



NEWS RELEASE

Athersys and University Hospitals Cleveland Medical Center Announce Activation of the First Clinical Site for the MACOVIA Study, a Pivotal Phase 2/3 Study Evaluating MultiStem® Cell Therapy for COVID-19 Induced ARDS

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University Hospitals Cleveland Medical Center, a nationally ranked hospital, is ready to start screening patients

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATHX) and University Hospitals Cleveland Medical Center (UH Cleveland) announced today that UH Cleveland is now open as the first clinical site for the MACOVIA (MultiStem®Administration for COVID-19 Induced Acute Respiratory Distress Syndrome) trial.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20200501005131/en/>

On April 13, 2020, Athersys announced authorization from the U.S. Food and Drug Administration (FDA) to begin the MACOVIA study and began the process of clinical site initiation. UH Cleveland has completed trial start-up activities enabling commencement of patient screening and enrollment in this important randomized, double-blind, placebo-controlled study.

Dr. Frank Jacono, MD, Associate Professor of Medicine and Pulmonary and Critical Care Medicine Physician at UH Cleveland and Cleveland VA Medical Center will serve as principal investigator. UH Cleveland is now screening COVID-19 induced ARDS patients for inclusion in the trial.

Acute respiratory distress syndrome (ARDS) is the leading cause of death among COVID-19 infected patients, according to the World Health Organization and other recent clinical and epidemiological data. With the spread of COVID-19, there is an immediate need for therapies for the treatment of ARDS. The MACOVIA trial aims to confirm the safety and efficacy of MultiStem therapy as a treatment for patients with moderate to severe ARDS due to COVID-19.

UH Cleveland is a leading pulmonary critical care center in the United States and participated in Athersys' completed Phase 1/2 MUST-ARDS study. The data from the MUST-ARDS study met its primary endpoint of tolerability, and study subjects receiving MultiStem experienced less mortality, more ventilator-free days and more intensive care unit (ICU)-free days during the 28-day clinical evaluation period than the subjects who received placebo. Based on this promising data, the FDA granted Fast Track designation to the Company's ARDS program.

"Progressing from an FDA authorization to a site activation in just a few weeks is a tremendous achievement," commented Dr. Anthony Ting, PhD, Vice President of Regenerative Medicine and Head of Cardiopulmonary Programs at Athersys. "This was only possible due to the diligent effort performed by UH Cleveland and its dedicated staff.

"Based on our prior clinical results, we are optimistic that MultiStem may be able to provide meaningful therapeutic benefits to critically ill patients with COVID-19 induced ARDS," concluded Dr. Ting.

The primary efficacy endpoint for the MACOVIA study will be number of ventilator-free days through day 28 as compared to placebo, and the secondary objectives are to evaluate clinical parameters (e.g., time in the intensive care unit), pulmonary function, all-cause mortality, tolerability and quality of life (QoL) among survivors. The study is designed to enroll approximately 400 subjects and will be conducted at leading pulmonary critical care centers throughout the United States.

MultiStem therapy's potential for multidimensional therapeutic impact may distinguish it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. Since MultiStem is not virus- or pathogen-specific, it may have the potential to treat ARDS that develops from a variety of causes, including COVID-19, as well as other pathogen-induced or non-infectious causes of severe lung inflammation leading to ARDS.

The Company is in discussions with the Biomedical Advanced Research and Development Authority (BARDA) to

advance the development of MultiStem to treat patients with ARDS resulting from the COVID-19 epidemic and other potential pandemic outbreaks.

For more detailed information on the Company's ARDS program, please visit the [ARDS page on the Athersys website](#).

ARDS

ARDS is a serious respiratory condition characterized by widespread inflammation in the lungs. ARDS can be triggered by pneumonia, sepsis, trauma or other events and represents a major cause of morbidity and mortality in the critical care setting. ARDS is associated with a high mortality rate and significant long-term complications and disability among survivors. Among survivors, the condition prolongs ICU and hospital stays and often requires extended convalescence in the hospital and rehabilitation care settings. There are limited interventions and no effective drug treatments for ARDS. There is a large unmet need for a safe treatment that can reduce mortality and improve Quality of Life (QoL) for those surviving ARDS. Additionally, given the high healthcare resource burden associated with treatment of ARDS patients, a successful therapy could be expected to generate significant savings for the healthcare system by reducing days on a ventilator and in the ICU, or in the setting of a widespread high pathogenicity respiratory virus pandemic, make those resources more rapidly available to other patients.

About COVID-19

COVID-19 is the infectious disease caused by the most recently discovered human coronavirus, SARS-CoV-2. This new disease was unknown before the outbreak was first discovered in Wuhan, China, in December 2019. Older people and those with underlying medical problems such as high blood pressure, heart problems or diabetes, are more likely to develop serious illness, but even young, previously healthy people can suffer severe disease and complications such as ARDS. Data are still emerging, but recently published case series suggest mortality rates among COVID-19 patients who develop ARDS may be 50% to 70%, or perhaps even higher in some environments.

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 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 University Hospitals

Founded in 1866, University Hospitals serves the needs of patients through an integrated network of 18 hospitals, more than 50 health centers and outpatient facilities, and 200 physician offices in 16 counties throughout northern Ohio. The system's flagship academic medical center, University Hospitals Cleveland Medical Center, located in Cleveland's University Circle, is affiliated with Case Western Reserve University School of Medicine. The main campus also includes University Hospitals Rainbow Babies & Children's Hospital, ranked among the top children's hospitals in the nation; University Hospitals MacDonald Women's Hospital, Ohio's only hospital for women; University Hospitals Harrington Heart & Vascular Institute, a high-volume national referral center for complex cardiovascular procedures; and University Hospitals Seidman Cancer Center, part of the NCI-designated Case Comprehensive Cancer Center. UH is home to some of the most prestigious clinical and research programs in the nation, including cancer, pediatrics, women's health, orthopedics, radiology, neuroscience, cardiology and cardiovascular surgery, digestive health, transplantation, and urology. UH Cleveland Medical Center is perennially among the highest performers in national ranking surveys, including "America's Best Hospitals" from U.S. News & World Report. UH is also home to Harrington Discovery Institute at University Hospitals – part of The Harrington Project for Discovery & Development. UH is one of the largest employers in Northeast Ohio with 28,000 physicians and employees. Advancing the Science of Health and the Art of Compassion is UH's vision for benefitting its patients into the future, and the organization's unwavering mission is To Heal. To Teach. To Discover. Follow UH on LinkedIn, Facebook @UniversityHospitals and Twitter @UHhospitals. For more information, visit UHhospitals.org.

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 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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