



SpinalCyte Announces Positive 12 Month Pain Data From Phase 1/Phase 2 Clinical Trial for Degenerative Disc Disease

Pain Relief from CybroCell™ Dermal Fibroblasts Could Eliminate Need for Opioids in Some Patients

HOUSTON – October 25, 2018 – SpinalCyte, LLC, a Texas-based regenerative medicine company focused on regrowth of the spinal disc nucleus using human dermal fibroblasts (HDFs), today announced 12-month endpoint data from its Phase 1/Phase 2 clinical trial for treatment of degenerative disc disease (DDD). The analysis showed that patients who received intradiscal injections of the HDF product CybroCell™ had sustained improvement in pain relief and increased back mobility after 12 months. The sustained pain relief suggests that there is a regenerative process stimulated by its cell-based therapy, CybroCell. CybroCell is the first off-the-shelf allogeneic HDF product for treatment of degenerative disc disease.

The landmark Phase 1/Phase 2 clinical trial included 24 patients with chronic lower back pain caused by DDD. The patients' pain levels were measured using the Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS) at 6 and 12-months post-treatment. At the 12-month endpoint, more than 90% of the treatment group had over a 10-point reduction in ODI and 100% had improvement in VAS. On average, treatment group patients showed a 61% improvement over baseline ODI scores, compared to 29% improvement in the placebo group. Patients received intradiscal injections in one to three spinal discs and were randomly assigned to treatment groups which received: a saline injection, an injection of 10 million HDFs or an injection of 10 million HDFs in combination with platelet-rich plasma (PRP).

Previous MRI data from the 6-month endpoint demonstrated superior outcomes in the treatment versus the control group. Of the treatment group, 83% demonstrated increased disc height or no change in one or more discs compared to 66% of control patients. More than half 52% of CybroCell-treated discs showed either increased disc height or no change versus only 38% of control discs. Preclinical animal studies have demonstrated that an intradiscal injection of CybroCell resulted in significant increase in regeneration, disc height, gene expression of structural genes such as collagen type I and collagen type II, and the contents of structural proteins such as proteoglycan, which in turn regenerate the disc nucleus.

“We are encouraged by the significant pain reduction of the CybroCell patients over the control patients,” said SpinalCyte Chief Scientific Officer, Thomas Ichim, Ph.D. “CybroCell has demonstrated clinically relevant outcomes in the area of pain reduction for those patients who received treatment injections. The data suggests CybroCell possesses tangible pain reduction benefits for people suffering from degenerative disc disease, a chronic condition for which previous treatments have not demonstrated a physical improvement in the degenerated disc.”

“We are excited about the sustained pain reduction we witnessed in the treatment arm patients from 6 months to 12 months,” said Pete O’Heeron, Chief Executive Officer, SpinalCyte. “This study provides evidence of long-term reduction in pain and quality of life improvement for treated patients. This will ultimately lead to a reduction or elimination in need for opioids for chronic back pain patients and address the critical opioid epidemic in the U.S.”

SpinalCyte's Phase 1/Phase 2 clinical trial is the first allogeneic use of fibroblasts outside of skin conditions. Considering how relatively easy it is to collect large numbers of fibroblasts which would otherwise be disposed of, researchers believe this trial will advance the clinical translation of fibroblasts into other areas of regenerative medicine.

About SpinalCyte

Based in Houston, Texas, SpinalCyte, LLC is a regenerative medicine company developing an innovative solution for spinal disc regeneration using human dermal fibroblasts. Currently, SpinalCyte holds 33 U.S. and international issued patents and has filed for an additional 43 patents pending. Funded entirely by angel investors, SpinalCyte represents the next generation of medical advancement in cell therapy. Visit www.spinalcyte.com.

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