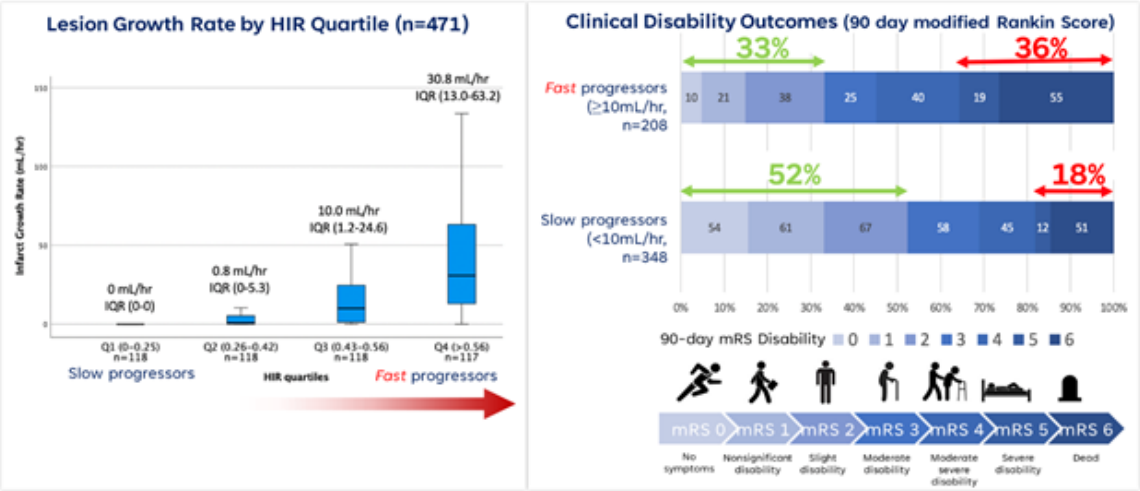
Astrocyte Pharmaceuticals 2024 Q1 Investor Update

To all Astrocyte Pharmaceuticals Shareholders and Noteholders,

We are very pleased to report that on March 7th, 2024, the U.S. Food and Drug Administration (FDA) cleared Astrocyte's Investigational New Drug (IND) Application (see Press Release here). The FDA's clearance of the IND application signifies the agency's acknowledgment of Astrocyte's commitment to rigorous scientific research and dedication to patient safety, and that the extensive preclinical and Phase 1 studies conducted have demonstrated the necessary efficacy and safety of AST-004 for its progression into clinical trials in the U.S. This important milestone provides a green light for our Phase 2 stroke trial, and paves the way for other U.S. studies of the IV formulation of AST-004 including TBI clinical trials.

The IND described our planned Phase 2 clinical trial in acute ischemic stroke patients called AST-004 Stroke Therapeutic Effect on Limiting Lesions Alongside Reperfusion or STELLAR. The innovative trial design builds upon the recent successful stroke clinical trial designs used by medical device companies where standard emergency department imaging identifies a more homogenous group of patients – a strategy that has successfully identified patients that can benefit from mechanical thrombectomy surgery. In STELLAR, we plan to take another leap forward in stroke trial design by further selecting the patients with the fastest progressing strokes, who even with a successful thrombectomy surgery, have substantial growth of their brain lesions and worse clinical outcomes (see Figure below). These patients have the greatest need for a cerebroprotective treatment and there is a greater opportunity for AST-004 to show its beneficial effects. For those of you interested in the additional science behind identifying fast and slow progressors using standard CT perfusion imaging and a "Hypoperfusion Intensity Ratio" (HIR), you can read the recent publication by Pierre Seners and Greg Albers at this link.

The Astrocyte team has been actively planning for the STELLAR study including identification of the initial clinical sites, identifying key vendors and partners, developing contracts and budgets, etc. The



STELLAR study will take about $15M and 2 years to complete. We are currently in discussions with multiple venture capital and strategic investors for a Series B financing round that would fund the STELLAR study. Given the substantial unmet need in stroke, the U.S. government also supports Phase 2 clinical trials in this area through an established clinical trial platform called StrokeNet. Astrocyte is also applying to StrokeNet with the possibility that the STELLAR study could be funded non-dilutively. On either path, we will not start the Phase 2 study until we have the funding committed to see the study through to completion.

We are also aggressively pursuing grant funding on multiple fronts and are encouraged by the receptivity we are receiving. We received an impressive Impact Score of 21 on a new $3.0M NIH SBIR grant from the National Institute of Neurological Diseases and Stroke (NINDS), which could be awarded to Astrocyte as early as April. There continues to be a lot of enthusiasm for an oral tablet version of AST-004 that could be widely used to treat concussions. As many of you excitedly saw in the earliest videos of our studies of mice exposed to repeated concussions and their ability or inability to climb down vertical poles, our neuroprotectant treatment has significant potential to help both acute and long-term complications from repetitive concussions. This new grant would provide additional funds to advance the oral formulation of AST-004 through an efficacy study in a pig TBI model and oral regulatory toxicology studies. We will issue a press release if/when the award is official. I also welcome you to follow the Astrocyte X/Twitter account (@AstrocytePharma) as well as LinkedIn accounts (Astrocyte and William Korinek).

Related to the potential of a new therapeutic to treat concussions, I was recently interviewed and featured in an article in Genetic Engineering & Biotechnology News (GEN). The article “Game On for Concussion Therapies” highlights Astrocyte Pharmaceuticals as one of the few promising companies in this space, and why there is reason for optimism given the significant increase in concussion awareness and advances in biomarkers and imaging for clinical trials! The full article can be found here.

If any shareholder/noteholder has difficulty accessing any of the links herein, please let me know.

Sincerely,

William S. Korinek
CEO, Astrocyte Pharmaceuticals Inc.

Visit the Astrocyte Website

Forward-Looking Statement: This newsletter update 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 newsletter is provided only as of the date of this update, 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.