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BioRestorative Therapies Hosts Principal Investigator Meeting for its BRTX-100® Phase 2 Clinical Trial to Treat Chronic Lumbar Disc Disease

MELVILLE, N.Y., April 29, 2022 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. (the “Company” or “BioRestorative”) (NASDAQ: BRTX), a clinical stage biopharmaceutical company focused on stem cell-based therapies, today announced that it is hosting a Principal Investigators Meeting in Uniondale, NY on April 29th - 30th, 2022 for the Company’s lead clinical candidate BRTX-100®, an autologous bone marrow-derived hypoxic cultured stem cell intended for investigational use in its Phase 2 clinical trial to treat chronic lumbar disc disease.

The meeting will be attended by all principal investigators currently selected across the United States to help coordinate the study, entitled “A Phase 2, Double-Blind, Saline-Controlled, Randomized Study to Evaluate the Safety and Preliminary Efficacy of a Single Dose Intradiscal Injection of BRTX-100 for Patients with Chronic Lumbar Disc Disease (cLDD)”

“I’m pleased to announce that we continue to execute our BRTX-100® development plan in accordance with our previously stated timeline objectives,” said Lance Alstodt, Chief Executive Officer of BioRestorative Therapies. “The Principal Investigator Meeting will be attended in person and will enable a mutual understanding of the study’s goals and set best in class procedures to share experiences among the Principal Investigators.”

The Company plans to recruit 99 subjects for its Phase 2 trial in 15 leading clinical sites across the United States.

Low back pain (LBP) is a common, often confounding, problem for patients and physicians. In the United States, at least 80% of adults experience at least one episode of LBP during their lifetime. Low back pain is the most common cause of disability among Americans between 45 and 65 years of age. Further, of all musculoskeletal conditions, LBP imposes the highest economic burden on the U.S. healthcare system.

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 received authorization from the Food and Drug Administration to commence 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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Source: BioRestorative Therapies, Inc