NEWS RELEASE

Athersys Announces Commencement of Patient Enrollment in the MACOVIA Study, a Pivotal Phase 2/3 Trial Evaluating MultiStem® Cell Therapy for COVID-19 Induced ARDS

5/5/2020

Rapid advancement of clinical program for the treatment of ARDS based on prior clinical data reflecting favorable tolerability data and meaningful benefits on mortality, ventilator-free days and ICU-days

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (NASDAQ: ATHX) announced today that the first patients have been enrolled in Athersys' pivotal Phase 2/3 study entitled, MultiStem® Administration for COVID-19 Induced Acute Respiratory Distress Syndrome (MACOVIA). The patients were enrolled at University Hospital's Cleveland Medical Center (UH Cleveland), a leading pulmonary critical care center and a nationally ranked hospital. Medpace, a leading contract research organization (CRO) based in Cincinnati, Ohio, is serving as the CRO for this study.

With the continued spread of COVID-19 and the resulting cases of severe respiratory distress among those patients that become seriously ill, there is an immediate need for therapies. The Company's program evaluating administration of MultiStem for the treatment of ARDS was recently granted Fast Track designation by the FDA based on the promising Phase 1/2 data from its previously completed MUST-ARDS trial. Currently there are no FDA-approved medicines for the treatment of ARDS.

“New treatment options are needed for patients with severe COVID-19 induced ARDS. However, it is important that potential therapies are scientifically evaluated as part of a clinical trial,” commented Site Principal Investigator, Dr. Frank Jacono, MD, Associate Professor of Medicine and a Pulmonary and Critical Care Medicine Physician at University Hospitals Cleveland and the Cleveland VA Medical Center. “We are pleased to partner with Athersys to advance this important clinical study to evaluate treatment of critically ill patients with COVID-19-induced ARDS,” concluded Dr. Jacono.

Other MACOVIA clinical investigators at UH Cleveland include Dr. Rana Hejal, MD, Pulmonary and Critical Care Medicine Specialist and Medical Intensive Care Unit (MICU) Director, Dr. Catalina V. Teba, MD and Dr. Olivia Giddings, MD, PhD, both Pulmonary and Critical Care Medicine Specialists.

This study is designed to enroll approximately 400 subjects. The first patients were enrolled into the first cohort of the study, which is an open-label, single active treatment arm to evaluate the safety of MultiStem administered at two dose levels to study subjects with moderate to severe ARDS associated with COVID-19. If the treatment is well tolerated in this first cohort, the study is designed to further evaluate MultiStem efficacy, safety and tolerability in this patient population using a robustly powered, double-blind, randomized and placebo-controlled trial protocol.

The primary efficacy endpoint for the MACOVIA study will compare the number of ventilator-free days through day 28 among MultiStem and placebo treatment groups. Secondary objectives of the study are to evaluate 60-day all-cause mortality, time in the intensive care unit, pulmonary function, tolerability and quality of life (QoL) among survivors through one-year of follow-up.

MultiStem cell 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 expedite the advancement 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**.

About 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 reduced 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 Medpace

Medpace is a scientifically driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages regulatory and therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-

infective. Headquartered in Cincinnati, Ohio, Medpace employs approximately 3,600 people across 37 countries.

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.

View source version on **businesswire.com**: **https://www.businesswire.com/news/home/20200505005315/en/**

Ivor Macleod
Chief Financial Officer
Tel: (216) 431-9900
ir@athersys.com

Karen Hunady
Director of Corporate Communications & Investor Relations
Tel: (216) 431-9900
khunady@athersys.com

David Schull
Russo Partners, LLC
Tel: (212) 845-4271 or (858) 717-2310
David.schull@russopartnersllc.com

Source: Athersys, Inc.