ArmaGen Achieves Clinical Milestone in Hunter Syndrome Collaboration with Shire

Patient dosing initiated in AGT-182 Phase 1 Clinical Trial

Calabasas, Calif., June 15, 2015 – ArmaGen, Inc., a privately held biotechnology company focused on developing revolutionary therapies to treat severe neurological disorders, announced today that it achieved a clinical milestone in its worldwide licensing and collaboration agreement with Shire plc (LSE: SHP, NASDAQ: SHPG). The milestone was achieved in conjunction with dosing patients in its Phase 1 clinical trial of AGT-182, an investigational treatment of Hunter syndrome, and under terms of the agreement, the Company is entitled to a milestone payment from Shire. Also known as MPS II, Hunter syndrome is a rare, severe, progressive and life-limiting lysosomal storage disorder.

The primary objective of the Phase 1 trial is to test the safety and determine a well-tolerated dose of AGT-182, an investigational enzyme replacement therapy (ERT), in adult patients with Hunter syndrome. ArmaGen plans to enroll 12 patients 18 years and older into the study. These patients will be treated for a total of eight weeks, with all enrolled patients receiving AGT-182. Further details on the trial can be found at http://breakingbarriershuntertrial.com/, or https://clinicaltrials.gov/ct2/show/NCT02262338?term=AGT-182&rank=1 using the identifier number NCT02262338.

AGT-182 is designed to also address the current high unmet medical need around the neurological complications of the disease by utilizing the body's natural system for transporting products non-invasively across the blood-brain barrier (BBB) by targeting the receptor that delivers insulin to all cells of the body.

"This development reflects ArmaGen's transition into a clinical stage company and we look forward to eventually providing a treatment option for currently unaddressed neurological complications of Hunter syndrome," said James Callaway, Ph.D., Chief Executive Officer of ArmaGen. "The progress of our lead compound provides momentum to our pipeline of therapies designed to non-invasively cross the blood-brain barrier."

ArmaGen entered into a worldwide licensing and collaboration agreement with Shire plc in 2014 which could include potential payments of up to $225 million to develop AGT-182 for the treatment of both the central nervous system (CNS) and somatic (body-related) manifestations of Hunter syndrome. ArmaGen is responsible for conducting the Phase 1 study of AGT-182. Under the terms of the agreement, ArmaGen will receive R&D funding, development and sales milestones, and future royalties from Shire.

About Hunter Syndrome
Hunter syndrome, also known as mucopolysaccharidosis type II, or MPS II, is a lysosomal storage disorder caused by inadequate activity of the enzyme iduronate-2-sulfatase (IDS), which is needed to break down complex sugars produced by the body. The buildup of these complex sugars, known as mucopolysaccharides, interferes with functioning of certain cells and organs, leading to serious complications including developmental delays and mental impairment. Symptoms of Hunter syndrome include growth delay, joint stiffness and coarsening of facial features. In severe cases, patients experience respiratory and cardiac problems, enlargement of the liver and spleen, and neurological deficits that can lead to premature death. Hunter syndrome primarily affects males and is almost always severe, progressive and life-limiting. Available treatments for Hunter syndrome are not expected to cross the BBB in clinically relevant amounts and therefore do not address the progressive neurological complications of the disease.

About AGT-182
AGT-182 is a novel, investigational ERT that has received orphan drug designation from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Using ArmaGen's proprietary technology, AGT-182 is designed to take advantage of the body's natural system for transporting products across the BBB by binding to the same receptor that delivers insulin to the brain. AGT-182 is engineered by the fusion of the replacement IDS enzyme to an antibody that is attracted to a receptor on the BBB. The IDS enzyme is designed to travel through the BBB attached to that antibody.

About ArmaGen
ArmaGen, Inc. is a privately held biotechnology company focused on developing revolutionary therapies for severe neurological disorders. The company is developing a robust pipeline of innovative therapies for the treatment of neurological complications of lysosomal storage disorders such as Hunter syndrome, Hurler syndrome, metachromatic leukodystrophy and Sanfilippo A syndrome, as well as central nervous system diseases such as Alzheimer's and Parkinson's. ArmaGen's pipeline is based on decades of scientific leadership in engineering therapies to cross the BBB and a dominant intellectual property portfolio. The company is advancing its pipeline through licensing and collaboration agreements, in-house development programs, and future partnering opportunities. For more information, visit www.armagen.com.

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Contacts:

ArmaGen, Inc.
Derek Kelaita, Vice President, Business Development
818-252-8200
dkelaita@armagen.com

For media inquiries:
Smitha Dwarakanath
SmithSolve LLC
973-442-1555 ext. 122
smitha.dwarakanath@smithsolve.com