ArmaGen completes Pre-IND Meeting with FDA for AGT-181

August 17, 2010

ArmaGen has completed a Pre-IND Meeting with the FDA for a phase I-II trial of intravenous AGT-181 for treatment of the brain in Mucopolysaccharidosis (MPS) Type I, also known as Hurler's syndrome. MPS-I is a lysosomal storage disorder that affects the brain and spinal cord. Standard Enzyme Replacement Therapy (ERT) does not treat the brain, because the recombinant enzyme does not cross the blood-brain barrier (BBB). The lysosomal enzyme missing in MPS-I is iduronidase (IDUA). AGT-181 is a re-engineered form of human IDUA, where the lysosomal enzyme is fused to an IgG. The IgG is a genetically engineered monoclonal antibody (MAb) to the human insulin receptor (HIR). The HIRMAb part of the AGT-181 fusion protein acts as a molecular Trojan horse to ferry the fused IDUA across the BBB and across the target cell membrane, by binding to the endogenous insulin receptor. A dose-ranging study in 8 Rhesus monkeys demonstrated an excellent AGT-181safety profile, as described in the 2009 Journal of Biotechnology. ArmaGen will now perform GLP toxicology, safety pharmacology, and tissue cross-reactivity investigations to support the IND of AGT-181 for the treatment of the brain in MPS-I. ArmaGen manufactures the Toxicology Lot and Reference Standard for AGT-181 at its manufacturing facility in Santa Monica, CA.