



NEWS RELEASE

Athersys Reports That Its Partner, HEALIOS K.K., Provides Updates on MultiStem® Clinical Programs in Japan

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- Last 365-day patient follow-up visit was completed on schedule for the Phase 2/3 TREASURE study for ischemic stroke
- Topline results expected to be announced in May

CLEVELAND--(BUSINESS WIRE)-- Athersys, Inc. (Nasdaq: ATHX) announced today that its partner, HEALIOS K.K. (Healios), has provided updates on its two clinical programs evaluating MultiStem® (invimestrocel, HLCM051) cell therapy, for which Healios has a license and is responsible for the development and commercialization of MultiStem for ischemic stroke and acute respiratory distress syndrome (ARDS) in Japan on an exclusive basis.

Healios reported that the last patient in its Phase 2/3 TREASURE study, evaluating MultiStem for the treatment of ischemic stroke, completed the 365-day follow-up visit. Additionally, Healios updated its progress in its discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) regarding its MultiStem ARDS program and results from its ONE-BRIDGE study.

The last patient follow-up visit represents an important milestone in the TREASURE study, as it completes the collection of all patient data and enables the final validation of the data, analyses, and preparation of results by its contract research organization for unblinding and topline disclosures. Healios anticipates that it will receive the final topline results and make disclosures in May 2022.

TREASURE is a randomized, double-blind, placebo-controlled study in Japan evaluating the administration of MultiStem treatment within 18-36 hours after an ischemic stroke in over 200 patients with moderate to moderate-severe strokes. The TREASURE study, like its global counterpart, Athersys' MASTERS-2 study, was designed based on the promising results from Athersys' MASTERS-1 study for stroke patients treated with MultiStem therapy within 36 hours of the stroke. In the MASTERS-1 study, stroke patients receiving early MultiStem treatment had better outcomes than placebo patients at 90 days following treatment, and further improved outcomes at one year. Athersys expects that the TREASURE 90-day and one-year results would be strong indicators of the potential results from Athersys' MASTERS-2 study.

"We are happy to report that Healios has completed the last patient follow-up visit and will soon disclose topline results from this important study," commented Dr. John Harrington, Chief Scientific Officer of Athersys. "Furthermore, we are optimistic about the results and look forward to evaluating the data and better understanding its implications for our MASTERS-2 study."

In addition, Healios has announced feedback received from the PMDA after recent consultation meetings to obtain guidance and advice pertaining to its application for MultiStem approval for ARDS, an orphan regenerative medicine program, on the basis of its Phase 2 ONE-BRIDGE study. The ONE-BRIDGE clinical trial was designed as a 30-patient, open label study, and demonstrated promising impact from MultiStem treatment on ventilator free days (VFD) and mortality. While the PMDA did not disagree with the efficacy and safety conclusions of the ONE-BRIDGE study, the PMDA advised Healios that additional supporting data is necessary for application for approval of MultiStem treatment for the ARDS indication. As a result of the guidance from the PMDA, Healios does not currently plan to apply for approval in Q2 2022. Healios will continue discussions with PMDA and work toward early application, and while it is undetermined at this time, it is expected that the application for approval is unlikely to take place in the current fiscal year.

Athersys is currently conducting its Phase 2/3 MACOVIA study, evaluating MultiStem treatment for ARDS patients, which includes patients diagnosed with ARDS due to COVID-19. The Company recently announced FDA approval to use product manufactured with its next generation bioreactor-based platform in the MACOVIA study.

Athersys continues to believe that MultiStem treatment has potential to have a substantial, positive impact on ARDS patients based on favorable data from its own double-blind, placebo-controlled Phase 1/2 MUST-ARDS study and strong supporting data from the Healios ONE-BRIDGE study. For example, on a combined basis, MultiStem-treated

subjects had, on average, 5.5 more VFD in the first 28-days following diagnosis than non-treated subjects (with a p-value = 0.07) and, on a median basis, 10.5 more VFD during the 28-day period. Further, there was also strong evidence of a favorable impact from treatment on mortality and quality of life metrics. Athersys plans to work closely with Healios to build the supporting data necessary to apply for approval in Japan, including exploring the possibility of using certain MACOVIA clinical data.

“We congratulate Healios for achieving this important milestone in the TREASURE study and look forward to the topline results in May,” said Mr. Dan Camardo, Chief Executive Officer of Athersys. “We also look forward to continuing our work with Healios to advance the ARDS program in Japan. This is a very exciting time for both companies, and we remain committed to our partnership with Healios to work toward bringing MultiStem to market in Japan and eventually to the U.S. and other regions.”

Please refer to the following Healios disclosures for more information: <https://ssl4.eir-parts.net/doc/4593/tdnet/2103272/00.pdf> and <https://ssl4.eir-parts.net/doc/4593/tdnet/2103271/00.pdf>

About Ischemic Stroke

Stroke represents an area where the clinical need is particularly significant, since it is a leading cause of death and serious disability worldwide, with a substantially impaired quality of life for many stroke victims. Currently, there are nearly 17 million people who suffer a stroke globally and more than two million stroke victims each year in the United States, Europe and Japan, combined. Ischemic strokes, which represent the most common form of stroke, are caused by a blockage of blood flow in the brain that cuts off the supply of oxygen and nutrients and can result in long-term or permanent disability due to neurological damage. Unfortunately, current therapeutic options for ischemic stroke victims are limited, since the only available treatments, administration of the clot dissolving agent tPA, or “thrombolytic,” or surgical intervention to remove the clot, must be conducted within several hours of the occurrence of the stroke. As a consequence of this limited time window, only a small percentage of stroke victims are treated with the currently available therapy—most simply receive supportive or “palliative” care. The long-term costs of stroke are substantial, with many patients requiring extended hospitalization, extended physical therapy or rehabilitation (for those patients that are capable of entering such programs), and many require long-term institutional or family care.

About ARDS

Acute respiratory distress syndrome (ARDS) is a serious immunological and inflammatory condition characterized by widespread inflammation in the lungs. ARDS can be triggered by COVID-19, pneumonia, sepsis, trauma or other events and represents a major cause of morbidity and mortality in the critical care setting. It has significant implications, as it prolongs intensive care unit (ICU) and hospital stays and requires convalescence in the hospital

and rehabilitation. There are limited interventions and no effective drug treatments for ARDS, making it an area of high unmet clinical need with high treatment costs. Given these high treatment costs, a successful cell therapy could be expected to generate significant savings for the healthcare system by reducing days on a ventilator and in the ICU and importantly, could reduce mortality and improve quality of life for those suffering from the condition.

About MultiStem®

MultiStem® cell therapy (invimestrocel) 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 outcome data, its novel mechanisms of action, and favorable and consistent tolerability data in clinical studies, we believe that MultiStem therapy may 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 MultiStem cell therapy toward commercialization. Investors and others should note that we may post information about the Company 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 the Company 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 the Company 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.

About Healios

Healios is Japan's leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan, where it has established a proprietary, gene-edited "universal donor" induced pluripotent stem cell (iPSC) line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need. Healios' lead iPSC-derived cell therapy candidate, HLCN061, is a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene-editing. Its near-term pipeline includes the somatic stem cell product HLCM051 (MultiStem®), which is currently being evaluated in Japan in Phase 2/3 and Phase 2 trials in ischemic stroke and acute respiratory distress syndrome (ARDS), respectively. Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593).

<https://www.healios.co.jp/en>.

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, statements regarding the potential benefits of our MultiStem product candidate; anticipated results of clinical trials involving our MultiStem product candidate; 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: 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 raise capital to fund our operations, including but not limited to, our ability to access our traditional financing sources and to continue as a going concern; 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 clinical trial in Japan evaluating the treatment in stroke, including the timing of the release of data by Healios from its clinical trials; the ability of Healios to apply for approval for MultiStem for the treatment of ARDS in Japan, which could be delayed by, among other things, the regulatory process with the PMDA; 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 or globally; 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, 2021 under Item 1A, “Risk Factors” and our other filings with the SEC. Although we currently believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee our future results, levels of activity or performance. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law. You are advised, however, to consult any further disclosures we make on related subjects in our reports on Forms 10-Q, 8-K and 10-K furnished to the SEC. You should understand that it is not possible to predict or identify all risk factors. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.

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