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Aldagen Announces Data Presented at American Society of Hematology Annual Meeting

- Key preclinical findings support trial design for Aldagen's ongoing clinical programs -

Durham, NC – December 8, 2009 – Aldagen, Inc. today announced that results from preclinical studies were presented at the 51st American Society of Hematology (ASH) Annual Meeting and Exposition in New Orleans, Louisiana. A total of fourteen abstracts related to Aldagen's technology were presented at the conference, including several supporting the clinical importance of adult stem cells expressing high levels of an enzyme known as aldehyde dehydrogenase, or ALDH. Aldagen has developed a proprietary technology to isolate these cell populations, known as ALDH^{br} cells. The preclinical findings are directly relevant to the ongoing clinical programs for Aldagen's cell therapy product candidates ALD-101, ALD-301 and ALD-201.

ALD-101: Improving Engraftment Following Cord Blood Transplants

ALD-101 is the population of ALDH^{br} stem cells Aldagen produces from a portion of a cord blood unit using its proprietary technology. Researchers from Duke University and Aldagen presented results of animal experiments modeling the clinical effects of ALD-101 in reducing the time to engraftment following a cord blood transplant. The study was designed to evaluate neutrophil and platelet engraftment of sorted ALDH^{br} cell populations in mice, as compared to unsorted cord blood containing the same number of ALDH^{br} cells.

In this preclinical model, the mice were divided into three groups. The first group received sorted ALDH^{br} cells, a preparation that is similar to ALD-101. The second group received unmanipulated cord blood that contained the same number of ALDH^{br} cells. The third group initially received the same dose of unmanipulated cord blood as the second group, but four hours later the group also received the same dose of sorted ALDH^{br} cells as the first group. This dosing procedure for the third group models the way ALD-101 is administered in Aldagen's clinical trials. Four weeks after administration, researchers noted the following:

- The group receiving only the sorted ALDH^{br} cell population yielded over 10 times more human neutrophils and other cells that are clinically important than did the group receiving only unmanipulated cord blood.
- The number of circulating human platelets in the mice reached levels of detectability in the group receiving only the sorted cells but was undetectable in the group receiving only the unmanipulated cord blood.
- The group receiving unmanipulated cord blood followed by sorted ALDH^{br} cells showed similar results to the group that received only the sorted ALDH^{br} cell population.

Based on these results, Aldagen believes that administering sorted ALDH^{br} cells promotes improved engraftment when compared to administering unsorted conventional cord blood units, both when the



sorted cells are administered alone, or following a conventional cord blood transplant. Aldagen is currently conducting a pivotal Phase 3 clinical trial of ALD-101 to evaluate its efficacy in accelerating the engraftment of platelets and neutrophils in pediatric patients undergoing umbilical cord blood transplants for the treatment of inherited metabolic diseases.

ALD-301 and ALD-201: Aldagen's Cardiovascular Product Candidates to Promote Angiogenesis

ALD-301 and ALD-201 are ALDH^{br} stem cell populations Aldagen produces using its proprietary technology to sort a specified quantity of bone marrow collected from the patient receiving the therapy. Aldagen is developing ALD-301 for the treatment of critical limb ischemia and ALD-201 for the treatment of ischemic heart failure.

Aldagen researchers presented preclinical results showing the potential of ALDH^{br} cell populations to induce angiogenesis, or the creation of new blood vessels, at sites of ischemic damage and promote perfusion, or improved blood flow. Based on previous research by Aldagen and other scientists, Aldagen believes that progenitor cells present in ALDH^{br} cell populations might themselves differentiate into blood vessels. The results presented at the ASH meeting suggest that ALDH^{br} cells might also induce the generation of new blood vessels from existing vessels or from other progenitor cells within the patient by secreting angiogenic proteins and providing chemical signals that promote angiogenesis. Aldagen observed the following growth-enhancing and protective characteristics of ALDH^{br} cells in these preclinical studies:

- ALDH^{br} cells produce factors that protect endothelial cells, which are the cells that line the blood vessels, from damage under conditions of inadequate oxygen and nutritional stress;
- ALDH^{br} cells highly express many angiogenic growth factors, proteins and cellular matrix remodeling molecules;
- The expression of 35 different angiogenic factors is increased, or upregulated, in ALDH^{br} cells exposed to endothelial cells under conditions of inadequate oxygen;
- ALDH^{br} cells protect serum-starved endothelial cells from cell death; and
- ALDH^{br} cells rapidly migrate to and are retained at the sites of ischemic endothelial cells.

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 intends to commence a pivotal Phase 3 clinical trial of ALD-301 in 2010 to evaluate its efficacy in treating critical limb ischemia. Aldagen has also completed a Phase 1 clinical trial of ALD-201 for the treatment of ischemic heart failure. Aldagen is developing additional product candidates based on the company's proprietary technology for isolating adult stem cells that express high levels of ALDH, including product candidates 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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