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BioRestorative Therapies Announces Publication of Study Results Validating the Benefits of Using Hypoxic Cultured Cells to Treat Patients with Degenerative Disc Disease

MELVILLE, N.Y., Aug. 15, 2018 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative" or the "Company") (OTC: BRTX), a life sciences company focused on stem cell-based therapies, today announced that the *Journal of Translational Medicine* has published the results of the Company's study evaluating the benefits of long-term hypoxic (low oxygen) culturing of human bone marrow-derived mesenchymal stem cells (cells used in the Company's product, *BRTX-100*). The study included data on cell fitness and whole genome expression and discussed its implication on cellular therapies targeting intervertebral discs and its microenvironment.

The intervertebral disc, due to its avascular (lack of blood cells) nature and anatomy, is extremely hypoxic and this low oxygen environment limits the therapeutic benefits of most cell-based biologics. Based on the study results, expanding cells in hypoxic culture conditions impacts cell fitness and gene expression that may contribute to cell potency and therapeutic benefits. Hypoxia may be of particular importance to select and condition cells that will be best suited for the targeted microenvironment of the disc in order to obtain an optimal therapeutic response.

The manuscript, entitled "Comparing Atmospheric and Hypoxic Cultured Mesenchymal Stem Cell Transcriptome: Implication For Stem Cell Therapies Targeting Intervertebral Discs," can be found online at:

https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-018-1601-9

The study demonstrated that, as compared to cells cultured under normal atmospheric conditions ("normoxic"), hypoxic culturing improves mesenchymal stem cell properties and positively influences whole genome expression profiles with respect to the development of cellular therapies targeting the microenvironment of the intervertebral disc.

The FDA has authorized BioRestorative to commence a Phase 2 clinical trial using hypoxic cultured bone marrow-derived mesenchymal stem cells in its lead candidate, *BRTX-100,* to treat chronic lower back pain. With the results obtained in this study, the Company expects improved patient outcomes using hypoxic cultured cells versus normoxic ones.

"Based on our research, it is clear that the use of hypoxic cells that are used in our product, *BRTX-100*, provides substantial benefits as compared to cells that are cultured in

normoxic conditions," said Francisco Silva, VP of Research and Development. "The therapeutic benefits, as identified by genes involved in chondrogenesis, inflammation and immunomodulation, cellular survival, migration and proliferation, as well as genes involved in vasculogenesis and angiogenesis, all impact the potential clinical outcomes in our contemplated Phase 2 trial."

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 painful lumbosacral disc disorders. The *BRTX-100* production process utilizes proprietary technology and 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. We have received authorization from the Food and Drug Administration to commence a Phase 2 clinical trial using *BRTX-100* to treat persistent lower back pain due to painful degenerative discs.

- 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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