SpinalCyte Applies with FDA to Expand Human Clinical Trial of CybroCell™ Dermal Fibroblasts as Investigational New Drug (IND)

HOUSTON – **April 12, 2018** – SpinalCyte, LLC, a Texas-based regenerative medicine company focused on regrowth of the spinal disc nucleus using Human Dermal Fibroblasts, has filed an Investigational New Drug (IND) Application with the U.S. Food and Drug Administration (FDA) to expand its study of CybroCell Human Dermal Fibroblasts to treat degenerative disc disease.

"The filing of this IND is a milestone that positions SpinalCyte to lead the industry in validating a human fibroblast-based solution for disc regeneration," said Pete O'Heeron, Chief Executive Officer, SpinalCyte. "We believe this IND application can become the catalyst for further advancement in the quality of life for chronically diseased patients and address an urgent public need and impact the national opioid crisis in the U.S."

SpinalCyte's landmark Phase 1/Phase 2 clinical trial, which is still ongoing, currently includes 24 patients with chronic lower back pain caused by degenerative disc disease. The patients are randomly assigned to one of three groups and receive intradiscal injections in up to three discs. The first group receives placebo in the form of saline only; the second group receives 10 million HDFs and the third group receives 10 million HDFs in combination with platelet-rich plasma (PRP).

While the current treatment for degenerative disc disease is limited to surgical or palliative care, SpinalCyte is focused on a cell therapy solution to this chronic disease. According to preliminary six-month data:

- 83 percent of CybroCell patients according to MRI imaging, demonstrated increased disc height or no change in one or more discs compared to only 66 percent of control patients.
- More than half (52 percent) of CybroCell-treated discs on MRI showed either increased disc height or no change (a clinically relevant outcome) versus only 38 percent of control discs.
- The administration of CybroCell appears to be safe and well tolerated with no adverse events associated with the cell product.

"The future treatment for degenerative disc disease is most assuredly cell therapy," said SpinalCyte Chief Scientific Officer Thomas Ichim, Ph.D. "SpinalCyte has demonstrated its CybroCell product shows significant promise as a long-term therapy and cure."

Over 50 percent of patients treated with CybroCell in the trial reported significant therapeutic improvement. Preclinical animal studies demonstrated that intradiscal injection of CybroCell resulted in a 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 generate the jelly-like material (disc nucleus) that provides cushioning for the spine.

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 from a simple skin biopsy, researchers believe this trial will advance the clinical translation of fibroblasts into other areas of regenerative medicine.

About SpinalCyte, LLC

Based in Houston, Texas, SpinalCyte, LLC is a regenerative medicine company developing an innovative solution for spinal nucleus replacement using human dermal fibroblasts. Currently, SpinalCyte holds 25 U.S. and international issued patents and has filed for an additional 48 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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