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## **Athersys and Healios Announce Binding Letter of Intent to Expand MultiStem® Collaboration**

***Equity investment and binding letter of intent outlines expansion of Japan collaboration, including exclusive option for China development and commercialization***

***Benefits to include consolidated development of MultiStem indications in key Asian markets, provision of capital to Athersys for support of Phase 3 stroke study in North America, Europe***

CLEVELAND, March 13, 2018 (GLOBE NEWSWIRE) -- Athersys, Inc. (NASDAQ:ATHX) and HEALIOS K.K. ("Healios") announced today their intent to significantly expand their existing development and commercialization collaboration. As part of this expansion, Healios is making an approximate \$21 million equity investment at \$1.76 per share, will deposit \$10 million into escrow, and has entered into a letter of intent ("LOI") with Athersys to expand Healios' license to develop MultiStem® products for indications to include acute respiratory distress syndrome ("ARDS"), trauma in Japan and the use of MultiStem products in conjunction with organ bud technology and certain ophthalmological indications globally. Healios will also obtain an exclusive option to a license to develop and commercialize MultiStem products for ischemic stroke, ARDS and trauma in China, and obtain certain other rights. In exchange, Athersys would receive committed payments of \$35 million, as well as additional payments, including milestones and royalties. If Healios elects to exercise its option for a license in China, Healios would pay Athersys license fees, milestone payments and escalating royalties or profit-sharing for each indication.

In addition to its purchase of 12 million shares of common stock as part of its equity investment, Healios will receive a warrant that will give it the right, but not the obligation, to purchase additional shares of Athersys common stock up until September 1, 2020, subject to certain conditions and limitations, including a fixed exercise price with respect to certain of the warrant shares and a floating exercise price with respect to certain of the warrant shares that will be based on the greater of a minimum floor price and the then current market price, as well as a cap on the total number of shares Healios may own during the term of the warrant of 19.9% of Athersys' outstanding common stock. The warrant becomes exercisable if the collaboration expansion becomes effective.

The parties will work under the terms of the LOI to execute the agreements necessary to expand the existing collaboration, which is expected to be completed by April 30, 2018. As part of Healios' equity investment, Dr. Hardy Kagimoto, CEO of Healios, would be nominated for election to the Athersys Board of Directors at the next scheduled annual stockholders' meeting in June 2018.

In conjunction with the execution of the LOI and in addition to the equity investment, under the binding portion of the LOI, Healios will fund \$10 million into escrow. That amount will be paid to Athersys as either (1) the initial portion of the \$35 million in payments associated with the execution of the expansion agreements described above or (2) if such agreements described above are not executed on or before April 30, 2018, payment for expanding the scope of the current Japan license to include ARDS, ophthalmological indications and organ bud. The expansion of the collaboration between these existing partners is expected to benefit both parties through the consolidation of development and commercialization of important indications in the key Asian markets of Japan and China, and provides Athersys with capital to support its development activities, including its pivotal Phase 3 stroke study, MASTERS-2, in North America and Europe.

In conjunction with the collaboration expansion, and in addition to the approximate \$21 million equity investment and the \$10 million payment from escrow, Healios will pay an additional \$25 million in license/option fees, in installments. This \$25 million payment obligation cannot be terminated or otherwise abrogated over time, and though the payments are non-refundable, they can be used as credit against certain milestone payments due under the MultiStem license for stroke, ARDS or trauma in Japan.

"This is a significant opportunity for both Healios and Athersys," commented Dr. Gil Van Bokkelen, CEO of Athersys. "It provides for a meaningful expansion of the existing partnership, providing a much broader scope of rights for Healios, while

providing Athersys with substantial additional capital and a committed development partner in key areas."

"Through this meaningful expansion of our relationship with Athersys, we aim to leverage MultiStem to accelerate the practical application of regenerative medicine across a variety of unmet patient needs. We are delighted to be working even more closely with them in this regard," commented Dr. Hardy Kagimoto, CEO of Healios.

### **Stroke Program Update: TREASURE and MASTER-2 Ischemic Stroke Studies**

In Japan, Healios is conducting the TREASURE study, evaluating MultiStem therapy for ischemic stroke, and has received a priority review designation under Sakigake from Japan's Pharmaceutical and Medical Devices Agency. The TREASURE study, designed to enroll 220 subjects, is being conducted at hospitals in Japan that have extensive experience at providing care for stroke victims. Based on the experience from our B01-02 study, subjects enrolled in the trial receive either a single dose of MultiStem or placebo, administered within 18 to 36 hours of the occurrence of the stroke, in addition to standard of care. The study is evaluating patient recovery through approximately 90 days following initial treatment based on Excellent Outcome (mRS less than or equal to 1, NIHSS less than or equal to 1, and Barthel Index less than or equal to 95) and other neurological, functional and clinical endpoints.

Athersys is preparing to launch in the North America and Europe its Phase 3, registration study, entitled MASTERS-2, which has received special protocol assessment, Fast Track and RMAT designations from the FDA and a Final Scientific Advice positive opinion from the European Medicines Agency. The MASTERS-2 clinical trial will be a randomized, double-blind, placebo-controlled clinical trial designed to enroll 300 patients who have suffered moderate to moderate-severe ischemic stroke. The enrolled subjects will receive either a single intravenous dose of MultiStem cell therapy or placebo, administered within 18 to 36 hours of the occurrence of the stroke, in addition to the standard of care. The primary endpoint will evaluate disability using modified Rankin Scale (mRS) scores at three months, comparing the distribution, or the "shift", between the MultiStem treatment and placebo groups. The mRS shift analysis considers disability across the full spectrum, enabling recognition of large and small improvements in disability and differences in mortality and other serious outcomes, among strokes of different severities. The study will also assess Excellent Outcome at three months and one year as key secondary endpoints. Additionally, the study will consider other measures of functional recovery, biomarker data and clinical outcomes, including hospitalization, mortality and life-threatening adverse events, and post-stroke complications such as infection.

### **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 that suffer a stroke globally and, on average, someone in the United States has a stroke every 40 seconds. 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 therapies, administration of the clot dissolving agent tPA, or "thrombolytic," or surgical intervention using mechanical reperfusion 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 MultiStem®**

MultiStem® cell therapy is a patented regenerative medicine product 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 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 therapy 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 clinical studies, MultiStem therapy could provide a meaningful benefit to patients, including those suffering from serious diseases and conditions with unmet medical need.

### **About Athersys**

Athersys is an international biotechnology company engaged in the development of therapeutic products 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 a broad network of collaborations to further advance MultiStem cell therapy toward commercialization. More information is available at [www.athersys.com](http://www.athersys.com). Follow Athersys on Twitter at [www.twitter.com/athersys](http://www.twitter.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 regulatory approval and 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 ability to work with Healios under the terms of the letter of intent described elsewhere in the press release to successfully negotiate the terms of and execute, the agreements necessary to expand the existing collaboration; the success of our collaboration with Healios and others, 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 possible inability to realize commercially valuable discoveries in our collaborations with pharmaceutical and other biotechnology companies; 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, including the MASTERS-2 Phase 3 clinical trial and the TREASURE trial in Japan; the possibility of delays in, adverse results of, and excessive costs of the development process; our ability to successfully initiate and complete clinical trials within the expected time frame or at all; 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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### Contact:

William (B.J.) Lehmann  
President and Chief Operating Officer  
Tel: (216) 431-9900  
[bjlehmann@athersys.com](mailto:bjlehmann@athersys.com)

Karen Hunady  
Corporate Communications & Investor Relations  
Tel: (216) 431-9900  
[khunady@athersys.com](mailto:khunady@athersys.com)

David Schull  
Russo Partners, LLC  
Tel: (212) 845-4271 or (858) 717-2310  
[David.schull@russopartnersllc.com](mailto:David.schull@russopartnersllc.com)

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