February 8, 2017

BioRestorative Therapies Receives FDA Clearance to Initiate Phase 2 Clinical Trial for the Treatment of Patients with Degenerative Disc Disease

MELVILLE, N.Y., Feb. 08, 2017 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BRT" or the "Company") (OTCBB:BRTX), a life sciences company focused on stem cell-based therapies, today announced that it has received clearance by the U.S. Food and Drug Administration (FDA) to commence a Phase 2 clinical trial using its lead cell therapy candidate, *BRTX-100*, to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

The Phase 2 clinical trial is a 72 patient, randomized, double-blind, controlled, multi-center study designed to evaluate safety and efficacy of a single dose of *BRTX-100* in treating chronic lower lumbar disc disease. *BRTX-100* will be administered via intradiscal injection into one disc of a subject with chronic lumbar disc disease and whose pain is not responsive to conservative treatment measures (e.g., oral medication, epidural injections and physical therapy). The primary goal of the treatment is to both reduce pain and increase function in these patients.

In January 2017, the Company had submitted an Investigational New Drug Application (IND) to the FDA to obtain clearance to commence this clinical trial using *BRTX-100. BRTX-100* is a product formulated using a patient's own cell population (autologous), which consists of hypoxic (low oxygen) cultured mesenchymal stem cells (MSCs) that are optimized for specific use for a non-surgical, conservative intradiscal procedure that can be performed in a physician's office.

"We are excited to be able to begin our clinical development of *BRTX-100* with this Phase 2 clinical trial," said Mark Weinreb, President and Chief Executive Officer of BioRestorative Therapies. "This treatment has the potential to positively impact millions of Americans suffering from chronic lumbar disc disease as an alternative to surgery. We believe that this technology can be truly transformative and addresses a large market underserved by current therapies."

About BioRestorative Therapies, Inc.

BioRestorative Therapies, Inc. (www.biorestorative.com) develops therapeutic products using cell and tissue protocols, primarily involving adult stem cells. Our two core programs, as described below, relate to the treatment of disc/spine disease and metabolic disorders:

• Disc/Spine Program (brtxDISC™): Our lead cell therapy candidate, *BRTX-100,* is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected

from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of protruding and bulging lumbar discs in patients suffering from chronic lumbar disc disease. The *BRTX-100* production process involves collecting a patient's bone marrow, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, *BRTX-100* is to be injected by a physician into the patient's damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-invasive procedures and who potentially face the prospect of surgery.

• Metabolic Program (ThermoStem®): We are developing a cell-based therapy to target obesity and metabolic disorders using brown adipose (fat) derived stem cells to generate brown adipose tissue ("BAT"). BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in the body may be responsible for additional caloric burning as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. You are cautioned that such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events or results to differ materially from those projected in the forward-looking statements as a result of various factors and other risks, including those set forth in the Company's Form 10-K filed with the Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included herein, and not place undue reliance on such statements. The forward-looking statements in this release are made as of the date hereof and the Company undertakes no obligation to update such statements.

CONTACT:
Email: ir@biorestorative.com

Source: BioRestorative Therapies, Inc.