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Athersys Announces Positive Interim Results From Ongoing Phase I Study of MultiStem(R) for Hematopoietic Stem Cell Transplant Support and Graft-Versus-Host Disease

SAFETY AND REDUCTION IN GVHD OBSERVED IN STEM CELL TRIAL

CLEVELAND, OH – Athersys, Inc. (Nasdaq:ATHX) today announced positive interim results from an ongoing Phase I clinical trial of MultiStem®, its cell therapy product, administered to individuals undergoing allogeneic hematopoietic stem cell transplants (HSCTs) for the treatment of leukemia and related conditions. The study results for the single infusion arm of this Phase I clinical trial demonstrate that MultiStem was well tolerated at all dose levels and also suggest that the product may reduce the incidence of severe Graft-versus-Host Disease (GvHD), a potentially life-threatening complication of such transplants, as compared to historical clinical experience. The repeated dose administration arm of the clinical trial is ongoing and enrollment is expected to be completed in 2011. In 2010, Athersys was granted orphan drug designation by the U. S. Food and Drug Administration for MultiStem for the prevention of GvHD.

Interim data highlights from the single dose administration arm of the study included:

- No observations of infusional or product-related toxicities over 30 days following treatment, and no product-related serious adverse events (SAEs) over 100 days following treatment;

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- No primary or secondary HSCT-graft failure through day 100;
- Overall, a low cumulative incidence of acute GvHD over the 100-day observation period for all subjects enrolled (28% grade II-IV, 6% grade III-IV), which compares favorably with expectations for this patient population based on historical experience;
- In the high dose group, no cases of grade III-IV GvHD, and only one case of grade II GvHD, which was subsequently resolved with treatment; and
- Other clinical parameters, such as infection and survival, were in line with or better than expectations for this patient population based on historical data.

Dr. Richard Maziarz, M.D., co-principal investigator of this study and Medical Director, Adult Stem Cell Transplantation Program and Center for Hematologic Malignancies at the Oregon Health & Science University Knight Cancer Institute, commented, "GvHD remains a major obstacle for treatment of patients with blood associated cancers. Continued exploration of novel approaches to prophylaxis and treatment of GvHD is necessary as this complication remains one of the major limiting factors to achieving wider application of donor blood and marrow transplantation. The results obtained to date, within this Phase 1 clinical trial, certainly would justify further study in this arena." "We are very encouraged by the interim results from this Phase I trial," said Gil Van Bokkelen, CEO of Athersys, Inc. "These data continue to build our understanding of the safety profile for MultiStem and also suggest promising potential for the treatment of the side effects associated with donor-derived hematopoietic stem cell transplants, especially GvHD. We believe this also suggests the potential for using MultiStem for treating other immunological disorders, including complications associated with solid organ transplantation, and conditions like inflammatory bowel disease, both of which remain areas of significant clinical need."

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Safety

During the first 48 hours following MultiStem administration, patients were assessed for infusion-related toxicity and other acute adverse events. The primary endpoint for the study was the determination of the maximum tolerated dose, as determined by a continual reassessment methodology. Regimen-related toxicities and infusion-related allergic toxicities through 30 days after MultiStem administration were also monitored. Additionally, patients were evaluated for adverse events and infections through 100 days following the HSCT.

The administration of MultiStem was found to be well tolerated at each of the three dose levels evaluated in the single dose administration arm. There were no dose limiting toxicities associated with the administration of MultiStem. Immediately following dosing, there were no clinically significant changes to vital signs or evidence of allergic reaction associated with MultiStem administration. Over the 30-day observation period, no infusional toxicities or clinically significant adverse events related to MultiStem occurred.

MultiStem had a favorable safety profile over the 100-day period following the HSCT. There were no primary or secondary graft failures. There were no SAEs characterized as related to the administration of MultiStem. Overall, there were two relapses and two deaths among the 18 patients treated over the observation period, which was in line with or lower than what would be expected for this high risk patient population.

HSCT Support

While the primary objective of this Phase I clinical trial is to evaluate the safety of MultiStem administered to HSCT recipients, additional data regarding secondary endpoints, GvHD incidence, infection and survival, are being collected and evaluated for safety and evidence of efficacy signals to facilitate planning for subsequent clinical

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studies. Specifically, following MultiStem administration, patients were assessed weekly by the investigator for GvHD (and regimen-related toxicities), and information regarding infections and adverse events was collected as they occurred, through day 100. The clinical trial is being conducted at transplant centers in the United States and Europe, including the Oregon Health & Science University, University Hospitals Case Medical Center, Texas Transplant Institute, University of Pennsylvania, Mayo Clinic Hospital Arizona, and UZ Leuven.

Based on the preliminary data, over the 100-day observation period for all 18 patients in the single dose administration arm, five patients developed grade II acute GvHD and one progressed to grade III acute GvHD, resulting in a cumulative incidence of acute GvHD for all subjects enrolled of 28% for grade II-IV and 6% for grade III-IV, using Kaplan-Meier estimates censored for study withdrawal due to relapse and death. In the high dose group (10 million cells per kilogram body weight) with nine patients, just one patient developed grade II acute GvHD, which was resolved with treatment over the 100-day follow-up period, and no patients developed grade III-IV GvHD. The 100-day cumulative incidence of acute GvHD for the high dose group (11% grade III-IV and 0% grade III-IV, n=9) compares favorably with the expectations for this patient population based on historical experience and scientific literature. For the low and medium dose groups with nine patients combined, the 100-day cumulative incidence of acute GvHD was 44% for grade II-IV and 11% grade III-IV, which is comparable to or better than historical rates. With respect to the data, it is important to note that this was an uncontrolled study and eleven of the 18 patients in this single dose administration arm were enrolled at a single site.

Importantly, the incidences of infections and mortality over the observation period appear to be in line with or better than what would be expected for this high risk patient population. Overall, the Kaplan-Meier estimate of relapse-free survival at 100 days

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was 88%, compared to an expectation of around 70% based on published results from previously published clinical studies using comparable treatment approaches and patient groups. There were one relapse and one death in each of the combined low and medium dose groups (n=9) and the high dose group (n=9) over the 100-day period.

About the Disease Condition and Study Design

Leukemia and certain related conditions are often treated with radiation and chemotherapy to eliminate cancerous or diseased cells, but this process also severely compromises the native blood forming and immune system in the patient, leaving them susceptible to infection and other complications. To address this, a patient will often receive an allogeneic HSCT, whereby following radiation and chemotherapy treatment a patient's blood stem cells are replaced with a transplant of hematopoietic stem cells obtained from the bone marrow or peripheral blood of a healthy donor. Donors may be related or unrelated to the patient, but are matched according to tissue type in order to minimize the potential for GvHD, where donor immune cells transplanted with the donor HSCT attack tissue and organs of the patient. Following the transplant, the patient will often remain hospitalized in specialized units until successful engraftment provides a sufficiently functional immune system.

According to the Center for International Blood and Marrow Transplant Research, there are approximately 25,000 allogeneic HSCTs performed annually globally, although this number is projected to increase due to the anticipated growth in incidence of hematologic malignancies associated with an aging population. While this treatment approach can be an effective medical therapy for these types of cancer, it is often associated with substantial tissue damage and side effects, such as GvHD. GvHD is a frequent complication associated with allogeneic HSCT, affecting approximately half or more of transplant recipients, and advanced GvHD can be severely debilitating or

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even fatal. Several factors affect a patient's likelihood of having GvHD and GvHD severity, including the treatment protocol used, the degree of tissue match between donor and recipient (with lower GvHD rates and severity associated with related donors and better tissue matches), and the condition of the patient among other factors. In addition, higher GvHD rates are typically observed in patients receiving peripheral blood stem cell (PBSC) transplants, as compared to patients receiving bone marrow-derived stem cell transplants.

The Phase I clinical trial is an open label, multi-center trial evaluating the safety and maximum tolerated dose of single or repeated dose administration of MultiStem following an allogeneic HSCT in patients being treated for leukemia or related cancers of the blood or immune system. The interim results were obtained from the single dose administration arm of the study, in which enrolled patients received MultiStem administered intravenously two days following a peripheral blood or bone marrow HSCT. The single dose arm included patients in three dose groups, based on cells per kilogram body weight —1 million (n=6), 5 million (n=3) and 10 million (n=9) — as determined using the continual reassessment methodology that was utilized following consultation with the FDA.

Ten male and eight female subjects enrolled in the single dose administration arm, ranging in age from 31-61 years old. Eleven patients received HSCT from matched unrelated donors (MUD), including one with a slight degree of mismatch, and seven received HSCT from matched related donors (MRD). With respect to HSCT source, 16 grafts were from peripheral blood and two were from bone marrow. Successful engraftment occurred in all 18 subjects, averaging 16 days for MUD transplants and 14 days for MRD transplants.

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About MultiStem

MultiStem is a patented and proprietary allogeneic cell therapy product candidate that can be manufactured on a large scale, frozen and stored for an extended period, and subsequently thawed and administered intravenously, similar to traditional biologics.

MultiStem consists of a clinical grade preparation of non-embryonic stem cells obtained from bone marrow that have the potential to produce a range of factors and form multiple cell types. MultiStem appears to work through several mechanisms that promote healing and tissue repair, but a primary mechanism appears to be the production of therapeutic proteins and other molecules produced in response to inflammation and tissue damage. Athersys believes that MultiStem may represent a unique "off-the-shelf" stem cell product based on its apparent ability to be used without tissue matching or immunosuppression and its capacity for large scale production.

About Athersys

Athersys is a clinical stage biopharmaceutical 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 MultiStem[®], a patented, adult-derived "off-the-shelf" stem cell product platform for multiple disease indications in the cardiovascular, neurological, inflammatory and immune disease area. The Company currently has several clinical stage programs, including for treating damage caused by myocardial infarction, bone marrow transplantation and oncology treatment support, ischemic stroke, and inflammatory bowel disease. The Company also has developed a portfolio of other therapeutic programs, including orally active pharmaceutical product candidates for the treatment of metabolic and central nervous system disorders, utilizing proprietary technologies, including Random Activation of Gene Expression (RAGE[®]). Athersys has forged several key strategic alliances 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

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products. Athersys has licensed Oregon Health & Science University's rights in intellectual property co-invented by Dr. Maziarz, which may apply to the use of this cell-based product in this treatment area. The potential individual and institutional conflict of interest has been reviewed and managed by Oregon Health & Science University.

The Athersys, Inc. logo is available at

<http://www.globenewswire.com/newsroom/prs/?pkgid=4548>

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," "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

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disease indications, 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: final results from the Phase I clinical trial of MultiStem for individuals undergoing allogeneic HSCTs; 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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