NEWS RELEASE

FDA Grants RMAT Designation to MultiStem Cell Therapy for the Treatment of Acute Respiratory Distress Syndrome

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ARDS program well-positioned for an expedited path to commercialization with RMAT and Fast Track designation

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc., a leading regenerative medicine company in late-stage clinical development, announced today that MultiStem® cell therapy was granted Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA) for the acute respiratory distress syndrome (ARDS) program. The RMAT designation enables sponsors to work closely with the FDA and receive their guidance on expediting development of their products, including providing advice on generating the evidence needed to support approval in an efficient manner. RMAT designation invites the Company to schedule a Type B meeting with the FDA to discuss multidisciplinary strategic development plans, including expediting manufacturing development for commercialization to support priority review and/or accelerated approval.

The RMAT designation for ARDS is granted in addition to the previously obtained Fast Track designation awarded in May 2019. MultiStem is the only cell therapy program for ARDS that has both Fast Track and RMAT designation from the FDA. Also, the Company's partner in Japan, HEALIOS K.K. (Healios), is anticipating the completion of

enrollment in its orphan designated ARDS clinical trial (ONE-BRIDGE) by the end of this year.

“We are very pleased to have received our second MultiStem program RMAT designation,” commented Dr. Manal Morsy, Senior Vice President and Head of Global Regulatory Affairs. “We have enjoyed close and highly efficient interactions with the FDA on our RMAT-designated ischemic stroke program and are looking forward to similar benefits and advantages of this Expedited Program for Regenerative Medicine Therapies for Serious Conditions RMAT designation, this time for ARDS.”

The Company has conducted extensive research exploring MultiStem cell therapy for the treatment of pulmonary distress and recently completed an exploratory Phase 1/2 clinical trial for the treatment of ARDS (the MUST-ARDS study). Participants in the randomized, double-blind, placebo-controlled MUST-ARDS study were evaluated through 28 days for the primary clinical assessment and further assessed through a one-year follow-up period. Patients that received MultiStem experienced lower mortality, fewer days on a ventilator, fewer days in the intensive care unit, and reported a higher quality of life after one-year post-ARDS than patients that received the placebo.

Following the encouraging results of the MUST-ARDS study, the Company began planning for the next stage of clinical evaluation. In response to the COVID-19 pandemic, the Company expedited the initiation of a pivotal Phase 2/3 clinical trial evaluating MultiStem cell therapy for the treatment of COVID-19 induced ARDS (the MACOVIA study), which is now enrolling patients. The primary efficacy endpoint for the randomized, double-blind, placebo-controlled 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 QoL among survivors through one-year of follow-up. MultiStem 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 because it is not virus- or pathogen-specific. For more detailed information on the Company’s ARDS program, please visit the **ARDS page on the Athersys website**.

About RMAT

Established under the 21st Century Cures Act, RMAT designation is a dedicated program designed to expedite the development and review processes for promising regenerative medicine therapies, which are defined as a cell therapy, a therapeutic tissue engineering product, or a human cell and tissue product. An investigational drug is eligible for RMAT designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease; and preliminary clinical evidence indicates that the therapy has the potential to address unmet medical needs for that disease. Advantages of the RMAT designation include all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with FDA that may be used to discuss potential surrogate or intermediate endpoints to support accelerated approval.

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 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 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 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; 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 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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