly as we can, to meet the high level of patient need.”

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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

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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.

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.

For more information, please contact:

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