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UTHealth in Houston and Athersys Announce Funding for Clinical Trial using MultiStem® to Treat Trauma Patients

Pioneering Phase 2 study of cell therapy in Trauma to be conducted at major Level 1 Trauma Center in the U.S. with funding from MTEC Grant Award

CLEVELAND, April 23, 2018 (GLOBE NEWSWIRE) -- The University of Texas Health Science Center at Houston (UTHealth) and Athersys, Inc. (NASDAQ:ATHX) today announced plans to conduct a Phase 2 clinical trial evaluating Athersys' MultiStem® cell therapy for early treatment and prevention of complications after severe traumatic injury. This first-ever study of a cell therapy for treatment of a wide range of traumatic injuries will be conducted at Memorial Hermann-Texas Medical Center, one of the busiest Level 1 trauma centers in the United States.

In conjunction with this planned study, UTHealth reported that its McGovern Medical School has received a grant award from the Medical Technology Enterprise Consortium (MTEC) to support the study. The MTEC grant will provide $2.0 million in funding and the Memorial Hermann Foundation will provide an additional $1.5 million. Athersys will provide the investigational clinical product for the conduct of the trial, as well as regulatory and operational support, as its contribution to the trial. Dr. Charles S. Cox Jr., the George and Cynthia Mitchell Distinguished Chair in Neurosciences in the Department of Pediatric Surgery and co-Director of the Red Duke Trauma Institute at Memorial Hermann-Texas Medical Center, will serve as principal investigator. Co-investigators are Charles Wade, Ph.D. and John B. Holcomb, M.D. Memorial Hermann-Texas Medical Center is the teaching hospital of McGovern Medical School.

"Traumatic injury is the leading cause of death and disability among children and members of the military and also has a significant impact on the elderly," commented Dr. Cox. "Extensive clinical experience indicates that following serious trauma, an acute hyperinflammatory response is frequently triggered, resulting in Systemic Inflammatory Response Syndrome, a condition that can impair recovery and lead to additional complications. Our prior research demonstrates that administration of MultiStem following acute neurological injury can help improve recovery and reduce the occurrence or severity of certain complications, so we are excited about the clinical potential in this area."

The objective of the clinical study, as proposed by UTHealth in its grant application, is intended to evaluate the safety and effectiveness of MultiStem for the treatment of severely injured patients for the prevention and early treatment of complications after severe traumatic injury. The proposed study is anticipated to be a randomized, double-blind, placebo-controlled Phase 2 clinical trial estimated to enroll approximately 150 severely-injured trauma patients within hours of hospitalization who have survived initial treatment and are admitted to the intensive care unit. These patients will be randomly assigned to receive MultiStem or placebo and both groups will receive standard care for their injuries. The MTEC grant will provide funding for approximately 50% of the trial cost, with additional funding being provided by the Memorial Hermann Foundation. Athersys' support will include its cost of providing clinical product for the conduct of the trial and regulatory and operational support. The proposed Phase 2 clinical trial must still go through review and approval by the U.S. Food and Drug Administration (FDA), and therefore, the design is subject to additional input.

"Our preclinical data suggest that administration of MultiStem following injury mitigates the inflammatory cascade that ensues after traumatic injury that causes considerable damage to end organs, such as the lungs and kidneys," said Dr. Robert Mays, Vice President of Athersys and Head of the company's neuroscience programs. "We and the team at UTHealth also believe MultiStem has the potential to respond to signals of inflammation and tissue damage in various ways, including protection of injured cells, stimulation of new blood vessels, and the recruitment of other cell types to promote tissue repair and healing, as well as the reduction of complications following the initial injury."

"Now that the formal grant award has been awarded, we will continue our preparations with UTHealth to finalize the design and planning for the study and will subsequently present that information to the FDA and other relevant regulators for their review, consideration and input," concluded Dr. Mays.

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 that suffer trauma and members of the military. The CDC reports that, in the most recent year evaluated, 2013, there were more than 2.5 million emergency department visits for traumatic brain injury (TBI) and more than 282,000 hospitalizations. Over 5 million people in the U.S. are living with a TBI-related disability, and an estimated 80,000 - 90,000 people suffer a serious disability from TBI each year in the U.S. at an estimated cost of $37.8 billion, annually.
Source: https://www.cdc.gov/traumaticbraininjury/get_the_facts.html

Seventy-five percent of trauma-related deaths occur during the first three days after injury and are primarily due to uncontrolled bleeding and TBI. After three days, the remaining twenty-five percent of deaths occur at a low, but steady, rate and result from inflammation or immune complications, blood vessel damage, and poor clotting associated with the initial injury, shock and resuscitation. These inflammatory-related complications include acute kidney injury, acute respiratory distress syndrome, venous thromboembolic disease, multiple organ failure, neurological swelling and tissue death after TBI, as well as secondary infections.

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 schools of biomedical informatics, biomedical sciences, dentistry, nursing and public health and the John P. and Kathrine G. McGovern Medical School. UTHealth includes The University of Texas 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 MultiStem

MultiStem cell therapy is a patented regenerative medicine product that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors produced in response to signals of inflammation and tissue damage. MultiStem therapy's potential for multidimensional therapeutic impact distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The product represents a unique "off-the-shelf" stem cell product 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 its efficacy profile, its novel mechanisms of action, and a favorable and consistent safety profile demonstrated in both preclinical and clinical settings, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need. Athersys has forged strategic partnerships and a broad network of collaborations to develop MultiStem cell therapy for a variety of indications, with an initial focus in the neurological, cardiovascular and inflammatory and immune disorder areas.

About Athersys

Athersys is an international 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, cardiovascular, and inflammatory and immune disease areas, 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.

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 human therapeutics, such as the uncertainty regarding regulatory approval and market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of traumatic injury, ischemic stroke, acute myocardial infarction, spinal cord injury, trauma and acute respiratory distress syndrome and other disease indications, including graft-versus-host disease. 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 our collaboration with Healios and others, including our ability to reach milestones and receive milestone payments, and whether any products are successfully developed and sold so that we earn royalty payments; our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs; our ability to raise additional capital; results from our MultiStem clinical trials, including the Phase 2 clinical trial for early treatment and prevention of complications after severe traumatic injury, the MASTERS-2 Phase 3 clinical trial and the TREASURE trial in Japan; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials within the expected time frame or at all; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect our intellectual property portfolio; 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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Source: Athersys, Inc.