



NEWS RELEASE

Athersys Reports Interim Analysis Results of MASTERS-2 Clinical Study with MultiStem in Ischemic Stroke, Signs Memorandum of Understanding (MOU) for Global ARDS License with Healios

10/10/2023

The MOU includes \$1.5M to \$4.5M near term payments plus up to \$150M in milestones

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (Nasdaq: ATHX), a cell therapy and regenerative medicine company developing MultiStem® (invimestrocel) for critical care indications, announces that the independent data safety monitoring board (DSMB) has completed a pre-planned interim analysis of the Company's ongoing Phase 3 MASTERS-2 pivotal clinical trial evaluating MultiStem® for the treatment of acute moderate-to-severe ischemic stroke, and concluded that the current sample size of 300 patients is insufficiently powered to achieve the primary endpoint of mRS Shift analysis at Day 365. There were no safety issues identified. Because the sample size required to achieve statistical significance is considerably larger, Athersys intends to conduct additional data analysis with independent statisticians. The Company plans to pause enrollment of new patients while this analysis is being conducted.

Separately, Athersys announces that it has entered into a Memorandum of Understanding (MOU) granting HEALIOS K.K. (Healios) global rights to develop and commercialize MultiStem for the treatment of acute respiratory distress

syndrome (ARDS). Under the terms of the MOU, Athersys will receive between \$1.5M and \$4.5M in near term payments with up to \$150 million in potential development and sales milestones and additional royalties. Athersys also expects to receive revenue from the sale of existing clinical doses of MultiStem-- which were manufactured in accordance with its 3D bioreactor process that earlier this year received approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA)--for Healios to use in its Phase 3 clinical trial in ARDS.

Athersys intends to continue exploring available strategic options. However, in the event Athersys is unable in the near-term to enter into a strategic transaction or obtain adequate financing, it expects to have to file for protection under the bankruptcy laws to allow the Company to conduct an orderly wind down of operations. In the interim, the Company is streamlining its operations to preserve its capital and cash resources.

"I'd like to thank the many patients, clinicians and vendors that have supported this pivotal phase 3 trial since its start in 2018. We're disappointed with the results of the unblinded interim analysis indicating a large sample size adjustment would be required to achieve our primary endpoint. We intend to conduct further analysis to better understand these results. The new MOU we've signed with Healios for ARDS provides the company near-term capital and the potential for meaningful milestone payments as we continue to pursue various strategic solutions," said Dan Camardo, Chief Executive Officer of Athersys.

About MultiStem ®

MultiStem® (invimestrocel) cell therapy is a patented regenerative medicine product 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 distinguishes it from traditional biopharmaceutical therapies focused on a single mechanism of benefit. The therapy 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 tolerability demonstrated 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. Athersys 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, 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 MultiStem cell therapy toward commercialization. Investors and others should note that we may post information about Athersys on our website at www.athersys.com and/or on our accounts on Twitter, Facebook, LinkedIn or other social media platforms. It is possible that the postings could include information deemed to be material information. Therefore, we encourage investors, the media and others interested in Athersys to review the information we post on our website at www.athersys.com and on our social media accounts. Follow Athersys on Twitter at www.twitter.com/athersys. Information that we may post about Athersys on our website and/or on our accounts on Twitter, Facebook, LinkedIn or other social media platforms may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. You should not place undue reliance on forward-looking statements contained on our website and/or on our accounts on Twitter, Facebook, LinkedIn or other social media platforms, and we undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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 anticipated use of grant funding, the anticipated completion of any study or studies funded using grant funding, the anticipated outcome of any study or studies funded using grant funding, 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. In addition, 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 risk that we will be unable to raise capital to fund our operations in the near term and long term, including our ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to us or at all, and to continue as a going concern. 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 in the near term and long term, including our ability to obtain funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, on terms acceptable to us or at all, and to continue as a going concern; whether we receive a grant from BARDA; our collaborators' ability and willingness to continue to fulfill their obligations under the terms of our collaboration agreements and generate sales related to our technologies; the

possibility of unfavorable results from ongoing and additional clinical trials involving MultiStem; the risk that positive results in a clinical trial may not be replicated in subsequent or confirmatory trials or success in an early stage clinical trial may not be predictive of results in later stage or large scale clinical trials; our ability to successfully license our SIFU technology; our ability to regain and maintain compliance with the Nasdaq continued listing requirements; 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; our ability to meet milestones and earn royalties under our collaboration agreements, including the success of our collaboration with Healios; 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 availability of product sufficient to meet our clinical needs and potential commercial demand following any approval; 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, contamination, operational restrictions due to COVID-19 or other public health emergencies, labor constraints, regulatory issues or other factors that 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; the success of our efforts to enter into new strategic partnerships and advance our programs; 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 ability to execute our strategic review process; 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, 2022 under Item 1A, "Risk Factors" and our other filings with the U.S. Securities and Exchange Commission. You should not place undue reliance on forward-looking statements, 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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