Queen's University Belfast to study the Innate Repair Activator ARA 290 in Diabetic Macular Edema

TARRYTOWN, NY, May 10, 2016. **Araim Pharmaceuticals**, a clinical stage drug development company with a unique platform technology for activating post-injury tissue repair and recovery, reported today that the first subject has been enrolled in a study evaluating the use of ARA 290 as treatment of diabetic macular edema. It is sponsored by the Belfast Health and Social Care Trust in Belfast, Northern Ireland,

ARA 290 is the lead compound in a family of novel peptides targeting chronic and acute diseases. It is a first-in-class synthetic peptide designed to activate innate repair mechanisms in the setting of tissue injury as a result of the inflammatory cascade. ARA 290 selectively binds to the Innate Repair Receptor (IRR) which activates tissue protective, reparative, and anti-inflammatory signaling pathways. The IRR was discovered by Araim Pharmaceuticals and is the basis for their platform of peptides and patent portfolio.

Since activation of the IRR has been shown to decrease retinal leakage (edema) in diabetes, and given its marked anti-inflammatory and anti-cell death properties, ARA 290 has been evaluated by investigators at the Centre of Vision and Vascular Sciences, Queen's University Belfast in two preclinical models of retinopathy. ARA 290, given ip daily for a month to rats with established diabetes, significantly improved retinal stress-related responses (ie, it reduced microglia and inflammatory cytokines including TNF-α and interleukin-6) and diabetes-linked retinal cell death. Additionally, ARA 290 improved retinal ischemia (chronic reduced blood flow to the eye) and decreased VEGF expression in murine oxygen-induced retinopathy.

Based on the compelling preclinical data and given the need for additional treatment options for Diabetic macular edema (DME), an open-label pilot study has been started by investigators at the Queens University Belfast to evaluate the safety and efficacy of ARA 290 for use in DME. Ten subjects with diabetic retinopathy and treatment-naïve severe DME (central retinal thickness of > 400 microns) will self-administer 4 mg ARA 290 subcutaneously daily for 12 weeks. The primary objective of the study is to determine whether ARA 290 has a beneficial effect on best-corrected visual acuity (BCVA) in people with diabetes and DME. Secondary objectives are to assess the effect of ARA 290 on central subfield thickness, central retinal sensitivity, tear production, retinal perfusion and quality of life. Inflammatory markers, indices of metabolic control, and adverse events and other parameters of safety will be monitored during the study.

"We are excited that this recently-started clinical study in people with diabetes, diabetic retinopathy and severe DME will add to and build upon our preclinical work with ARA 290 in DME," commented Professor Alan Stitt, Director of the Centre for Vision & Vascular Science in Queen's University Belfast. "Macular edema is a common cause of vision loss in patients with

diabetes. Despite their widespread use, incomplete responses to anti-VEGF therapies can be seen in up to half of treated patients, and researchers suspect that multiple pathways, not all currently identified, contribute to this complex and debilitating disease. Thus, helping to identify novel new therapies remains a priority for us."

Diabetic macular edema is caused by fluid accumulation in the macula, or the central portion of the eye. It affects more than 20 million people with diabetes worldwide, and is a leading cause of vision loss. About half of all people with the form of diabetic eye disease called diabetic retinopathy will develop DME. Inflammation is recognized to play a key role in the series of events that lead to the occurrence and persistence of diabetic retinopathy. Current treatment options for DME include macular laser surgery, corticosteroid drugs either injected or implanted into the eye, and anti-VEGF (vascular endothelial growth factor) drugs injected into the eye. These therapies improve DME outcome, but are invasive and not completely effective for many patients.

About Araim Pharmaceuticals, Inc.

Araim Pharmaceuticals, Inc. is a clinical stage drug development company with a novel platform technology designed to address devastating injuries and chronic diseases underserved by current therapies. With their discovery of the Innate Repair Receptor (IRR), Araim has identified the target for activating tissue repair and recovery from inflammatory and other injuries. Their novel peptide library of IRR specific ligands activate tissue protective, reparative and anti-inflammatory signaling pathways. Araim has an ongoing, active and promising preclinical program in a wide array of conditions involving tissue injury and repair, including neuropathy, cardiovascular injury, diabetes complications, wound healing and aging. Their lead compound, ARA 290, a novel 11 amino acid peptide, has received US and EU orphan drug and US Fast Track designations for the treatment of painful small fiber neuropathy in sarcoidosis, and is currently in Phase 2 peripheral neuropathy clinical trials. www.araimpharma.com

##

Media Contact:

Rita Kirk

Araim Pharmaceuticals, Inc.

rkirk@araimpharma.com