

DiscGenics Completes Patient Enrollment in Japanese Clinical Study of Cell Therapy for Disc Degeneration as US Study Achieves One-Year Follow-up Milestone

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Salt Lake City, UT and Tokyo, Japan – April 27, 2021 – [DiscGenics, Inc.](#), a clinical stage biopharmaceutical company focused on developing regenerative cell-based therapies that alleviate pain and restore function in patients with degenerative diseases of the spine, today announced that it has completed enrollment in its Japanese safety study of IDCT, an allogeneic, injectable Discogenic Cell therapy for lumbar disc degeneration, a major cause of chronic low back pain.

This Japanese 38-subject trial is being conducted at seven sites across the Country and [passed the first of two planned mid-trial safety reviews](#) by an Independent Data Monitoring Committee (IDMC). All treated subjects will be observed and evaluated for safety, primary efficacy, and secondary outcome measures for a period of six months, at which time another IDMC review will be completed. Per the study protocol, subjects will continue to be followed for a six-month extension period.

“Disc degeneration is a significant unmet medical need among Japan’s aging population, and I am pleased to be participating in the clinical evaluation of IDCT as a potential cell therapy to treat this condition,” said Dr. Daisuke Sakai, Associate Professor at the Department of Orthopaedic Surgery at Tokai University School of Medicine in Kanagawa, and the study’s principal investigator. “In preclinical observations of IDCT’s human Discogenic Cells in a canine disc degeneration model, I observed their ability to stop disc height degeneration while improving the structure of the intervertebral disc. If similar results are achieved in humans, the result could be reduced pain and disability associated with disc degeneration.”

This prospective, randomized, double-blinded, sham-controlled, multicenter clinical study is designed to evaluate the safety and preliminary efficacy of IDCT in patients with symptomatic, single-level, mild to moderate lumbar disc degeneration. Subjects who met all eligibility criteria were randomized to one of three treatment cohorts. Primary outcome measures include safety and reduction in pain. Secondary outcome measures include reduction in disability and radiographic improvement.

In Japan, IDCT is being investigated under a [Clinical Trial Notification \(CTN\)](#) through the Pharmaceuticals and Medical Devices Agency (PMDA). For more information, please visit <https://clinicaltrials.gov/ct2/show/NCT03955315>.

Concurrently in the U.S., DiscGenics is conducting an ongoing prospective, randomized, double-blinded, vehicle- and placebo-controlled, multicenter clinical trial of IDCT. All currently enrolled subjects have completed their one-year study visits in our U.S. clinical study of IDCT for lumbar disc degeneration. The study has a one-year extension period, so subjects will continue to be evaluated for safety, primary efficacy, and secondary outcome measures at two additional study visits over the coming year. Through this study, IDCT is being evaluated under an investigational new drug (IND) application through the U.S. Food and Drug Administration (FDA) and will be regulated as a biologic through the Center for Biologics Evaluation and Research (CBER). The U.S. study completed enrollment in Q1 2020, [passed all three planned mid-trial safety reviews](#) and has commenced its second year of patient follow-up. For more information, please visit <https://clinicaltrials.gov/ct2/show/NCT03347708>.

“The achievement of patient enrollment in Japan and our one-year follow-up in the U.S. represent significant milestones for our company and are two very important steps in the development of this potentially regenerative solution for patients suffering from pain associated with disc degeneration,” said Flagg Flanagan, Chief Executive Officer and Chairman of the Board of Directors for DiscGenics. “We are deeply appreciative of the commitment the study investigators and hospitals have shown in helping us get to this critical stage and are looking forward to successful completion of both studies.”

About IDCT

IDCT is a homologous, allogeneic, injectable cell therapy that utilizes proprietary Discogenic Cells, which are biomedically engineered progenitor cells that have been derived from intervertebral disc tissue. Discogenic Cells are reproducibly manufactured in a highly controlled environment under current good manufacturing practices (cGMP) and subjected to extensive testing throughout production and prior to use, including identity, purity, potency and safety. The final product is cryopreserved and maintained as individual “off-the-shelf” doses for administration via percutaneous injection in an out-patient setting.

About Disc Degeneration

Disc degeneration is a painful, chronic and progressive disease that is characterized by inflammation and breakdown of extracellular matrix within the intervertebral disc. The condition is estimated to affect more than one million people, including 200,000 patients needing surgical intervention every year in Japan. Current treatment options for disc degeneration are limited to physical rehabilitation programs and pain management, in the earlier stages. In the more advanced stages, oftentimes a patient’s only option is surgical intervention to remove the painful disc(s), fuse two or more vertebral bones together and/or replace bone or tissue altogether. However, back surgeries often have limited success and may result in subsequent adjacent level degeneration.

About DiscGenics

DiscGenics is a privately held, clinical stage biopharmaceutical company focused on developing regenerative cell-based therapies that alleviate pain and restore function in patients with degenerative diseases of the spine. As the only company in the world to develop an allogeneic cell therapy derived from intervertebral disc cells to treat diseases of the disc, DiscGenics believes it has a unique opportunity to harness the restorative potential of the human body to heal millions of patients suffering from the debilitating effects of back pain. DiscGenics’ first product candidate, IDCT, is a homologous, allogeneic, injectable cell therapy that utilizes biomedically engineered progenitor cells derived from intervertebral disc tissue, known as Discogenic Cells, to offer a non-surgical, potentially regenerative solution for the treatment of patients with mild to moderate degenerative disc disease. For more information, visit discgenics.com.

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