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BioRestorative Therapies Receives Unanimous Recommendation from Data Safety Monitoring Board (DSMB) to Continue its Phase 2 Clinical Trial without any Changes

- ***No Dose Limiting Toxicity (DLT) was Observed in the Patients in the Safety Run-In Segment of Study***
- ***DSMB Recommendation Allows for Open Enrollment***

MELVILLE, N.Y., June 27, 2023 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a clinical stage company focused on stem cell-based therapies, today announced that the independent Data Safety Monitoring Board ("DSMB"), which is overseeing the Company's ongoing Phase 2 clinical trial to treat chronic lumbar disc disease ("cLDD"), unanimously recommended the continuation of BioRestorative's study in accordance with the current version of the protocol with no changes. The treated patients will receive BRTX-100, a product formulated from autologous (or a person's own) hypoxic cultured mesenchymal stem cells collected from the patient's bone marrow and autologous platelet lysate. Three patients in the safety run-in group received an intradiscal injection of 40,000,000 hypoxic cultured mesenchymal stem cells and one patient received an injection of saline placebo. This safety run-in was used to evaluate the safety and dose limiting toxicity of BRTX-100. There were no DLTs observed in the patients within the safety run segment of the study. Based on the clinical results of the safety run-in segment of the Phase 2 trial, the DSMB recommended that the Company be permitted to commence open enrollment of the 99 patient study. Each of these additional patients (other than those receiving a placebo) will be treated with BRTX-100, which includes 40,000,000 hypoxic cultured mesenchymal stem cells.

"This unanimous recommendation of the DSMB to allow BioRestorative to proceed without any changes to the protocol represents a significant binary outcome and major milestone for the continuation of our clinical program. With the safety profile of BRTX-100 now established through the DSMB process, we intend to accelerate the enrollment of the balance of our 99 patient study. In addition and more importantly, we intend to leverage the product technology platform across multiple indications further extending our pipeline opportunities," said Lance Alstodt, CEO of BioRestorative Therapies.

"The results of this in-depth safety review by an unbiased team of independent experts provides us with great confidence," said Francisco Silva, Vice President of Research and Development of BioRestorative Therapies. "The DSMB, which includes experts in chronic lumbar disc disease, has recommended that the study continue at the present dosage of cells. A DSMB recommendation is a critical step towards confirming the safety of our BRTX-

100. We hope that the treatment of the next set of patients will provide further evidence that BRTX-100 is a safe and effective treatment option for patients with chronic lumbar disc disease."

The Company's Phase 2 clinical trial to treat chronic lumbar disc disease is prospective, randomized, double-blinded and controlled. The multi-center trial will evaluate the safety and preliminary efficacy of a single dose of BRTX-100. A total of up to 99 eligible patients will be randomized at up to 15 clinical sites in the United States. The patients will receive either the investigational drug (BRTX-100) or a placebo in a 2:1 fashion.

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 or as a complementary therapeutic to a surgical procedure. 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 commenced a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain arising from degenerative disc disease.

• Metabolic Program (ThermoStem®): We are developing a cell-based therapy candidate 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 animals 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, without limitation, those set forth in the Company's latest 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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