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FOR IMMEDIATE RELEASE

Aldagen Announces Clinical Data for ALD-201 for Ischemic Heart Failure Presented at AHA

Durham, NC – November 18, 2009 – Aldagen, Inc. today announced that results from a Phase 1 clinical trial of ALD-201, a cell therapy being developed as a treatment for ischemic heart failure were presented at AHA. In the study, ALD-201 was found to be well-tolerated and to improve myocardial perfusion. 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 an oral session.

“We are very excited about the promise of using adult stem cells to treat heart disease, especially ischemic heart failure which is often so deadly,” said Dr. Perin. “In the study, ALD-201 was generally well-tolerated, and improvement was shown in treated patients.”

About the Study

This clinical trial was conducted as a randomized, double-blind, placebo-controlled trial. A total of 20 patients received either an injection of ALD-201, or an injection of an equivalent volume of placebo using the same catheter delivery system. ALD-201 is a population of stem cells (ALDH^{br} cells) produced using Aldagen’s proprietary technology, which express high levels of an enzyme known as aldehyde dehydrogenase, or ALDH, and exhibit a variety of activities, that Aldagen believes may promote the regeneration of multiple types of cells and tissues. Investigators assessed patients for endpoints for the first six months after the injection and then followed them for an additional six months. After the initial six-month assessment, patients in the control group were offered the opportunity to be treated with ALD-201 and then evaluated as though they had been initially placed in the ALD-201 treatment group.

The primary objective of this clinical trial was to evaluate the safety of ALD-201. Secondary endpoints included efficacy evaluations such as aerobic capacity and single-photon-emission computed tomography, or SPECT which is a nuclear imaging study that assesses diminished blood flow, or ischemia, in the heart.

Specific findings from the Phase 1 clinical study of ALD-201 were as follows:

- There were no major periprocedural complications, and adverse events were similarly distributed between the ALD-201 and placebo groups.
- As assessed by SPECT, there was evidence that subjects treated with ALD-201 had improved blood flow with less ischemia in the heart over 6 months. There was a statistically significant difference in the change in reversibility, or ischemia, for patients treated with ALD-201 compared to placebo. In the ALD-201 group there was a mean reduction in ischemia of 4.0% compared to a mean increase in ischemia of 3.7% in the placebo group (p=0.045). The mean amount of ischemia at 6 months was 2.6% in the ALD-201 group and 8.0% in the placebo group (p=0.012).



- The improvement in MVO_2 , which is reflective of aerobic capacity, was greater in the ALD-201 group than in the placebo group over 6 months, though the change was not statistically significant. MVO_2 in the ALD-201 group changed from 15.5 mL/kg/min at the beginning of the study to 17.7 mL/kg/min at the end of the study. MVO_2 in the placebo group changed from 14.1 mL/kg/min to 14.6 mL/kg/min.

About ALD-201

ALD-201 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. 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. ALD-201, which is being developed for the treatment of ischemic heart failure, is injected directly into the appropriate areas of the patient's heart muscle using a specialized catheter.

About Ischemic Heart Failure

Ischemic heart failure is caused by an obstruction of the arteries feeding blood to the heart tissue. The resulting damage to the heart muscle from insufficient oxygen and nutrients reduces the heart's ability to pump blood efficiently to the rest of the body. Current treatment options for ischemic heart failure include surgical procedures, bi-ventricular pacers, drug therapies, implantable cardiac defibrillators, and ventricular assist devices. For some patients, these treatments are not effective or appropriate. Once ischemic heart failure patients have exhausted all potential revascularization options, their only other option is a heart transplant, if they are eligible for one.

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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