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BioRestorative Therapies Announces Publication in Medical Journal of Positive Results of Long-Term Safety and Feasibility Study Using Cell Therapy to Treat Patients with Degenerative Disc Disease

No Adverse Events and Overall Improvement Reported by Study Patients

MELVILLE, N.Y., Sept. 12, 2016 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BRT" or the "Company") (OTCBB:BRTX), a life sciences company focused on stem cell-based therapies, today announced that the *Journal of Translational Medicine* has published the results of a long-term safety and feasibility study of the injection of autologous, hypoxic cultured mesenchymal stem cells (MSCs) into patients with chronic lumbar degenerative disc disease related to protruding/bulging discs. The Company is preparing for an Investigational New Drug (IND) submission with the FDA to seek clearance to commence a clinical trial using its lead therapy candidate, BRTX-100, which consists of hypoxic cultured MSCs to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

The manuscript, entitled "Intra-discal injection of autologous, hypoxic cultured bone marrow-derived mesenchymal stem cells in five patients with chronic lower back pain: a long-term safety and feasibility study," can be found online at:

http://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-1015-5

According to the publication, early human clinical data suggests safety and feasibility for the clinical use of hypoxic cultured bone marrow-derived mesenchymal stem cells for the treatment of lower back pain due to degenerative disc disorder. All five patients self-reported overall improvement, as well as improvement in strength, post stem cell treatment, and four of the five patients reported improvement in mobility.

The study was comprised of five patients diagnosed with lumbar degenerative disc disease related to protruding/bulging discs. These patients, in procedures performed in the United States, received autologous, hypoxic cultured, bone marrow-derived MSCs between 2009 and 2010. The MSCs were directly injected into the protruding/bulging discs. Four to six years post-cell injection, 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.

Patients' lower back MRI showed absence of neoplasms or abnormalities surrounding the treated region. Based on the physical examination and the quality of life questionnaire, no adverse events were reported due to the procedure or to the stem cell treatment 4–6 years post autologous, hypoxic cultured mesenchymal stem cell injection. The findings indicate support for further studies utilizing hypoxic cultured bone marrow-derived stem cells.

"We are very encouraged by the results of this study and excited to have the data published in a peer-reviewed medical journal," said Mark Weinreb, CEO. "We believe these published results further reinforce the viability of BRTX-100 as a potentially attractive treatment for patients with degenerative disc disease."

"Treatment of disc degeneration and back pain represents a multi-billion-dollar market opportunity. The current non-surgical treatment regimen, including physical therapy, steroids, and narcotic pain medication, are limited to relief of symptoms. No current approved therapies promote disc repair and possible regeneration. We believe BRTX-100 has the potential to become a standard of care for the non-surgical treatment of protruding and bulging lumbar discs."

"This study will be included in our IND submission to the FDA. Upon approval of our IND, we plan to commence a double-blind, controlled, randomized clinical study with a significant number of patients with validated endpoint measurements in order to further demonstrate the 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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Source: BioRestorative Therapies, Inc.