MICSGOUP onferences Accelerating Scientific Discovery

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Clinical development of multistem® for treatment of CNS injury and disease

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A thersys, Inc. is developing MultiStem[®], a proprietary adult stem cell product, for the treatment of multiple disease indications. Athersys has undertaken extensive safety profiling of MultiStem in pre-clinical animal studies. Athersys has developed a clinical manufacturing platform for MultiStem and has filed and received authorization of Investigational New Drug (IND) applications for using MultiStem in 4 different indications including: Acute Myocardial Infarction (AMI), prophylaxis against graft vs. host disease (GVHD) and in treatment of ulcerative colitis in an ongoing Phase II study with Pfizer.

Athersys and collaborators have performed focused pre-clinical animal studies to address the mechanisms of action through which MultiStem provides benefit in models of ischemic stroke and other models of CNS injury and disease. Comparative microarray analysis of RNA isolated from the infarct region of stroke injured rats receiving cells vs. placebo indicates that cell treated animals have a statistically significant decrease in the expression pattern of transcripts associated with infiltrating activated immune cells. From these data, and similar data we have published testing MultiStem in models of traumatic brain injury and spinal cord injury, we hypothesize systemic administration of MultiStem provides protection to "at risk" neuronal tissues by slowing/halting the acute inflammatory response and mobilization of peripheral immune cells to the site of injury.

More recently, we filed for and received authorization of IND application #13852, a Phase I/II clinical study testing MultiStem in patients suffering an acute ischemic stroke, and are currently enrolling patients to determine the highest well tolerated dose of MultiStem in this patient population.

Biography

Since co-founding Athersys in 1995, Dr. Mays has directed the drug discovery applications of Athersys' cell biological platform technologies. Currently, Dr. Mays is the Head of Neurosciences and the Senior Director of Regenerative Medicine and is focused on the development of Athersys' novel human stem cell product MultiStem® and its applications in Regenerative Medicine, with a specific focus on injuries and diseases affecting the central nervous system. He received his B.S. from Carnegie Mellon in 1987, and his Ph.D. from Stanford University in Molecular and Cellular Physiology. He subsequently studied at the University of Utrecht, the Weizmann Institute and at the University of California, San Francisco. He is currently an adjunct professor at Case Western Reserve University and on faculty at the Center for Stem Cell and Regenerative Medicine and the National Center for Regenerative Medicine.

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