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Athersys' MultiStem® Promotes Recovery After Acute Spinal Cord Injury in Preclinical Study

Peer-Reviewed Study in Nature's Scientific Reports Demonstrates Stem Cell Therapy Promotes Improved Walking and Urinary Function

CLEVELAND, Nov. 19, 2015 (GLOBE NEWSWIRE) -- Athersys, Inc. (Athersys) (NASDAQ:ATHX) announced today that multipotent adult progenitor cells (MAPC®), used in Athersys' MultiStem® cell therapy currently in clinical development, are effective in improving the health of animals after acute rodent spinal cord injury. Intravenous administration of MAPC one day after injury prevented loss of spinal cord tissue resulting in significant improvement of walking function and urinary control. These exciting new findings were published today in a peer-reviewed article in Nature's *Scientific Reports* <http://www.nature.com/articles/srep16795>.

Nervous system injuries, including spinal cord injury, traumatic brain injury and stroke, result in excessive inflammation, which is toxic to surrounding healthy tissue. Therefore, modulation of the immune system has long been an acute therapeutic target for neurological injury and disease. In this study, a single dose of MAPC was administered to rodents one day following severe spinal cord injury. Injured animals that received treatment demonstrated significantly improved voluntary control of bladder function, walking ability and preservation of at-risk nervous tissue. Further, the study defines a key mechanism of action of MAPC treatment, which occurs through the modulation of neuro-inflammation, including a significant reduction of inflammatory cell accumulation within the injury.

"The results described in this important publication build on and are consistent with previously completed preclinical and clinical studies in acute neurological injuries, including the Phase 2 study in ischemic stroke," commented Dr. Robert Mays, Senior Vice President and Head of Neurosciences at Athersys. "The data show consistent mechanisms of action for MultiStem in targeting and modulating the immune system, and enhancing recovery and repair. Importantly, these results support our belief that the intravenous administration of MultiStem may lead to durable and substantial benefits in humans, which is consistent with our clinical observations in other programs. Athersys commends the outstanding work of Jerry Silver's lab at Case Western Reserve University School of Medicine, and we look forward to additional progress that will enable the clinical translation of this therapy for spinal cord injured patients."

The authors examined the biodistribution of MAPC cells following injury and observed that large numbers homed to the spleen, a primary reservoir for inflammatory cells in the body. These findings are consistent with other evidence suggesting that a primary effect of this cell therapy occurs through modulation of systemic inflammation via splenic interactions. Close examination of the spinal cord injury site, peripheral blood, and the spleen identified meaningful changes in inflammatory pathways after MAPC administration.

This study builds on a decade-long collaboration between Athersys and Case Western Reserve University School of Medicine, led by Professor Jerry Silver, Ph.D., of the Department of Neurosciences. Dr. Silver stated, "Spinal cord injury continues to devastate the lives of many. Although a great deal of research needs to be undertaken in the field, we are pleased to see that MultiStem therapy is efficacious in promoting the recovery of locomotor and urinary functions in rodents. I am especially excited with this therapy as it circumvents the need for directed therapeutic delivery into the vulnerable, recently injured spinal cord. We look forward to working with Athersys and other leaders in the science community to fill this critical treatment gap."

This study provides additional strong support for the use of MultiStem as a therapeutic for human acute spinal cord injury with the overall goals of improving quality of life, motor control, and reducing long-term patient care costs. According to the Christopher & Dana Reeve Foundation, the cost of spinal cord injury is estimated to be from \$500,000 to more than \$3 million per patient, depending on severity. Donna Sullivan, Project Director for Unite 2 Fight Paralysis, commented, "We are excited by these results in rodent models of spinal cord injury, which demonstrate that MultiStem therapy may have the potential to enhance patients' lives by improving critical locomotor and bladder functions. Improvement in these functions will reduce the many life threatening secondary conditions, which are a result of the loss of these functions. Unite 2 Fight Paralysis looks forward to additional opportunities to partner with this team of scientists to bring this cell therapy to the bedside."

The research was coordinated by Dr. Sarah Busch and other Athersys scientists in collaboration with Dr. Jerry Silver, graduate student Marc DePaul, and other scientists from Case Western Reserve University School of Medicine, with grant support from The Ohio Third Frontier.

About MultiStem

MultiStem cell therapy is a patented regenerative medicine product that has shown the ability to promote tissue repair and healing in a variety of ways, such as through the production of therapeutic factors produced 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 product 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 safety profile demonstrated in both preclinical and clinical settings, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need. Athersys has forged strategic partnerships and a broad network of collaborations to develop MultiStem cell therapy for a variety of indications, with an initial focus in the neurological, cardiovascular and inflammatory and immune disorder areas.

About Athersys, Inc.

Athersys is an international 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, cardiovascular and inflammatory and immune disease areas, and has several ongoing clinical trials evaluating this potential regenerative medicine product. Athersys has forged strategic partnerships and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions to further develop its platform and products. More information is available at www.athersys.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 human therapeutics, such as the uncertainty regarding market acceptance of our product candidates and our ability to generate revenues, including MultiStem for the treatment of ischemic stroke, acute myocardial infarction, spinal cord injury and acute respiratory distress syndrome and other disease indications, including graft-versus-host disease. 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: our possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; the success of our collaborations, including our ability to reach milestones and receive milestone payments, and whether any products are successfully developed and sold so that we earn royalty payments; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; the success of our efforts to enter into new strategic partnerships or collaborations and advance our programs; our ability to raise additional capital; results from our MultiStem clinical trials; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials; changes in external market factors; changes in our industry's overall performance; changes in our business strategy; our ability to protect our intellectual property portfolio; 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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