Phase 1/2 Clinical Trial Results Positive for SpinalCyte's CybroCell™ Dermal Fibroblasts

Landmark Human Trial Suggests Treatment Could Eliminate Need for Opioids in Some Patients

HOUSTON – **February 13, 2018** – Degenerative disc disease has long been considered an inevitable part of aging, but new breakthrough research from **SpinalCyte, LLC**, a Texas-based regenerative medicine company focused on regrowth of the spinal disc nucleus using human dermal fibroblasts (HDFs), suggests a new cell-based therapy could provide a cure for millions of sufferers. SpinalCyte has completed the first double blind, placebo-controlled human trial using HDF injections to treat sufferers of degenerative disc disease.

Almost 70 percent of patients who were treated with the first off-the-shelf allogeneic HDF product for treatment of degenerative disc disease, called CybroCell, reported significant therapeutic improvement. Prior research has shown that 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 generate the jelly-like material (disc nucleus) that provides cushioning for the spine[1].

"CybroCell, in my opinion is the future of cell therapy," said SpinalCyte Chief Scientific Officer Thomas Ichim, Ph.D. "The current data suggests that CybroCell has the ability to significantly reduce pain, improve patient quality of life and be more effective than conventional stem cells. It has the added benefit of being more economical to produce and easier to acquire. Compared to all of the stem cells that I have worked with in my career, fibroblasts used in CybroCell are much superior."

The landmark Phase 1/2 trial included 16 patients with chronic lower back pain caused by degenerative disc disease. The patients were randomly assigned to one of three groups. The first group received a placebo in the form of saline only; the second group received a single intradiscal injection of 10 million cells of CybroCell and the third group received a single intradiscal injection of 10 million cells of CybroCell in combination with platelet-rich plasma (PRP).

Using the Oswestry Disability Index (ODI), a widely used questionnaire measuring the intensity and disabling effect of lower back pain on daily activities, researchers determined that the ODI of four of the six patients (67 percent) treated with CybroCell decreased by more than 15 points, which is considered a significant therapeutic improvement. One of the four patients (25 percent) treated with CybroCell in combination with platelet-rich plasma (PRP) reported an ODI decrease of more than 15 points while one of six patients (17 percent) in the placebo group reported an ODI decrease of more than 15 points.

"The U.S. opioid crisis is a national emergency, so we consider the development of CybroCell, which may reduce or eliminate the need for opioids among patients suffering from chronic back pain as a result of degenerative disc disease, to be an urgent public health priority," said Pete O'Heeron, Chief Executive Officer, SpinalCyte. "Chronic lower back pain effects nearly 33 million Americans and over 7 million are

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related to degenerative disc disease [2]. This creates a national crisis for their quality of life. Our human trials exceeded our most optimistic projections and we believe it will ultimately lead to a cure for degenerative disc disease. On behalf of everyone at SpinalCyte, I would like to thank the patients and physicians who participated in our Phase 1/Phase 2 trial and let them know we are committed to advancing this novel approach so all patients can benefit."

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

Photo available for download: https://www.dpkpr.com/files/701/

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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 biologics.

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[1]Chee et al. ***Cell Therapy with Human Dermal Fibroblasts Enhances Intervertebral Disk Repair and Decreases Inflammation in the Rabbit Model.*** Global Spine J. 2016 Dec;6(8):771-779. https://0201.nccdn.net/1_2/000/000/18d/7d6/Global-Spine-Journal.pdf

[2]https://academic.oup.com/painmedicine/article-lookup/doi/10.1111/pme.12809