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FOR IMMEDIATE RELEASE**ALDAGEN ANNOUNCES POSITIVE PHASE 1/2 RESULTS FOR CRITICAL LIMB ISCHEMIA STEM CELL THERAPY ALD-301**

Durham, NC – November 20, 2008 — Aldagen today announced positive results from its multicenter Phase 1/2 clinical trial of ALD-301, a novel stem cell therapy being developed for the treatment of critical limb ischemia. In the 24-week Phase 1/2 trial, ALD-301 was well tolerated. Importantly, the study results also indicated that during the 12-week efficacy assessment period, there were improvements in overall clinical status as well as increased blood flow in the affected limb in the group of patients treated with ALD-301.

The Phase 1/2 clinical trial of ALD-301 was designed to assess its safety and potential efficacy as a treatment for patients with advanced critical limb ischemia. The trial was a randomized, double-blind, controlled trial with two treatment groups. A total of 21 patients were randomly selected to receive an injection of either ALD-301 or unsorted cells from their own bone marrow. The primary objective of the trial was to evaluate the safety of ALD-301 by monitoring for serious adverse events, including death, amputation, stroke, heart attack and hospitalization. Secondary endpoints of the trial included change in clinical status from baseline to 12 weeks, as measured by the Rutherford category, a well-accepted clinical categorization for the extent of critical limb ischemia. In addition, the trial assessed change in blood flow to the leg by two other well-accepted clinical tools for assessing critical limb ischemia, the ankle-brachial index (ABI) and transcutaneous partial pressure of oxygen, or TcPO₂.

The key findings from the Phase 1/2 study are summarized below:

- ALD-301 was well tolerated. None of the ALD-301 patients experienced a serious adverse event that the clinical investigators assessed as being related to the infusion of ALD-301.
- Four of the 11 patients in the ALD-301 treatment group improved in Rutherford category and were no longer categorized as having critical limb ischemia at 12 weeks.
- One of the 11 patients in the ALD-301 treatment group worsened clinically (as defined by a worsening of Rutherford category at 12 weeks or major amputation at 24 weeks) over the 24-week trial. 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 critical limb ischemia patients will require limb amputation and approximately 20% will die.
- There was a statistically significant increase ($p=.03$) in mean ABI in the ALD-301 treatment group at 12 weeks compared to baseline.
- There was an increase in mean TcPO₂ in the ALD-301 treatment group at 12 weeks compared to baseline.



“We are very pleased with the results from this Phase 1/2 trial of ALD-301 as they support our original hypothesis that ALD-301 could improve the clinical status of patients with severe critical limb ischemia and improve blood flow in their affected limbs,” said Mr. Tom Amick, Aldagen’s Chairman and Chief Executive Officer. “This represents the first clinical study completed in the U.S. using a unique population of stem cells to treat severe critical limb ischemia and we believe ALD-301 may offer a unique therapeutic option for these patients. We also plan to submit the full clinical data for presentation at an upcoming scientific meeting.”

ALD-301 Overview

ALD-301 is the population of stem and progenitor cells that are produced using Aldagen’s proprietary technology to sort a specified quantity of bone marrow collected from the patient receiving the therapy. To produce ALD-301, Aldagen receives 150 milliliters of bone marrow extracted from the patient. At Aldagen’s manufacturing facility, Aldagen processes the bone marrow to isolate and capture the key stem and progenitor cells. Typically within 36 hours of receipt of the bone marrow, Aldagen delivers the resulting ALD-301 cells either to an interventional cardiologist or to a vascular surgeon, who then administers ALD-301 to the patient by intramuscular injection into the patient’s leg. Aldagen’s technology isolates specific populations of adult stem cells that express high levels of aldehyde dehydrogenase (ALDH-bright cells). Preclinical studies conducted by leading research institutions and academic centers have shown that ALDH-bright cells from bone marrow 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 severe cases of critical limb ischemia may experience persistent 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, or FDA, 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 estimates that approximately 2.0 million people in the United States have been diagnosed with critical limb ischemia and projects that this patient population will grow to nearly 2.8 million by 2020. The Sage Group also estimates that there are approximately 160,000 leg amputations performed on critical limb ischemia patients annually in the United States.

About Aldagen, Inc.

Aldagen is a biopharmaceutical company developing proprietary regenerative cell therapies that target significant unmet medical needs. The company has four product candidates in clinical trials. Aldagen’s most advanced product candidate, ALD-101, is currently in a pivotal Phase 3 clinical trial to evaluate its efficacy in improving umbilical cord blood transplants used to treat inherited metabolic diseases in pediatric patients. The company also is conducting or supporting Phase 1 or Phase 1/2 clinical trials of three other product candidates: ALD 151 to improve umbilical cord blood transplants used in the treatment of leukemia, ALD-301 to treat critical limb ischemia, and ALD-201 to treat ischemic heart failure. Aldagen’s product candidates consist of specific populations of adult stem cells that the company isolates using its proprietary technology.

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