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BioRestorative Therapies Announces Completion of Human Safety and Feasibility Study on the Use of Hypoxic Cultured Stem Cells to Treat Chronic Lower Back Pain

Data Collected Showed No Adverse Events

MELVILLE, N.Y., June 28, 2016 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BRT" or the "Company") (OTCBB:BRTX), a life sciences company focused on stem cell-based therapies, today announced the completion of a human study entitled "Re-consenting and Follow-Up of Adults from a Retrospective Study Using Autologous Transplantation of Marrow Derived Mesenchymal Stem Cells to Degenerated Intervertebral Disc." The study showed that no adverse events related to the intra-discal injection of autologous, hypoxic cultured, bone marrow-derived mesenchymal stem cells (MSCs) occurred at the time of injection or up to 6 years post-injection, demonstrating initial long-term safety.

The study was comprised of five patients diagnosed with lumbar degenerative disc disease associated with protruding/bulging discs. These patients, in procedures performed in the United States, received autologous, hypoxic cultured, bone marrow-derived MSCs between 2009 and 2010. Four to six years post-cell transplant, these patients re-consented to participate in this study in order to evaluate long-term safety and feasibility. The study included prospective collection of data including a physical examination, the completion of a quality of life questionnaire, and a comparison of pre- and post-MRIs of the treated disc. The Company plans to submit a detailed review of the data to a peer-reviewed journal for publication.

Several independent studies have suggested that hypoxic pre-conditioning has beneficial biological effects that can impact the therapeutic activity of MSCs in the disc. Hypoxic culturing of MSCs produces many desirable effects that may impact the therapeutic activity of the MSCs post-transplant into the limited nutrient, low oxygen tension microenvironment of the degenerative disc.

"The study's findings are very encouraging for the further development of the Company's lead product, BRTX-100, which consists of autologous, hypoxic cultured, bone marrow-derived MSCs. Our study suggests that this procedure represents a potentially attractive avenue for the regenerative treatment of patients with degenerative disc disease," said Mark Weinreb, CEO. "Although these observations are encouraging, the Company is preparing for a larger double-blind, controlled, randomized clinical study with a significant number of patients and implementation of validated endpoint measurements in order to demonstrate safety as well as efficacy of BRTX-100."

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 (*brtx*DISC™): 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 out patient 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.

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