Aclipse Therapeutics Announces $2.2 Million Grant from UK's Medical Research Council for Development of M102

Funding Supports Aclipse Therapeutics' and Sheffield Institute of Translational Neuroscience's Development of M102 in Amyotrophic Lateral Sclerosis

Radnor, PA -- January 26, 2021 – Aclipse Therapeutics ("Aclipse" or "the Company"), a private biopharmaceutical company, today announced that the Company and its collaborator, The Sheffield Institute for Translational Neuroscience (SITraN) at the University of Sheffield in the United Kingdom (UK), were awarded a drug development research grant of £1.6 million (approximately US $2.2 million) from the UK's Medical Research Council (MRC), one of the largest funders of medical research worldwide, to support the translational development of M102. M102 is Aclipse's drug candidate for the treatment of amyotrophic lateral sclerosis (ALS), also referred to as motor neuron disease (MND) or Lou Gehrig's disease.

M102 is a potentially disease-modifying drug candidate that has shown promise to impede ALS disease progression in a wide array of preclinical models. Currently, there is no cure for ALS and there are no effective treatments to halt or slow the progression of the disease.

"This development funding from MRC is wonderful news for ALS/MND patients who are in dire need of an effective therapy to address this life-threatening neurodegenerative disease," stated Professor Dame Pamela Shaw, M.D., Director of SITraN and a primary contributor to M102's development program. "Along with my SITraN colleagues, Dr. Richard Mead and Dr. Laura Ferraiuolo, we spearheaded the ALS/MND biology research that led to the development of M102, including the discovery of a potential precision medicine approach for M102 in ALS/MND, so we are very appreciative of MRC's funding support."

Aclipse is taking a multiple biological pathway, multiple disease mechanism approach to ALS. M102 activates the NRF2 (nuclear factor erythroid 2-related factor 2) and HSF1 (Heat shock factor 1) signaling pathways, which are recently understood to impact ALS pathophysiology. M102 is expected to be mechanistically superior to currently available drugs and may lead to significant slowing of disease progression in both familial and sporadic ALS.

The MRC grant will also support the development of patient stratification biomarkers that will be applied in the M102 clinical studies, potentially enabling a personalized medicine approach in ALS. The goal of the patient stratification biomarkers is to identify M102 drug responders versus non-responders in order to target M102 to those ALS patients most likely to benefit from the drug.

"We greatly appreciate the support from MRC for our novel and broad multi-disease patho-mechanism approach to treating ALS patients," said Raymond K. Houck, CEO

of Aclipse Therapeutics. "The MRC award, coupled with our recent FightMND grant award, accelerates M102's development into its first-in-human clinical studies and validates M102's biology and potential for a precision medicine approach for the treatment of ALS."

"The research funding from these programs will be key as they will support the completion of our investigational new drug (IND)-enabling work and the regulatory filings for first-in-human studies. Importantly, M102 may have applications in a wide array of conditions associated with impaired neuronal function such as Friedreich's ataxia, Huntington's disease and Parkinson's disease," added Mr. Houck.

About ALS/MND

Amyotrophic lateral sclerosis (ALS), also known as motor neuron disease (MND) or Lou Gehrig's disease, is a progressive neurodegenerative disease that affects motor neurons (nerve cells) in the brain and the spinal cord. Eventually, people with ALS lose the ability to initiate and control muscle movement, which often leads to total paralysis and death within two to five years of diagnosis. There is no cure and limited life-prolonging treatments for the disease. Based on U.S. population studies, approximately 5,600 people in the U.S. are diagnosed with ALS each year and as many as 25,000 Americans have the disease at any given time.

About Medical Research Counsel

The United Kingdom's Medical Research Counsel's mission is to improve human health through world-class medical research. To achieve this, MRC supports research across the biomedical spectrum, from fundamental lab-based science to clinical trials, and in all major disease areas. MRC works closely with the UK's National Health Service and the UK Health Departments to deliver its mission and give a high priority to research that is likely to make a real difference to clinical practice and the health of the population.

About the Sheffield Institute for Translational Neuroscience

The Sheffield Institute for Translational Neuroscience (SITraN) is an international center of excellence recognized for its ground-breaking work in the fight against motor neurone disease and other common neurodegenerative disorders. SITraN brings together 300 staff and research students in multi-disciplinary teams with state-of-the-art laboratories and equipment to study neurological illness. The center is unique in its design to unite clinicians and multidisciplinary teams of scientists to translate discoveries in basic neuroscience into benefits for patients. The SITraN teams have developed a robust portfolio of *in vitro* and *in vivo* models to facilitate our understanding of disease mechanisms and identify new targets for therapeutic intervention which can be tested in our BRC experimental medicine programs.

The work of SITraN is a major pillar of the University of Sheffield's cross-faculty Neuroscience Institute, one of four flagship research institutes launched in 2019 to tackle the biggest global challenges through pioneering real-world solutions and involving >120 principal investigators in the Faculties of Medicine, Science and Engineering.

About Aclipse Therapeutics
Aclipse Therapeutics develops novel and differentiated drugs to treat orphan diseases with significant unmet medical needs. Our lead drug candidate, M102, is in development for the treatment of ALS with potential use in other neurodegenerative diseases such as Friedreich's ataxia, Huntington's disease and Parkinson's disease. M102 targets multiple disease pathomechanisms and enables a precision medicine approach for the identification of patients who are most likely to benefit from the drug. Aclipse has a very experienced orphan drug management team and a clinical advisory board of the top ALS physicians in the world. For more information about Aclipse, visit the website at https://www.aclipsetherapeutics.com or email info@aclipsetherapeutics.com.

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