

BioRestorative Therapies Announces Published Study of Licensed Technology to Treat Lumbar Degenerative Disc Disease

Study demonstrates substantially reduced pain, increased function and reduced disc bulge size in most patients

MELVILLE, N.Y., Oct. 05, 2017 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative" or the "Company") (OTC:BRTX), a life sciences company focused on stem cell-based therapies, today announced that an independent lower back pain study has been published in the *Journal of Translational Medicine*, featuring BioRestorative's licensed technologies for the treatment of lumbar degenerative disc disease.

The study, by a physician group based in Colorado, entitled "Treatment of lumbar degenerative disc disease-associated radicular pain with culture-expanded autologous mesenchymal stem cells: a pilot study on safety and efficacy," reported significant improvements in pain and function as well as overall subjective improvement.

The complete publication is available online at: https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-017-1300-y.

In April 2012, the Company licensed this advanced stem cell culture and injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the legs and feet. The Company's lead therapeutic candidate, *BRTX-100*, has received clearance from the Food and Drug Administration to commence a Phase 2 clinical trial.

Key study highlights:

- No serious adverse events
- Over 90% of patients reported overall improvement at 3 years
- Numeric pain scores (NPS) improved from an average of 5.2 prior to treatment to a range of 1.2 to 3.7 post treatment
- Functional rating index (FRI) improved from an average of 60.5 prior to treatment to a range of 31.1 to 44.9 post treatment
- 85% of patients displayed a decrease in posterior disc bulge dimensions

The publication related to 33 patients (in the treatment registry) with lower back pain and disc degeneration with a posterior disc bulge whom were treated with culture-expanded autologous mesenchymal stem cells. This study follows the Company's previously published (September 2016) case series of five patients receiving intradiscal hypoxic-cultured

mesenchymal stem cells and provides further evidence of safety and efficacy in treating lumbar degenerative disc disease. The Company's publication is available online at: https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-1015-5

Mark Weinreb, CEO of BioRestorative, commented, "This study provides strong validation of our core technology in advance of our upcoming Phase 2 trial. Importantly, we have since made further enhancements with respect to manufacturing and formulation by creating a more consistent and potent product, *BRTX-100*. It is important to note that the patients in this study had failed conservative treatment and elected to have this procedure rather than go on to surgery. We believe our treatment will further improve administration and therapeutic outcomes and provide an alternative to opioid use, as well as conventional surgery, a last resort treatment that can be debilitating for patients."

About BioRestorative Therapies, Inc.

BioRestorative Therapies, Inc. (<u>www.biorestorative.com</u>) 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. We have received clearance from the Food and Drug Administration to commence a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging 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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Source: BioRestorative Therapies, Inc.