February 7, 2022

BioRestorative Therapies Announces it has Initiated its Phase 2 Clinical Trial to Treat Chronic Lumbar Disc Disease – Site Selection Underway

BioRestorative Provides Update on its Active Phase 2 Clinical Trial

MELVILLE, N.Y., Feb. 07, 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 it has initiated the site selection process for its active Phase 2 clinical trial targeting chronic lumbar disc disease.

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 BRTX-100. A total of up to 99 eligible patients will be randomized at 15 centers in the United States to receive either the investigational drug (BRTX-100) or control in a 2:1 fashion.

"As we prepare to initiate enrollment for our Phase 2 clinical trial and first patient dosed, we will carefully vet our clinical sites so that each is capable of meeting our trial goals and timelines." said Lance Alstodt, the Company's CEO.

Mr. Alstodt continued, "Site selection is a critical process in clinical trials. PRC Clinical (the Company's CRO) and BioRestorative are evaluating clinical sites with a proven track record in disc and pain related studies. The track record will include a comprehensive understanding of, and a careful adherence to, good clinical practice (GCP) trial guidelines. A well-trained, experienced clinic staff is also essential, as is a patient population that is capable of meeting study enrollment goals and timelines."

"PRC Clinical has extensive experience in managing and executing clinical trials, especially as they relate to cell-based therapies to target pain related disorders. We are identifying qualified sites with a proven track record capable of meeting BioRestorative's enrollment and trial timeline," said Curtis Head, CEO of PRC Clinical.

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