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Athersys Updates on Development Strategy in Japan

CLEVELAND, Oct. 21, 2015 (GLOBE NEWSWIRE) -- Athersys, Inc. ("Athersys") (NASDAQ:ATHX) announced today that Athersys and Chugai Pharmaceutical Co., Ltd. ("Chugai") have ended the license agreement between them for the exclusive development and commercialization of MultiStem® cell therapy for ischemic stroke in Japan. The parties were unable to reach an agreement on the modification of the financial terms of the agreement and on development strategy in Japan, in light of the results from the Phase 2 clinical study. All rights will revert to Athersys, and Athersys will retain the $10 million license fee paid by Chugai.

"Athersys and Chugai have great respect for one another, and share common values and a desire to develop and advance innovative therapies that have the potential to address substantial unmet medical needs," said Gil Van Bokkelen, Chairman and CEO of Athersys. "Ultimately, however, we were not able to find common ground regarding the best way to advance the ischemic stroke program working together, and we agreed that a termination would better enable Athersys to pursue its envisioned development approach."

Additionally, Athersys announced today that it has entered into a letter of intent with a Japanese company, accompanied by a good faith payment, to collaborate on the development and commercialization of MultiStem cell therapy for several indications in Japan, including ischemic stroke. Athersys is also in ongoing discussions with several companies about collaborating on the development and commercialization of MultiStem therapy in multiple areas, including ischemic stroke outside of Japan. Partnership remains a key part of Athersys' development strategy for MultiStem cell therapy.

Athersys remains enthusiastic about the development of MultiStem cell therapy in Japan. Recent approvals by the Japanese Pharmaceutical and Medical Devices Agency ("PMDA") under PMDA's new framework for accelerated development and commercialization of regenerative medicine therapies have confirmed the significance and availability of this new regulatory pathway to product approval, as well as the potential for contingent or even full approval with evidence of safety and data that suggests a clinical benefit in patients. "We believe that this new regulatory framework represents an important opportunity for MultiStem in the treatment of stroke and potentially other indications with high unmet need in Japan," commented Gil Van Bokkelen. "We have already presented our initial thoughts regarding the next phase of clinical development in Japan to the PMDA and have received encouraging feedback. We intend to pursue this pathway, work with Japanese partners where it makes sense, and look forward to updating everyone on our further progress."

About Ischemic Stroke

Stroke represents an area where the clinical need is particularly significant, since it represents a leading cause of death and significantly lowers quality of life for stroke patients. Currently, there are more than 15 million people that suffer a stroke globally, and more than two million stroke victims per 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 tissue loss and neurological damage, as well as long-term or permanent disability. Unfortunately, current therapeutic options for ischemic stroke victims are limited, as the only available therapy, a clot dissolving agent, or "thrombolytic," must be administered 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 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 cardiovascular, neurological, 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, 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, including the ability to enter into a definitive arrangement with the Japanese company for the development and commercialization of MultiStem cell therapy in Japan; 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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Source: Athersys, Inc.