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MultiStem(R) Cell Therapy May Overcome Major Challenges in Organ Transplantations

Promising New Approach to Stem Cell Therapy Advanced Into Clinical Trial at Leading Transplant Center

CLEVELAND, July 9, 2013 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) announced today that an international team of researchers has published study results in ***STEM CELLS Translational Medicine*** demonstrating that Multipotent Adult Progenitor Cells (MAPC™) increase the long-term survival of organ transplants in instances when the cell donor is not related to the patient or the organ donor, and also appear to alleviate the need for long-term immune suppression. The preclinical research, conducted using a standard heart transplant model, also demonstrated that the transplanted organ retained its immunologically privileged state during a subsequent transplantation procedure into a naïve recipient, illustrating the durability of the effect. The risk of rejection and the requirement for long-term immunosuppression are key challenges in donor organ transplantations, which could be addressed by administering the clinical MAPC product, MultiStem®, to transplant patients.

Athersys and the team at Regensburg have moved quickly to advance these findings into a clinical setting by obtaining authorization to conduct a clinical trial in liver transplant patients. Athersys has established several clinical programs in the inflammatory and immune area, including a completed Phase 1 study in the U.S. in hematopoietic transplant support, and is working in collaboration with Pfizer Inc. to complete an ongoing Phase 2 clinical trial in Inflammatory Bowel Disease. Athersys also has clinical programs in other areas, including an ongoing Phase 2 clinical trial to treat ischemic stroke patients.

"The immunological attributes of MAPCs make them a promising candidate for providing immunomodulatory support after organ transplantation," explained Marc Dahlke, M.D., Ph.D., a lead investigator in the study that appears in the current issue of *STEM CELLS Translational Medicine*. "In contrast to other cell types, MAPCs can be expanded in a manner that makes them amenable to large scale production, potentially making them an optimal choice for routine clinical use — especially in the so-called 'third party' scenario in which the cell donor is unrelated to the organ donor and recipient."

Most other cell therapy trials have used cells of either the organ donor or recipient. However, the preparation of such customized cell therapies is costly and challenging, since it must be done one patient at a time, and can lead to inconsistent results. With this in mind, the Dahlke team decided to explore the potential of a third-party-derived MAPC to act as a universal donor. This is the approach being taken clinically by Athersys in several other disease areas. They conducted their study on rats that received allogeneic heart grafts. One group of animals was treated after the transplantation with a combination of MAPCs and short-term administration of low-dose immunosuppressive drug. Another group was administered immunosuppressive drugs only, while a third group received no extra treatment at all. Only grafts from those animals receiving MAPC and short-term immunosuppressive therapy survived long term.

When long-term accepted heart grafts were recovered from the MAPC-treated animals and re-transplanted into yet another group of untreated animals (genetically identical to the first group of recipients), they engrafted successfully, without triggering rejection, even when no immune suppressive drug was administered. This finding demonstrates that an immunoprivileged state, or "regional immune tolerance," had been induced in the graft that can be carried into another untreated animal.

"In the group with no treatment, the grafts were rejected in less than two weeks; short-term immunosuppressive drug treatments kept them intact just a few days longer. However, rats given a combination of short-term immunosuppressive treatment and MAPCs exhibited a high percentage of prolonged survival, even after treatment with immune suppressive drugs was stopped, indicating a promising pathway for clinical immunotherapy," Dr. Dahlke commented. "If transplantation procedures could be conducted with lower requirements for immunosuppressive drugs, this could provide a substantial benefit to patients, and could also broaden the impact of transplantation medicine, helping many more patients and providing a better quality of life."

The research effort was led by a team of renowned transplant specialists at the University Hospital in Regensburg, Germany, working in collaboration with scientists from Athersys and the U.S. National Center for Regenerative Medicine, located in Ohio. Other members of the team included scientists from Erasmus University Medical Center in Rotterdam and Case Western Reserve University in Cleveland.

"This pioneering work demonstrates that MultiStem may have broad relevance in the field of clinical transplantation by

addressing several of the major hurdles that represent real challenges for patients," said Dr. Gil Van Bokkelen, Chairman and CEO at Athersys. "We're excited by this research, because it supports the broader relevance of MultiStem in the treatment of inflammatory and immune conditions, such as our ongoing Phase 2 clinical trial with Pfizer in Inflammatory Bowel Disease. We think MultiStem could have a significant impact in transplantation medicine, as well as related areas, and are excited about the initiation of the clinical trial at Regensburg in liver transplant patients."

The full article, "Heart grafts tolerized through third-party Multipotent Adult Progenitor Cells can be re-transplanted to secondary hosts with no immunosuppression," can be accessed at: http://www.stemcellstm.com/content.

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 multiple therapeutic factors produced in response to signals of inflammation and tissue damage. MultiStem has demonstrated therapeutic potential for the treatment of inflammatory and immune disorders, neurological conditions, and cardiovascular disease, as well as other areas, and 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. The product is extensively characterized for safety, consistency and potency. Athersys has forged strategic partnerships with Pfizer Inc. to develop MultiStem for inflammatory bowel disease and is also being evaluated as a novel therapeutic approach for certain neurological and cardiovascular conditions.

About Athersys

Athersys is a clinical stage 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" regenerative medicine therapy for disease indications in the cardiovascular, neurological, inflammatory and immune disease areas. The Company currently has several clinical stage programs involving MultiStem, including for treating inflammatory bowel disease, ischemic stroke, damage caused by myocardial infarction, and for the prevention of graft versus host disease. Athersys has also developed a diverse portfolio that includes other technologies and product development opportunities, and has forged strategic partnerships and collaborations with leading pharmaceutical and biotechnology companies, as well as world-renowned research institutions in the United States and Europe to further develop its platform and products. More information is available at www.athersys.com.

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 inflammatory bowel disease, acute myocardial infarction, stroke and other disease indications, including traumatic brain injury, and the prevention of 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 ability to raise additional capital; final results from our MultiStem clinical trials including for ischemic stroke; 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 realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; our ability to meet milestones under our collaboration agreements; our collaborators' ability to continue to fulfill their obligations under the terms of our collaboration agreements; 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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