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**FOR IMMEDIATE RELEASE**

## **Aldagen Announces Publication of Phase 1/2 Results for ALD-301, a Stem Cell Therapy in Development for Critical Limb Ischemia**

**- Publication in *Catheterization and Cardiovascular Interventions* supports potential of ALD-301 to safely increase blood flow and improve clinical status-**

**Durham, NC – May 19, 2011** – Aldagen, Inc. today announced that results from the Phase 1/2 clinical trial of ALD-301 were published in *Catheterization and Cardiovascular Interventions*. ALD-301 is a stem cell therapy being developed as a treatment for critical limb ischemia (CLI), the most advanced form of peripheral arterial disease (PAD). The Phase 1/2 study was a multi-center study and included Cardiology PC, Duke University, Texas Heart Institute, and St. Joseph's Research Institute. Dr. Emerson Perin from the Texas Heart Institute is the lead author on the publication.

The Phase 1/2 double-blind study included a total of 21 subjects who were randomly selected to receive an injection of either ALD-301 or unsorted cells from their own bone marrow (autologous bone marrow mononuclear cells, or ABMMNC). The primary objective of the trial was to evaluate the safety of ALD-301. Secondary endpoints of the trial included change in clinical status from baseline to 12 weeks, as measured by the Rutherford scale, a well-accepted clinical categorization of the extent of CLI. In addition, change in blood flow to the leg was measured by two well-accepted clinical tools for assessing the extent of CLI, the ankle-brachial index or ABI, and transcutaneous partial pressure of oxygen, or TcPO<sub>2</sub>.

As detailed in the publication, ALD-301 was shown to be well tolerated, with no therapy-related serious adverse events. Patients treated with ALD-301 showed significant improvements in three efficacy endpoints, Rutherford category, ankle-brachial index (ABI) and quality of life (as measured by VascuQOL) compared to baseline at 12 weeks. Additionally, patients treated with ALD-301 showed a significant decrease in rest pain compared to baseline at 6 weeks.

"This scientific article represents the first peer-reviewed data publication from a U.S. clinical study of a stem cell therapy for CLI and is an important milestone in the development of ALD-301," said Lyle A. Hohnke, Ph.D., Chief Executive Officer of Aldagen. "The positive safety and efficacy data supports the continued development of ALD-301. We plan to initiate a 150 patient Phase 2 trial as the next step in the development of ALD-301. "



Aldagen's planned Phase 2 trial is a double-blind, placebo-controlled trial designed to assess the ability of ALD-301 to improve clinical outcomes in patients with critical limb ischemia. This trial will be the largest Phase 2 trial ever completed with a stem cell therapy in CLI and will allow Aldagen to determine the number of patients that will be required to demonstrate a statistically significant effect on a primary endpoint of six-month amputation-free survival in a subsequent pivotal Phase 3 study.

#### **About ALD-301**

ALD-301 is the population of ALDH(br) stem cells produced using Aldagen's proprietary technology to sort a specified quantity of bone marrow collected from the patient receiving the therapy. These adult stem cells express high levels of the enzyme ALDH, which plays an important role in controlling the developmental state of stem and progenitor cells. ALD-301 is injected into the patient's leg muscle. Preclinical research suggests that ALDH(br) cells derived from bone marrow may promote the repair of ischemic tissue damage, which is tissue damage caused by inadequate blood flow resulting from the obstruction of blood vessels supplying blood to the tissue.

#### **About Critical Limb Ischemia**

Critical limb ischemia is a condition characterized by significant impairment of blood flow to the legs and feet caused by a blockage of the arteries. Patients with critical limb ischemia may experience persistent severe pain in their lower extremities and may also suffer from severe tissue damage in the affected area. There are no drugs currently approved by the United States Food and Drug Administration for the treatment of this condition. For advanced critical limb ischemia patients with no other therapeutic options for improving blood flow, amputation of the affected limb is often the only available clinical option. The Sage Group, an independent research and consulting firm specializing in vascular diseases in the lower limbs, estimates that within six months of diagnosis up to 35% of CLI patients will require limb amputation and approximately 20% will die.

#### **About Aldagen**

Aldagen is a clinical-stage biopharmaceutical company developing proprietary regenerative cell therapies. Our product candidates consist of a specific population of a patient's own stem cells, which are isolated using our proprietary technology and which we believe have the potential to promote the regeneration of multiple types of cells and tissues, including the growth of new blood vessels. Our initial focus is on developing product candidates to address cardiovascular disease. Our clinical stage cardiovascular product candidates are ALD-301 for the treatment of critical limb ischemia, ALD-201 for the treatment of ischemic heart failure, and ALD-401 for the post-acute treatment of ischemic stroke.

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