



## **Athersys and Chugai Enter License Agreement and Collaboration to Develop MultiStem<sup>®</sup> Cell Therapy for Ischemic Stroke in Japan**

*Regenerative medicine partnership focused on development of novel stem cell therapy*

**March 2, 2015 (CLEVELAND, TOKYO)** – Athersys, Inc. (NASDAQ: ATHX) and Chugai Pharmaceutical Co., Ltd. (Tokyo Stock Exchange: 4519) have announced a partnership and license agreement to exclusively develop and commercialize MultiStem<sup>®</sup> cell therapy for ischemic stroke in Japan. Ischemic stroke represents a priority disease area in Japan, given the high healthcare burden of the condition and the expected increase in incidence associated with Japan's aging population.

Athersys' proprietary cell therapy product, MultiStem, is currently being evaluated in a Phase 2 clinical study for ischemic stroke in the United States and Europe, and Athersys has begun preparations for clinical development in Japan, including engagement with the Japanese Health Authority. Chugai is a leading research-based pharmaceutical company with strengths in biotechnology products, and brings to the collaboration substantial expertise and experience in late-stage development and commercialization in Japan.

“We are delighted to have concluded a license agreement with Athersys for the development and marketing of MultiStem, a very innovative cell therapy under clinical development,” said President and Chief Operation Officer at Chugai, Tatsuro Kosaka. “By combining Chugai's strong expertise in biological pharmaceuticals, we hope to bring MultiStem to the Japanese healthcare system as a new treatment modality during the critical phase of ischemic stroke.”

“We are excited to be working with Chugai in this important area and look forward to combining our respective capabilities and expertise to successfully develop and commercialize MultiStem for the treatment of ischemic stroke in Japan,” said Dr. Gil Van Bokkelen, Chairman and Chief Executive Officer at Athersys. “We believe that Chugai represents an outstanding partner with strong capabilities in all facets of the development, commercialization and marketing of novel medicines in the Japanese healthcare market. Chugai has been a leader in the development and introduction of innovative biologics and has successfully established one of the top sales forces in prescription drug field in Japan, which we believe represents a key competitive advantage that can help both companies maximize value. Athersys and Chugai are committed to working together to establish a leadership position in the regenerative medicine cell therapy area in Japan.”

As part of the collaboration, Chugai will be responsible for the development and commercialization of MultiStem for ischemic stroke in Japan, and Athersys will have responsibility for product supply. Under the financial terms of the agreement, Athersys will receive an up-front cash payment of \$10 million from Chugai and would receive additional payments as the program is further advanced. Athersys is eligible to receive milestone payments from Chugai of up to \$45 million upon the successful achievement of certain development and regulatory milestones, and sales milestones of up to 17.5 billion Yen (approximately \$150 million based on the current exchange rate). Athersys would also receive from Chugai tiered, double-digit royalties on any net sales, as well as payments for product supplied to Chugai.

In Athersys' ongoing Phase 2 clinical study, it is evaluating the administration of MultiStem cell therapy to patients who have suffered an ischemic stroke. Based on preclinical research to date, administration of MultiStem has shown significant benefits through several mechanisms, including reduction of inflammation and immune system modulation in the ischemic area, and the protection and rescue of damaged or injured cells, including neuronal tissue. Athersys is treating patients one to two days after the stroke has occurred, in contrast to thrombolytic tPA treatment, which is limited to the first three to four hours following the stroke. Preclinical studies have demonstrated that administration of a single dose of MultiStem therapy, even one week after a stroke, provides significant and durable improvements relative to controls. Enrollment in Athersys' double-blind, placebo-controlled trial is complete, and interim safety and initial efficacy results following the ninety-day patient data are expected to be announced in April 2015, following analysis and receipt of the unblinded clinical data.

### **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, since 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](http://www.athersys.com).

### **About Chugai Pharmaceutical Co., Ltd.**

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area. In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe. The consolidated revenue in 2014 of Chugai totaled 461.1 billion yen and the operating income was 77.3 billion yen (IFRS Core basis).

Additional information is available on the internet at <http://www.chugai-pharm.co.jp/english>.

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