



NEWS RELEASE

FDA Authorizes Initiation of a Phase 2 Trial Evaluating MultiStem® Cell Therapy in Trauma Patients

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CLEVELAND--(**BUSINESS WIRE**)--Athersys, Inc. (NASDAQ: ATHX) announced today that the U.S. Food and Drug Administration (FDA) has authorized an Investigational New Drug (IND) application to initiate a Phase 2 clinical trial evaluating Athersys' MultiStem® cell therapy for early treatment of traumatic injuries and the subsequent complications that result following severe trauma. Memorial Hermann-Texas Medical Center in Houston, Texas, one of the busiest Level 1 trauma centers in the United States, intends to conduct the trial. The study represents another important application of the company's MultiStem cell therapy in the critical care area, targeting the severe inflammatory responses associated with poor outcomes.

The objective of the clinical study is to evaluate the safety and effectiveness of MultiStem for the treatment of severely injured patients for the prevention and mitigation of complications that can result following severe traumatic injury. The proposed study will be a randomized, double-blind, placebo-controlled Phase 2 clinical trial estimated to enroll approximately 150 severely injured trauma patients following hospitalization, initial treatment and admission to the intensive care unit. These patients will be randomly assigned to receive MultiStem or placebo and both groups will receive the standard of care for their injuries.

A frequent complication following trauma is the occurrence of Systemic Inflammatory Response Syndrome (SIRS),

which can contribute to organ failure or other severe complications. MultiStem has shown promise in reducing the hyperinflammatory response that occurs in a range of situations, by upregulating key reparative mechanisms that may reduce complications and meaningfully improve patient recovery.

“We are appreciative of the FDA’s efforts and their timely feedback on the trauma IND, especially in light of all of the demands on the agency related to the COVID-19 pandemic. We are excited to collaborate with our colleagues at UTHealth and at Memorial Hermann to evaluate the potential for safety and efficacy of MultiStem cell therapy for treating patients that have sustained a severe traumatic injury,” stated Dr. Robert W. Mays, Vice President of Regenerative Medicine at Athersys. “Based on results from previous clinical experience evaluating MultiStem in other critical care indications, such as ischemic stroke and acute respiratory distress syndrome, as well as published studies in models of traumatic brain injury, spinal cord injury and other forms of trauma, we believe that the early administration of MultiStem cells can meaningfully mitigate, or lessen, the overt and often detrimental inflammatory cascade that results from the activation of the immune system following occurrence of traumatic injury.

“We believe that the timely administration of our MultiStem cell therapy, regardless of the nature of the acute injury, could lead to fewer complications, quicker recoveries and a better long-term outcome for patients,” added Dr. Mays. “The authorization of this study by the FDA is an important step forward that will help us better understand the potential of our technology in this clinical indication.”

As previously disclosed, this study is being supported under a grant awarded to UTHealth’s McGovern Medical School from the Medical Technology Enterprise Consortium (MTEC). Also, Memorial Hermann Foundation will provide additional funding. The study will be conducted under an Athersys IND, and Athersys will provide the investigational clinical product for the conduct of the trial, as well as regulatory and operational support. The trial protocol authorized by the FDA will be reviewed by the UTHealth Institutional Review Board to provide approval before trial initiation.

According to the Centers for Disease Control (CDC), trauma is the leading cause of death for individuals under the age of 45 and the third leading cause of death in the U.S., accounting for approximately 180,000 fatalities each year. It is also a leading cause of serious disability, especially among young people and members of the military that suffer trauma. According to independent research there are more than 31 million instances of non-fatal injury related hospitalizations annually.¹

¹Zonfrillo, M.R., Spicer, R.S., Lawrence, B.A. et al. Incidence and costs of injuries to children and adults in the United States. *Inj. Epidemiol.* **5**, 37 (2018). <https://doi.org/10.1186/s40621-018-0167-6>

MultiStem® cell therapy is a patented regenerative medicine product candidate in clinical development that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors in response to signals of inflammation and tissue damage. MultiStem therapy's potential for multidimensional therapeutic impact may distinguish it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. MultiStem represents a unique "off-the-shelf" stem cell product candidate that can be manufactured in a scalable manner, may be stored for years in frozen form, and is administered without tissue matching or the need for immune suppression. Based upon favorable efficacy data, its novel mechanisms of action, and favorable and consistent tolerability data in clinical studies, we believe that MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

About Athersys

Athersys is a biotechnology company engaged in the discovery and development of therapeutic product candidates designed to extend and enhance the quality of human life. The Company is developing its MultiStem® cell therapy product, a patented, adult-derived "off-the-shelf" stem cell product, initially for disease indications in the neurological, inflammatory and immune, cardiovascular and other critical care indications and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and a broad network of collaborations to further advance the MultiStem cell therapy toward commercialization. More information is available at www.athersys.com. Follow Athersys on Twitter at www.twitter.com/athersys.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. These forward-looking statements relate to, among other things, the expected timetable for development of our product candidates, our growth strategy, and our future financial performance, including our operations, economic performance, financial condition, prospects, and other future events. We have attempted to identify forward-looking statements by using such words as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "should," "suggest," "will," or other similar expressions. These forward-looking statements are only predictions and are largely based on our current expectations. A number of known and unknown risks, uncertainties, and other factors could affect the accuracy of these statements. Some of the more significant known risks that we face that could cause actual results to differ materially from those implied by forward-looking statements are the risks and uncertainties inherent in the process of discovering, developing, and commercializing products that are safe and effective for use as therapeutics, including the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues. These risks may cause our actual results, levels of activity, performance, or achievements to

differ materially from any future results, levels of activity, performance, or achievements expressed or implied by these forward-looking statements. Other important factors to consider in evaluating our forward-looking statements include: the success of the Phase 2 clinical trial evaluating MultiStem for early treatment of trauma to be conducted by the Memorial Hermann-Texas Medical Center, the success of our MACOVIA study; our ability to raise capital to fund our operations; our ability to successfully finalize and implement an alliance with BARDA, and the terms of any such alliance, including the amount, if any, of funding that we might receive; the timing and nature of results from MultiStem clinical trials, including our MASTERS-2 Phase 3 clinical trial and the HEALIOS K.K. (Healios) TREASURE and ONE-BRIDGE clinical trials in Japan; the impact on our business, results of operations and financial condition from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of infectious disease in the United States; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials of our product candidates; the possibility of delays, work stoppages or interruptions in manufacturing by third parties or us, such as due to material supply constraints or regulatory issues, which could negatively impact our trials and the trials of our collaborators; uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem cell therapy for the treatment of ischemic stroke, ARDS, acute myocardial infarction and trauma, and the prevention of graft-versus-host disease and other disease indications; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect and defend our intellectual property and related business operations, including the successful prosecution of our patent applications and enforcement of our patent rights, and operate our business in an environment of rapid technology and intellectual property development; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements and generate sales related to our technologies; the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in North America, Europe and Japan; our possible inability to execute our strategy due to changes in our industry or the economy generally; changes in productivity and reliability of suppliers; and the success of our competitors and the emergence of new competitors. You should not place undue reliance on forward-looking statements contained in this press release, and we undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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