Araim Pharmaceuticals' Innate Repair Receptor Activating Compound Accelerates Healing of Diabetic Wounds

TARRYTOWN, NY, December 19, 2017. **Araim Pharmaceuticals Inc.,** a biotechnology company with a platform of innate repair receptor (IRR) activating compounds, today announced the publication of preclinical research performed at the University of Messina, Italy, demonstrating the ability of their lead compound cibinetide to improve wound healing in a diabetic mouse model by accelerating wound closure, promoting blood vessel growth, and increasing the strength of the healing tissue. Cibinetide is a first-in-class novel peptide in a library of molecules designed to modulate tissue damage by decreasing inflammatory mediators and promoting repair in a wide variety of both chronic and acute inflammatory conditions.

Nonhealing chronic wounds are major complications of diabetes[1,2] resulting in >100,000 annual lower-limb amputations in the United States alone. Healing of skin injury is impaired in diabetes, and therapeutic options to accelerate or facilitate repair are limited. Even with the best care currently available, 30-50% of lower extremity ulcers are not fully healed after 6 months of treatment, resulting in up to $13 billion in annual costs. Factors which influence the incidence of debilitating and life-threatening wounds in diabetic patients include blood vessel damage with inadequate tissue oxygenation, impaired defense against infection, and chronic nerve injury decreasing the pain and awareness of developing wounds.

The IRR becomes expressed in response to pro-inflammatory molecules due to injury, including the diabetic state. Receptor binding leads to activation of multiple intracellular signaling pathways that suppress damage while simultaneously activating tissue repair. The current publication[3] in Biochimica et Biophysica Acta demonstrates that IRR activation by cibinetide accelerates diabetic wound healing via multiple biological pathways, resulting in increased protein synthesis, new blood vessel growth, and reduced oxidative stress. "These results signal another potential complication of diabetes that our platform of molecules could address, given the obvious fit based on the mechanism to activate repair and reduce inflammation," stated Daiva Bajorunas MD, Chief Medical Officer for Araim. "From both a patient and US health care perspective, diabetic wound healing remains a large and significant unmet need associated with increased morbidity and mortality, adverse consequences that have not changed much in the past 30 years despite clear advances in the medical treatment of persons with diabetes."

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[1] Singer AJ, Tassiopoulos A, Kirsner RS. N Engl J Med 2017;377:1559-67

[2] Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for
Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.

[3] https://doi.org/10.1016/j.bbadis.2017.12.006

"These promising new pre-clinical data in diabetes wound repair complement and expand on the accelerated healing we have previously demonstrated with cibinetide applied topically in pig and murine skin injury models, and we are actively researching topical delivery as a potential route of administration for this important complication of diabetes." said Joe Young, Chief Business Officer of Araim. "Araim is optimistic about the potential for broad clinical applicability of our novel technology. In addition to moving forward our late-stage clinical programs, we are committed to extending and strengthening the scientific foundations for the IRR platform that our library of compounds targets and activates, and are actively engaged with our network of leading academic collaborators in this endeavor."

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 activates 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 damage and repair, including neuropathy, cardiovascular damage, diabetes complications, wound healing and aging. Cibinetide is a first-in-class synthetic 11-amino acid peptide IRR agonist. The most advanced clinical program with cibinetide is in sarcoidosis-related small fiber neuropathy (Phase 3, in preparation). Cibinetide has been granted US and EU Orphan Drug Designation for the treatment of sarcoidosis, and has received US Orphan Drug and Fast Track designations for the treatment of neuropathic pain in patients with sarcoidosis. Cibinetide was granted EU Orphan Medicinal Product designation for prevention of graft loss in pancreatic islet transplantation, and US Orphan Drug Designation for treatment to increase survival and improve functioning of pancreatic islets following transplantation. A pilot study evaluating the safety and efficacy of cibinetide in diabetic macular edema was recently completed at Queen's University Belfast. www.araimpharma.com

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