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Athersys Announces New Patents in Japan for Stem Cell and Regenerative Medicine Technology

Key Patents Provide Support for MultiStem(R) Product Development and Business Strategy in Japan

CLEVELAND, Jan. 9, 2014 (GLOBE NEWSWIRE) -- Athersys, Inc. (Nasdaq:ATHX) today announced that it has been granted patents from the Japan Patent Office for several inventions involving its proprietary cell therapy technology. Patent No. 5398941 covers non-embryonic, multipotent stem cells, such as MultiStem, and applies to all therapeutic applications. Patent No. 5399709 covers the use of such stem cell therapies for the treatment of immune dysfunctions, such as graft-versus-host disease (GvHD), and inflammatory diseases and autoimmune disorders (e.g., inflammatory bowel disease (IBD)). And, the third patent covers the treatment of brain injuries, such as stroke and traumatic brain injury, with such multipotent stem cells.

"These patents will provide the Company important protection for its cell therapy products in Japan and their use in a number of significant disease areas, including stroke, IBD, GvHD and others," said William Lehmann, President and Chief Operating Officer at Athersys. "Additionally, we are encouraged by regulatory events in Japan, which have created an accelerated development path for stem cell therapies. Recognizing these developments, Japan's sizable pharmaceutical market, and the expected growth in demand for more effective treatments of age- and lifestyle-related diseases and conditions, we consider Japan a high priority market for the development of MultiStem cell therapy product candidates."

Recently, Japan's parliament enacted new legislation to promote the safe and accelerated development of treatments using stem cells. The new regenerative medicine law and revised pharmaceutical affairs law define products containing stem cells as regenerative medicine products and allow for the conditional approval of such products if safety has been confirmed in clinical trials, even if their efficacy has not been fully demonstrated. The legislation creates a new, faster pathway for cell therapy product approval, and offers the potential to enable more rapid entry into the Japanese market. The Ministry of Health, Labour and Welfare has been directed to develop and adopt new rules and procedures to implement this legislation.

"Japan is showing tremendous international leadership in an area that it recognizes has the potential to effectively address areas of serious unmet medical need. The new framework is intended to benefit patients through the rapid development and approval of innovative and cost-effective stem cell therapies," commented Gil Van Bokkelen, Chairman and Chief Executive Officer of Athersys. "We are actively evaluating the potential for accelerated development of MultiStem cells in a number of therapeutic areas in Japan, and will seek to establish strategic collaborations to assist in the rapid development of products that will help Japanese patients."

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. It 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 a strategic partnership with Pfizer Inc. to develop MultiStem for treating inflammatory bowel disease, while independently evaluating it as a novel therapeutic approach for indications in the neurological, cardiovascular and transplant support areas, as well as other potential opportunities.

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" stem cell product platform 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.

The Athersys, Inc. logo is available at: http://www.globenewswire.com/newsroom/prs/?pkgid=4548

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 lysosomal storage disorders, 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; the timing of the results from Pfizer's Phase II clinical study involving MultiStem cell therapy to ulcerative colitis patients; final 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 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; the success of our efforts to enter into new strategic partnerships and advance our programs, including, without limitation, in 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; 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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