

Neuroprotection in Stroke Drug Development

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Challenge/Problem:

Neurotrophins are potent neuroprotective agents for the treatment of acute ischemic stroke, as well as for chronic neurodegeneration. However, recombinant neurotrophins cannot be developed as drugs for the human brain, because neurotrophins do not cross the blood-brain barrier (BBB).

Current/Near Term Products:

ArmaGen has developed a new IgG-neurotrophin fusion protein for the treatment of acute ischemic stroke. The fusion protein is a bi-functional molecule which both induces neuroprotection and crosses the primate BBB.

Approach:

A new approach to the BBB drug delivery problem is the use of molecular Trojan horses to ferry the biopharmaceutical across the human BBB. The recombinant neurotrophin is re-engineered as a fusion protein with the Trojan horse, which is a monoclonal antibody against a BBB-specific receptor.

Future Plans:

Phase 0 toxicology and safety pharmacology tests in 56 Rhesus monkeys have been completed with no toxicity at any dose. The IgG-neurotrophin is presently being manufactured under cGMP conditions, and a phase I clinical trial in healthy volunteers will be initiated in the 4th quarter, 2009.

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Collaboration/Partnering Opportunities:

The Company is seeking partners to finance a multi-center, double-blind, dose-escalation phase IIA clinical trial of patients with acute ischemic stroke treated within the first 5 hours of the stroke with a single intravenous injection of the IgG-neurotrophin fusion protein.

Keywords: blood-brain barrier, monoclonal antibody, fusion protein, biopharmaceuticals, neurotrophin