NEWS RELEASE

UTHealth in Houston and Athersys Announce Commencement of Patient Enrollment in a Phase 2 Trial Evaluating MultiStem® Cell Therapy in Trauma

12/21/2020

Initiation of innovative clinical trial focused on reducing complications and enhancing patient recovery following trauma at Memorial Hermann-Texas Medical Center, a major Level 1 Trauma Center, with funding from MTEC

CLEVELAND--(BUSINESS WIRE)-- The University of Texas Health Science Center at Houston (UTHealth) and Athersys, Inc. (NASDAQ: ATHX) announced today that the first patient has been enrolled in a clinical study evaluating MultiStem® cell therapy for the potential early treatment of traumatic injuries and the subsequent complications that result. The MATRICS-1 (MultiStem Administration for Trauma Related Inflammation and Complications) study is being conducted at Memorial Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States.

The Phase II randomized, double-blinded, placebo-controlled study is being funded by a grant award from the Medical Technology Enterprise Consortium (MTEC) awarded to McGovern Medical School at UTHealth. In addition, the Memorial Hermann Foundation is providing additional funding. Athersys is the trial sponsor and is supplying the investigational clinical product for the conduct of the trial, as well as providing regulatory and operational

support. Dr. Charles S. Cox Jr., the George and Cynthia Mitchell Distinguished Chair in Neurosciences in the Department of Pediatric Surgery at McGovern Medical School at UTHealth and co-Director of the Red Duke Trauma Institute at Memorial Hermann-Texas Medical Center, is serving as the principal investigator.

The objective of the clinical study is to evaluate the safety and efficacy of MultiStem in the treatment of injured patients with severe hemorrhage for the prevention and mitigation of complications that can result following severe traumatic injury. The single-center trial will enroll up to 156 subjects. Subjects will be randomized and administered either placebo or MultiStem cellular therapy following admission to the intensive care unit and after initial resuscitation has concluded and stabilizing procedures have been performed to stop bleeding. All study subjects will also receive all standard of care treatments for their injuries.

“The use of this treatment strategy leverages a long legacy of investigation into the common mechanism of action of down-regulation of the inflammatory response to injury and how it mitigates complications of trauma,” commented Dr. Charles S. Cox Jr., Principal Investigator at UTHealth.

Although the causes of traumatic injury are diverse, evidence suggests the hyperinflammatory response following these injuries is similar to other causes of acute tissue injury, such as acute ischemic stroke, acute respiratory distress syndrome (ARDS), traumatic brain injury and spinal cord injury. Activation and mobilization of the peripheral immune system after an injury contributes to local secondary tissue damage. This immune activation may also result in systemic inflammatory response syndrome (SIRS), which can leave the patient susceptible to a range of complications, including secondary infections and organ failure conditions, that prevent or complicate recovery. Results of pre-clinical injury models and clinical data from human trials in other indications suggest early administration of MultiStem cells may reduce the inflammatory cascade that ensues after severe acute injury by reducing the number of inflammatory systemic immune cells in and around sites of injury, and by decreasing immune cell activation and the release of inflammatory cytokines in response to circulating products of tissue injury. The study will evaluate whether MultiStem’s modulation of these immune responses to traumatic injury can mitigate secondary tissue injury, organ failure states, and other complications that impede patient recovery following severe traumatic injury.

“Prior research conducted in collaboration with UTHealth suggests that administration of MultiStem following traumatic injury has the potential to downregulate the resultant hyperinflammatory cascade, and upregulate key repair mechanisms, improving overall recovery. Athersys is very appreciative of the support provided by MTEC and the Memorial Hermann Foundation for the conduct of this study and the tremendous amount of hard work and effort we've experienced in this collaboration with researchers, clinicians and staff at UTHealth,” commented Dr. Robert W. Mays, Vice President of Regenerative Medicine and Head of Neuroscience Programs at Athersys. “We are pleased to enroll the first patient and look forward to evaluating the effects of MultiStem cellular therapy on patient

outcomes. Severe trauma and the related downstream pathologies it can initiate is a clear unmet medical need of significance."

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 non-fatal injuries treated in U.S. hospitals each year.1

Athersys released an educational video today to provide additional information about this first-ever clinical study evaluating a cell therapy for treatment of traumatic injuries. The video features interviews with the clinical investigators that will be participating in the trial and other key personnel at Athersys. The video may be assessed from the Athersys website at **www.athersys.com** or at the following YouTube link: **https://youtu.be/qyxn2Z78aW0**

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**

About MultiStem ®

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 outcome data, its novel mechanisms of action, and favorable and consistent tolerability data in clinical studies, we believe that MultiStem therapy may provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

About MTEC

MTEC is a biomedical technology consortium collaborating with multiple government agencies under an agreement with the U.S. Army Medical and Materiel Command. The MTEC mission is to assist the Army's Medical Research and Materiel Command by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry.

About UTHealth

Established in 1972 by **The University of Texas System Board of Regents**, The University of Texas Health Science Center at Houston (UTHealth) is Houston's Health University and Texas' resource for health care education, innovation, scientific discovery and excellence in patient care. The most comprehensive academic health center in **the UT System** and the U.S. Gulf Coast region, UTHealth is home to **Jane and Robert Cizik School of Nursing**, **John P. and Kathrine G. McGovern Medical School**, and schools of **biomedical informatics**, **biomedical sciences**, **dentistry**, and **public health**. UTHealth includes the **UTHealth Harris County Psychiatric Center**, as well as the growing clinical practices **UT Physicians**, **UT Dentists**, and **UT Health Services**. The university's primary teaching hospitals are **Memorial Hermann-Texas Medical Center**, **Children's Memorial Hermann Hospital**, and **Harris Health Lyndon B. Johnson Hospital**. For more information, visit **www.uth.edu**.

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 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. The following risks and uncertainties 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: our ability to raise capital to fund our operations, including but not limited to, our ability to access our traditional financing sources on the same or reasonably similar terms as were available to us before the COVID-19 pandemic; the timing and nature of results from MultiStem clinical trials, including the MASTERS-2 Phase 3 clinical trial evaluating the administration of MultiStem for the treatment of ischemic stroke, and the Healios TREASURE and ONE-BRIDGE clinical trials in Japan evaluating the treatment in stroke and ARDS patients, respectively; the success of our MACOVIA clinical trial evaluating the administration of MultiStem for the treatment of COVID-19 induced ARDS, and the MATRICS-1 clinical trial being conducted with The University of Texas Health Science Center at Houston evaluating the treatment of patients with serious traumatic injuries; the impact of the COVID-19 pandemic on our ability to complete planned or ongoing clinical trials; the possibility that the COVID-19 pandemic could delay clinical site initiation, clinical trial enrollment, regulatory review and the potential receipt of regulatory approvals, payment of milestones under our license agreements and commercialization of one or more of our product candidates, if approved; the availability of product sufficient to meet commercial demand shortly following any approval, such as in the case of accelerated approval for the treatment of COVID-19 induced ARDS; 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 impact of the COVID-19 pandemic on the production capabilities of our contract manufacturing partners and our MultiStem trial supply chain; the possibility of delays, work stoppages or interruptions in manufacturing by third parties or us, such as due to material supply constraints, contamination, operational restrictions due to COVID-19 or other public health emergencies, labor constraints, regulatory issues or other factors 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 neurological, inflammatory and immune, cardiovascular and other critical care 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; the success of our competitors and the emergence of new competitors; and the risks mentioned elsewhere in our Annual

Report on Form 10-K for the year ended December 31, 2019 under Item 1A, “Risk Factors” and our other filings with the SEC. 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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