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Denver Spine Physicians Begin Enrollment in United States Stem Cell Therapy Study

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GREENWOOD VILLAGE, Colo., Dec. 13, 2011 /PRNewswire-iReach/ -- DenverSpine today announced that it has enrolled its first patient in a nationwide FDA- cleared adult stem cell study testing novel treatment for chronic low back pain. The study will test the use of Mesenchymal Precursor Cells (MPCs) – adult stem cells derived from bone marrow that will be directly injected into the lumbar disc. The minimally invasive procedure may offer an alternative to back surgery for eligible patients with chronic pain from degenerative discs.

An estimated 30 million people in the United States suffer from back pain. Degenerative disc disease is the most common cause of low-back pain, which develops with the gradual loss of a material called proteoglycan, which cushions the bones of the spine and enables normal motion.

Most patients with low-back pain respond to physical therapy and medications, but in advanced cases, artificial disc replacement or spinal fusion -- removal of the degenerated discs and the fusion of the bones of the spine -- is necessary. However, these surgeries often are not entirely effective.

J. Scott Bainbridge, M.D. is the lead researcher providing spinal injections for the study, and Gary Ghiselli, M.D. is the principal investigator. Both doctors agree on the critical need for a minimally invasive solution to a common, debilitating condition.

"The study is the first of its kind in the United States and we are very excited by the potential of these adult stem cells to provide a novel therapeutic approach," said Dr. Bainbridge.

Researchers will enroll approximately 100 study participants. About 10 – 20 participants will be enrolled at the Denver site and the rest at 11 other medical centers throughout the United States. The trial is scheduled to last for three years.

DenverSpine is enrolling study participants suffering from moderate low-back pain for a minimum of six months and whose condition has not responded to other, conventional treatments.

Once enrolled, patients are randomly assigned to one of four treatment groups:

- One group will receive a high dose of MPCs, plus hyaluronic acid, a substance that facilitates the localization and retention of the stem cells;
- A second group will receive a lower dose of MPCs, plus the hyaluronic acid;
- A third group will receive the hyaluronic acid alone;
- A fourth group will receive only the saline solution.

Patients will receive a single injection of their assigned test agent directly into the center of the target discs within their spine and will be monitored for safety. Patients will also be monitored using imaging to identify any changes in their disease condition or disease progression. Use of pain medications, self-reports of pain, subsequent surgical interventions and assessments of disability, quality of life, productivity and activity will be evaluated. Repair of the disc and reduction of chronic back pain will be assessed in each patient.

Promising results have been observed in prior research using animal models when stem cells were investigated for the repair of damaged spine discs. The cells were well tolerated in these study animals.

This study is sponsored by Mesoblast Limited, a world leader in the development of biologic products for the broad field of regenerative medicine. Mesoblast has the worldwide exclusive rights to a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of adult Mesenchymal Precursor Cells (MPCs). The MPCs are derived from young adult donors' bone marrow and are immune tolerant.

For more information, go to www.denverspine.com.

For additional information on the clinical trial, please see the listing on www.clinicaltrials.gov study identifier number NCT01290367

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DenverSpine is the regional resource for back and neck pain in Denver. It takes a comprehensive approach to complex spine problems, combining the expertise of physical therapists, chiropractors, physical therapists, fellowship-trained spine surgeons and spine therapists.



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