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DiscGenics Receives FDA Fast Track Designation for Cell Therapy for Disc Degeneration

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SALT LAKE CITY, Aug. 26, 2019 /PRNewswire/ -- DiscGenics, Inc., a clinical stage biotechnology 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 the U.S. Food and Drug Administration (FDA)has granted Fast Track designation for its investigational cell therapy, IDCT, currently being evaluated in regulator-allowed clinical trials in the U.S. and Japan for the reduction in pain and disability associated with degenerative disc disease (DDD), a major cause of chronic low back pain.

Fast Track is a special regulatory designation that companies can apply for once they have sufficient preclinical and clinical evidence that a product may be able to treat an unmet medical need for a serious medical condition. With this designation, Sponsors may benefit from early and frequent communication with FDA, eligibility for Accelerated Approval and Priority Review programs, as well as a Rolling Review application process for marketing licensure.

"We are thrilled to receive Fast Track designation for IDCT as it recognizes the extremely compelling preclinical (1) and safety data we have generated for IDCT through our robust research and development and clinical programs, and underscores FDA's acknowledgement of low back pain as a serious medical condition with a profound lack of treatment options," said Flagg Flanagan, Chairman and CEO of DiscGenics, Inc. "This Fast Track designation reinforces our commitment to working with regulators to identify ways to accelerate development and expedite approval of the therapy within existing regulatory

frameworks to make IDCT available to patients as quickly as possible."

IDCT is a homologous, allogeneic, injectable cell therapy that utilizes biomedically engineered progenitor cells, known as Discogenic Cells, that have been derived from intervertebral disc tissue to offer a non-invasive, potentially regenerative solution for the treatment of mild to moderate DDD. As a manufactured allogeneic cell therapy, IDCT is regulated by FDA's Center for Biologics Evaluation and Research (CBER) under Section 351 of the Public Health Service Act (PHSA). As a result, DiscGenics is adhering to the rigors of a regulated drug pathway that require the Company to not only prove that the product has a therapeutic effect through clinical evaluation, but also that it meets critical safety standards and is produced consistently from lot to lot through adherence to current good manufacturing practice (cGMP) standards for a cell therapy.

DiscGenics is conducting two parallel prospective, randomized, double-blinded, controlled, multicenter clinical trials of IDCT in the U.S. and Japan. IDCT is being evaluated in the U.S. under an investigational new drug (IND) allowance by the FDA and will be regulated as a drug-biologic through a biologics license application (BLA). In Japan, the trial is supported by a Clinical Trial Notification (CTN) approved by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). Primary outcome measures include safety and reduction in pain. Secondary outcome measures include reduction in disability and radiographic improvement. Importantly, the U.S. study has shown safety in the first cohort of patients. For both studies, enrollment is ongoing.

About Chronic Low Back Pain and Degenerative Disc Disease
Chronic low back pain is a serious medical condition that represents a leading cause of disability worldwide (2) and is the most common non-cancer reason for opioid prescription in the U.S. (3). It affects 12-30% of U.S. adults at a given time (4) and is estimated to cost the U.S. healthcare system over $100 billion each year (2), creating a significant burden on the economy and individual patients dealing with the condition. In nearly 40% of patients, low back pain is caused by DDD (5-7), a chronic and progressive condition where the intervertebral disc breaks down and causes pain.

About DiscGenics
DiscGenics is a privately held, clinical stage biotechnology 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, visit www.discgenics.com.

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Media Contact
Lindsey Saxon
lindsey@discgenics.com