Araim Pharmaceuticals' ARA 290, a Peptide Engineered to Activate Innate Repair, Receives Orphan Drug Designation from the European Commission

OSSINING, N.Y., October 10, 2013 -- Araim Pharmaceuticals, Inc. (Araim), a privately-held company engaged in developing novel treatments, announced today that the European Commission has granted Orphan Drug Designation to ARA 290 for the treatment of sarcoidosis. The designation follows the earlier positive opinion and recommendation of the European Medicines Agency (EMA) Committee of Orphan Medical Products. The Orphan Drug Designation provides Araim access to protocol assistance and certain financial incentives from the EMA, as well as 10 years marketing exclusivity for ARA 290 upon the receipt of marketing approval.

Araim previously received orphan drug designation for ARA 290 from FDA. "A significant number of patients with persistent sarcoidosis suffer disabling and unrelenting symptoms arising from small nerve fiber loss and damage, including autonomic and sensory dysfunction. I am delighted with this designation on behalf of these patients. The European Orphan Drug Designation is a critical step, together with our US designation, for the support of the international development of ARA 290 that we believe can bring significant improvement in the quality of life to these patients." said Anthony Cerami, Ph.D., Araim's Chief Executive Officer.

ARA 290 is an 11-amino acid peptide that activates the innate repair receptor, resulting in suppression of inflammation and promotion of nerve repair and regeneration. ARA 290 is currently undergoing Phase 2b clinical trials in Europe in diabetic patients with small nerve fiber loss and damage, and Araim anticipates starting phase 3 clinical trials in sarcoidosis patients in Europe and the US in 2014. Small nerve fiber loss and damage can be the result of many inflammatory diseases and is believed to be greatly underdiagnosed.

Sarcoidosis is a disease of unknown cause that affects multiple organs. The disease resolves in some patients, but in a significant number, the disease becomes persistent and the most common complication is small nerve fiber damage. Autonomic and sensory symptoms from small nerve damage and loss can consist of burning or shooting pain, allodynia, numbness, sweating disorders, diarrhea/constipation, sexual dysfunction, blurry vision, dry eyes, and orthostatic hypotension which limit physical function and well-being. Traditional analgesics, opioids and anti-inflammatory based therapies are ineffective in many patients, and as of yet no therapy has resulted in disease modification.

Araim recently reported results of a 28-day, placebo-controlled, double-blind phase 2 study that demonstrated ARA 290 is safe and well tolerated and resulted in significant improvement in small nerve fiber disease in sarcoidosis patients who failed prior therapies. After 4 weeks of daily dosing, a significant change from baseline was observed using the Small Fiber Neuropathy Screening List assessment as compared to placebo, and a significant change from baseline in the pain and physical functioning components of the SF-36 assessment. "ARA 290 is poised as a breakthrough therapy for treating small nerve fiber loss and damage, and based on published preclinical studies and initial clinical results on this peptide, it could very well be a disease modifier that provides a sustained benefit to afflicted patients," said Daniel Culver, D.O., F.C.C.P, a sarcoidosis physician and researcher at the Cleveland Clinic.

For more information on Araim Pharmaceuticals and ARA 290, please visit www.araimpharma.com.