



Astrocyte Pharmaceuticals Announces Milestones in the Fight Against Concussions: Launch of Phase 2 Clinical Trial and New \$3M NIH Grant

Groton, CT, June 17, 2025 – [Astrocyte Pharmaceuticals Inc.](#), a clinical-stage biotechnology company today announced two major milestones that could change the way we protect brains from the damage caused by concussions and repeat head impacts - one of the most pressing health concerns for athletes, military personnel, and families around the world.

The company has dosed the first patient in its Phase 2 clinical trial in athletes who suffer concussions during competitive play. This trial, conducted in Australian football players, will test whether AST-004 delivered shortly after a concussion can lessen the deleterious effects on the brain and speed recovery. In addition, the company has been awarded a highly coveted \$3M grant from the U.S. National Institutes of Health (NIH) to accelerate the development of an easy-to-use oral version of AST-004 in order to make the drug more readily available to patients and athletes.

A First-of-Its-Kind Drug for Concussion Protection

AST-004 is the first drug to show the ability in preclinical studies to protect the brain from the harmful effects of both mild and severe brain injuries. It is designed to preserve and protect brain function at the cellular level, limiting the short and long-term damage that can occur after head trauma.

“The world has searched for a way to reduce the brain damage caused by concussions - and now we’re seeing that possibility with AST-004,” said Theodore Liston, Ph.D., Vice President of Research at Astrocyte Pharmaceuticals. “In our early research, the drug consistently protected the brain in multiple models of concussion and head injury. With the support of the NIH and the launch of our Phase 2 clinical trial, we are now one step closer to getting this potential solution into the hands of those who need it most.”

First Human Phase 2 Trial Now Underway

Astrocyte has begun dosing athletes in its Phase 2 STARFAST (**S**tudy of **T**BI/concussions in **A**ustralian-**R**ules **F**ootballers receiving **AST**-004) trial, a first-of-its-kind study taking place in Adelaide, Australia, with players from the Adelaide Football League. Male and female athletes diagnosed with a sports-related concussion on game day will receive intravenous AST-004 or a placebo within 6 hours of the concussion.

This trial offers a unique opportunity to evaluate the effects of a single, well-characterized concussion in athletes who are not routinely exposed to repetitive sub-concussive impacts. The absence of these confounding factors makes it an optimal trial setting to assess whether AST-004 can mitigate acute injury effects and support a more complete and timely recovery. The study will measure safety, speed of recovery from symptoms, and biological markers in the blood that show brain response to injury.

Designed for the Real World - Sports Fields and Beyond

The new NIH grant will accelerate the development of the oral tablet formulation of AST-004 to make it available anywhere concussions happen - on the field, in the arena, at the roadside, or on the battlefield.

“There are millions of people around the world who suffer traumatic brain injuries and concussions each year - athletes, accident victims, and military personnel among them - yet there are no approved treatments,” said COL (Ret) Dallas C. Hack, M.D., M.P.H., Advisor to Astrocyte Pharmaceuticals and former Director of the U.S. Army Combat Casualty Care Research Program. “The ability to deliver a simple, safe, oral neuroprotective tablet at the time and place of injury could revolutionize how we treat concussions and dramatically alter short- and long-term outcomes for patients.”

A Turning Point in the Concussion Crisis

Every year, millions of people suffer concussions—in contact sports from youth leagues to the pros, but also in everyday settings like homes, playgrounds, and workplaces—where head injuries can happen in an instant. While many recover quickly, many face long-term effects: memory issues, mood changes, sleep problems, and a higher risk of conditions like depression and dementia later in life.

Yet, despite this growing crisis, no approved treatment exists to protect the brain from damage. Astrocyte Pharmaceuticals is aiming to change that.

“Parents, coaches, and communities have been waiting for a real breakthrough - something that doesn’t just diagnose or monitor concussions, but actually helps the brain recover,” said Dr. Liston. “That’s what we believe AST-004 can offer, and these milestones take us one step closer to making that vision a reality.”

About AST-004

AST-004 is an investigational drug in development for the treatment of stroke, traumatic brain injury (TBI), concussion, and Alzheimer's disease. The compound is a selective agonist of the adenosine A1 and A3 receptors and is designed to support brain recovery by enhancing mitochondrial energy metabolism in glial cells following injury. In preclinical models, AST-004 has been shown to reduce tissue damage, brain swelling, and biomarkers linked to neuroinflammation and cellular damage. Two Phase 1 clinical studies involving 80 healthy volunteers have successfully established the drug's safety and tolerability. Astrocyte Pharmaceuticals is advancing both intravenous and oral formulations to address the need for timely intervention in both hospital and non-hospital environments.

About Astrocyte Pharmaceuticals Inc.

Astrocyte Pharmaceuticals Inc. is a privately held, clinical-stage drug discovery and development company dedicated to advancing innovative therapies for brain injury and neurodegeneration. 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 on Astrocyte and the AST-004 program, please visit us at [Astrocyte Pharmaceuticals Inc.](#)

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. Research described in this press release is supported by the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health under Award Number R44NS137896. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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