Aclipse Therapeutics Awarded AUD 1 Million Grant from FightMND

Aclipse Therapeutics was awarded a US$720,000 drug development grant from FightMND for the development of M102, a targeted therapy for Amyotrophic Lateral Sclerosis (ALS)

Radnor, PA, USA, September 29, 2020 – Aclipse Therapeutics, a private Pennsylvania biopharmaceutical company, was awarded an AUD 1 million (approximately US $720,000) drug development research grant from FightMND, the largest independent funder of ALS research in Australia. The grant will support the translational development of M102, a drug candidate for the treatment of amyotrophic lateral sclerosis (ALS), also known as motor neuron disease (MND) or Lou Gehrig's disease. M102 showed promise to stop and reverse ALS disease progression, as evidenced by data in preclinical models. Currently, there is no cure for ALS and no effective treatments to halt or reverse the progression of this devastating disease.

“We are very excited for ALS/MND patients, as FightMND is supporting our effort to advance this important therapy, which looks so promising in preclinical models, into clinical trials for our patients,” said Professor Dame Pamela Shaw MD, a primary contributor to M102’s development program. Professor Shaw is Professor of Neurology and the Director of the Sheffield Institute for Translational Neuroscience (SITraN) at the University of Sheffield (UK). Professor Shaw and her SITraN colleagues Dr. Richard Mead and Dr. Laura Ferraiuolo have led the key ALS/MND biology research and drug discovery of M102, as a fruition of their commitment and dedication to push the frontiers of science in ALS/MND for the benefit of patients over the last 20 years.

The FightMND grant will progress M102 into first-in-human trials. M102 is a disease-modifying drug candidate for ALS that activates NRF2 (nuclear factor erythroid 2-related factor 2) and HSF1 (Heat shock factor 1) signaling pathways, recently understood and important disease pathways in ALS. Aclipse is taking a multiple biological pathway, multiple disease mechanism approach to ALS. M102 is expected to be mechanistically superior to currently available drugs and may lead to significant slowing and reversal of disease progression in both familial and sporadic ALS. The FightMND grant will also support the development of patient stratification biomarkers that will be applied in the M102 clinical studies, and potentially enable a personalized medicine approach which is capable of identifying M102 responders vs. non-responders in the ALS patient population, and thus enriching M102’s clinical trial patient population.

FightMND is excited about the prospects of this potential treatment. ”M102 has shown promise as an effective new treatment for ALS/MND patients,” said Dr Bec Sheean, PhD, Research Director at FightMND. “We are delighted to be supporting the development of M102, which has the potential to be a disease-modifying drug

that improves on current standard-of-cares that only minimally delay disease progression for most MND patients."

"We are honored by the support from FightMND which shares our vision for a novel and broad multi-disease pathomechanism approach to treating ALS patients," said Raymond K. Houck, CEO of Aclipse Therapeutics. He continued, "The FightMND award also confirms M102's success to date and validates M102's potential for a precision medicine approach for the treatment of ALS."

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/MND 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 Australian population studies, more than 2,000 people are currently fighting ALS/MND in Australia: 60% male and 40% female. In 2013, ALS/MND accounted for 1 in 200 deaths in Australia. Based on U.S. population studies, approximately 5,600 people in the U.S. are diagnosed with ALS/MND each year and as many as 20,000 Americans have the disease at any given time. ALS/MND patients exist on all populated continents.

About FightMND

Founded in 2014, FightMND was established in Australia with the purpose of finding effective treatments and ultimately a cure for motor neuron disease (MND), also referred to as ALS or Lou Gehrig's Disease. FightMND, with its vision of a world without MND, is the largest independent funder of MND research in Australia. What FightMND has done since 2014, is be the voice and the guiding star for Australians who want to fight "The Beast". Integral to this vision is the determination to help facilitate the translation of the growing body of new knowledge about the disease into a cure for MND patients in Australia and abroad. For more information about FightMND, visit the website at https://fightmnd.org.au.

About Aclipse Therapeutics

Aclipse Therapeutics develops novel and highly 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 upside uses in Huntington's disease, Friedreich's ataxia, 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://aclipsetherapeutics.com or email info@aclipsetherapeutics.com.

Contact:
Raymond K. Houck
rhouck@aclipsetherapeutics.com
+1-412-606-7214