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BioRestorative Therapies Announces Clinical Site Initiation for the Company's Phase 2 Clinical Trial to Treat Chronic Lumbar Disc Disease (cLDD)

-- First Site Will Enroll First Patient in the Clinical Study--

MELVILLE, NY., June 13, 2022 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. (the "Company" or "BioRestorative") (NASDAQ: BRTX)**,** a clinical stage company focused on stem cell-based therapies, today announced site initiation for its Phase 2 clinical trial targeting chronic lumbar disc disease (cLDD). The Denver Spine and Pain Institute is the first clinical site to be initiated. Additional selected sites are expected to be initiated in 2022.

BioRestorative's Phase 2 trial is a double-blind controlled, randomized study to evaluate the safety and preliminary efficacy of a single dose intradiscal injection of the Company's autologous investigational stem cell-based therapeutic, BRTX-100. A total of up to 99 eligible patients will be randomized at up to 15 centers in the United States to receive either the investigational drug (BRTX-100) or control in a 2:1 fashion.

"Currently there are no approved, cell-based therapies for cLDD. While there is encouraging data that suggests that patients with cLDD could benefit from autologous stem cell transplants, the low oxygen micro-environment of the disc makes cell-based therapies challenging. BRTX-100 is manufactured under low oxygen conditions and engineered to survive this environment," said Scott Bainbridge, M.D., Principal Investigator for the BRTX-100 trial at The Denver Spine and Pain Institute. "Positive proof-of-concept data in this trial could be disruptive and support the potential applicability of BRTX-100 to other spine and musculoskeletal disorders where low oxygen micro-environments are found."

"We are pleased to initiate the first of several sites across the United States that will be enrolling for the trial," said Lance Alstodt, Chief Executive Officer of BioRestorative Therapies. "Our sites have been carefully reviewed and selected and have clinical expertise in treating patients who could potentially benefit from BRTX-100. We look forward to working with the principal investigators and their clinical trial teams."

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. Pursuant to authorization received from the Food and Drug Administration, 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 and other public filings. 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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