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**FOR IMMEDIATE RELEASE**

## **Phase 1/2 Results for Aldagen's ALD-301 Critical Limb Ischemia Clinical Study Presented at AHA**

**Durham, NC – November 16, 2009** – Aldagen, Inc. today announced that researchers presented results from its multicenter Phase 1/2 clinical trial of ALD-301, a cell therapy being developed as a treatment for advanced critical limb ischemia (CLI), the most severe form of peripheral arterial disease (PAD). In the study, ALD-301 was well-tolerated, and patients in the treatment group were shown to have increased blood flow and improved clinical status. The data were presented at the American Heart Association Scientific Sessions 2009 by Emerson C. Perin, MD, PhD, FACC, Director, Clinical Research for Cardiovascular Medicine, and Medical Director, Stem Cell Center, Texas Heart Institute in a general poster session.

"We are very excited with the results from this study, which addresses a patient group with very limited therapeutic options," said Dr. Perin. "This is the first study in the United States to use sorted stem cells for the treatment of critical limb ischemia, and these results support the hypothesis that treatment with these purified cells may increase the blood flow to the legs and feet."

### **About the Study**

The 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). ALD-301 is a population of stem cells (ALDH<sup>br</sup> cells) produced using Aldagen's proprietary technology. ALDH<sup>br</sup> cells express high levels of an enzyme known as aldehyde dehydrogenase, or ALDH, and exhibit a variety of activities that Aldagen believes may promote the repair of tissues suffering from ischemia, or reduced blood flow. The mean number of autologous ALDH<sup>br</sup> cells injected into the calf in the ALD-301 treatment group was  $1.1 \times 10^6$  or 1.1 million cells and the number of bone marrow mononuclear cells injected into the ABMMNC group was  $1.2 \times 10^9$  or 1.2 billion cells.

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>.

Specific findings from the Phase 1/2 clinical study of ALD-301 were as follows:

- All subjects randomized to the treatment arm of the trial were successfully dosed with ALD-301.
- None of the ALD-301 subjects experienced a serious adverse event that the clinical investigators assessed as being related to treatment with ALD-301.
- Subjects treated with ALD-301 demonstrated improvements in clinical status determined by Rutherford category over 3 months. In the ALD-301 treatment group there was a 0.64



reduction in Rutherford category ( $p=0.05$ ; lower category represents improvement). In the ABMMNC group there was a reduction of 0.56 in Rutherford category (not significant).

- There was evidence of improved blood flow over 3 months in subjects treated with ALD-301. In the ALD-301 treatment group there was a statistically significant increase in ABI of 0.14 ( $p=0.03$ ), which is considered a clinically meaningful change, and a non-significant increase in TcPO<sub>2</sub> of 6.6 mmHg. In the ABMMNC group there was a similar increase in ABI of 0.14 ( $p=0.03$ ) and the change in TcPO<sub>2</sub> was 0.7 mmHg (not significant).
- One major amputation occurred in each treatment group over 6 months.

### **About ALD-301**

ALD-301 is the population of ALDH<sup>br</sup> stem cells produced using Aldagen's proprietary technology to sort a specified quantity of bone marrow collected from the patient receiving the therapy. ALD-301 is injected into the patient's leg muscle. Preclinical research suggests that ALDH<sup>br</sup> 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. In August 2009, Aldagen received an SPA concurrence letter from the FDA for the design of a pivotal Phase 3 clinical trial of ALD-301 for the treatment of CLI, which is expected to commence in 2010.

### **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, Inc.**

Aldagen is a biopharmaceutical company developing proprietary regenerative cell therapies that target significant unmet medical needs. The company's most advanced product candidates are ALD-101, ALD-301 and ALD-201. Aldagen is currently conducting a pivotal Phase 3 clinical trial of ALD-101 to evaluate its efficacy in improving engraftment following umbilical cord blood transplants used to treat inherited metabolic diseases in pediatric patients. The company also intends to commence a pivotal Phase 3 clinical trial of ALD-301 to evaluate its efficacy in treating critical limb ischemia and is developing ALD-201 for the treatment of ischemic heart failure. Aldagen is pursuing the development of additional product candidates based on the company's proprietary technology for isolating adult stem cells that express high levels of ALDH, including products to improve engraftment following cord blood transplants used to treat leukemias, for the treatment of inherited metabolic diseases and for the post-acute treatment of ischemic stroke.

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