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#### FOR IMMEDIATE RELEASE

# Aldagen Announces First Subject Enrolled and Clears Initial Safety Assessment in Stem Cell Study for Ischemic Stroke

First U.S. Patient Enrolled by Dr. George Rappard at the Los Angeles Brain and Spine Institute -

Durham, NC - May 31, 2011 - Aldagen, Inc. today announced that Dr. George Rappard and the Los Angeles Brain and Spine Institute (LABSI) enrolled the first subject in a clinical trial that studies Aldagen's ALD-401, a unique stem cell population derived from patient's own bone marrow, for the treatment of stroke. The study subject has cleared an initial seven-day safety assessment by an independent Data Safety Monitoring Board (DSMB). Aldagen will now continue to enroll additional subjects in the trial.

"We are very excited to have enrolled the first subject in such a potentially ground breaking clinical study. Stroke represents the leading cause of disability in the U.S. and is the third leading cause of death. Currently the treatment of stroke is limited to a small number of patients presenting early enough for clot busting drug therapy. ALD-401 will be delivered about two weeks after a stroke, greatly broadening the number of patients that may benefit from this potential neuro-regenerative therapy," said Dr. Rappard, a Neurointerventional Surgeon, specializing in minimally invasive surgery of the brain and spine. Dr. Rappard is the lead LABSI investigator studying ALD-401 stem cells.

"We are pleased to have the first subject clear the initial safety assessment by the DSMB and we look forward to continuing to enroll subjects in the study," stated Dr. Lyle Hohnke, CEO of Aldagen.

The Phase 2 trial is designed to assess the safety of ALD-401 and its potential efficacy to improve clinical outcomes in patients with ischemic strokes when administered between 13 and 19 days after the stroke. The trial size will be approximately 100 patients, with roughly 60% receiving an injection of ALD-401 into the carotid artery. Aldagen has decided to perform its initial clinical study in a relatively homogenous population of stroke patients. Therefore, only patients with unilateral ischemic strokes will be eligible to participate in the Phase 2 clinical trial. In addition, the patient must have at least a moderate to severe stroke, in terms of residual disability and loss of neurological function.

#### **About Stroke**

Strokes are characterized by a loss of brain function due to a significant diminution in the blood supply to the brain. Strokes are typically classified into two major categories, ischemic and hemorrhagic. Ischemic strokes result from an inadequate supply of blood and oxygen to the brain due to blockage of an artery, such as by a blood clot, while hemorrhagic strokes result from rupture of a blood vessel or an abnormal vascular structure. The American Heart Association estimates that approximately 800,000 patients in the United States suffer a stroke each year, approximately 87% of strokes are ischemic, and the yearly cost of stroke in the US is estimated at between fifteen and thirty billion dollars.



#### **About ALD-401**

ALD-401 is the population of stem cells produced using Aldagen's proprietary technology to sort a specified quantity of bone marrow collected from the patient set to receive stem cell therapy. Preclinical research suggests that these stem cells may promote the repair of stroke damaged brain. Investigators have completed preclinical research in which ALD-401 was administered two weeks after a stroke. This preclinical research showed improvements in motor function, improvements in the slowing of decrease in brain volume, the reversal of decline in stroke-induced cell viability, and improved blood flow, or perfusion, in the brain.

## **About the Los Angeles Brain and Spine Institute**

The Los Angeles Brain and Spine Institute is a community based, sub-specialty oriented multidisciplinary provider of neurological care. It is within the mission of the Los Angeles Brain and Spine Institute to provide state of the art care, including cutting edge research, to the community setting. For more information, visit www.labrainandspine.com

### **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 vascular diseases. 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.