

Astrocyte Announces Initiation of First-In-Human Phase 1 Study of the Promising Stroke and Traumatic Brain Injury Therapeutic, AST-004

Groton, CT, June 15, 2022 – [Astrocyte Pharmaceuticals Inc.](#), a drug discovery and development company advancing novel cerebroprotective therapeutics for patients with brain injuries, announced that the Company's first-in-human Phase 1 clinical study initiated today with the dosing of a first subject with AST-004. The promising investigational therapeutic, AST-004, is being advanced as a potential acute treatment for stroke and traumatic brain injury (TBI) victims, and as a chronic treatment for neurodegenerative diseases like Alzheimer's. AST-004 has demonstrated a broad range of cerebroprotective efficacy when treating preclinical animal models, including preserving up to 45 percent more brain tissue in a non-human primate model of stroke, beyond that of reperfusion standard of care (study published in [Stroke](#)).

The primary objective of the first-in-human study, designated AST-004-1-02, is to evaluate the safety, tolerability and pharmacokinetic profile of AST-004 in healthy normal human subjects. The study will include up to 52 healthy participants aged 18 to 55 years and is funded in part by the Medical Technology Enterprise Consortium (MTEC) in cooperation with the U.S. Army Medical Research and Development Command (USAMRDC) of the United States of America Department of Defense.

"AST-004 demonstrated significant safety in the required regulatory animal studies, and we look forward to taking this next step of understanding its safety and pharmacokinetics in humans," explained Lisa Manna, Vice President of Clinical Development Operations at Astrocyte. "The study will assess AST-004 at multiple dose levels over the next six months at the clinical research site in Kistarcsa, near Budapest, Hungary."

"Initiating clinical studies is a major milestone as it reflects the many multi-disciplinary components of drug development such as preclinical pharmacology, efficacy, safety, pharmacokinetics, manufacturing, etc., have all been addressed to the satisfaction of regulatory authorities," said William Korinek, PhD, Chief Executive Officer, Astrocyte Pharmaceuticals.

Once AST-004 proves to be tolerated and have a favorable safety profile in the study, Astrocyte will progress to Phase 2 studies to evaluate its efficacy as a potential treatment approach for stroke and TBI patients. Dr. Korinek continued, "The AST-004 program continues its steady advancement, and we all look forward to additional data to understand its potential as a much needed treatment for the millions of people suffering from brain injuries."

About Astrocyte Pharmaceuticals Inc.

Astrocyte Pharmaceuticals Inc. is a privately held, clinical stage, drug discovery and development company dedicated to accelerating the recovery and well-being of brain injury patients. The company is committed to proving the cerebroprotective benefits of enhancing astrocyte function, and advancing breakthrough therapeutic agents for treating brain injury resulting from stroke, traumatic brain injury, concussion, and neurodegenerative disorders such as Alzheimer's disease. For more information, please visit us at [Astrocyte Pharmaceuticals Inc.](#)

About MTEC

The Medical Technology Enterprise Consortium is a biomedical technology consortium that is internationally-dispersed, collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement with the U.S. Army Medical Research and Development Command. The consortium focuses on the development of medical solutions that protect, treat,

and optimize the health and performance of U.S. military personnel and civilians. To find out more about MTEC, visit mtec-sc.org.

About U.S. Army Medical Research and Development Command

The U.S. Army Medical Research and Development Command is the Army's medical materiel developer, with responsibility for medical research, development, and acquisition. USAMRDC produces medical solutions for the battlefield with a focus on various areas of biomedical research, including military infectious diseases, combat casualty care, military operational medicine, medical chemical and biological defense. <https://mrdc.amedd.army.mil/>

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Forward Looking Statement

This press release contains certain forward-looking statements regarding, among other things, statements relating to goals, plans and projections regarding the company's financial position, results of operations, market position, product development and business strategy. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and the company undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.