June 30, 2022

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

First Patient Enrollment Milestone Completed

MELVILLE, NY., June 30, 2022 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. (the "Company" or "BioRestorative") (NASDAQ: BRTX)**,** a clinical stage company focused on stem cell-based therapies, today announced that the first patient has been enrolled in the Company's Phase 2 clinical trial evaluating the safety and preliminary efficacy of *BRTX-100*, an autologous bone marrow-derived mesenchymal stem cell targeting chronic lumbar disc disease (cLDD). The clinical study is being conducted at up to 15 sites in the United States.

"Announcing first patient enrollment is our most significant clinical milestone to date and an exciting milestone for BioRestorative's clinical programs overall," said Lance Alstodt, CEO of BioRestorative Therapies. "The initiation of patient enrollment in our study reinforces our commitment to treating back pain and is an important step in our efforts to provide patients with potentially improved therapeutic options to treat chronic lumbar disc disease. In addition, I am very proud of the BRTX team for its timely execution. This truly remarkable accomplishment of first patient enrolled in only 6 months from our trial initiation keeps us on schedule to meet our strategic targets."

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.

"Even with the rapid advancements in regenerative medicine across many musculoskeletal disorders over the last decade, there still remain many patients who continue to face unmet needs and experience a high burden of pain and disability," said Jason Lipitz, M.D., primary investigator in the clinical trial. "With BioRestorative's trial now underway, we look forward to seeing the potential clinical impact of *BRTX-100* to treat chronic lumbar disc disease, which could be a paradigm shift in treating back pain."

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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Source: BioRestorative Therapies, Inc