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BioRestorative Therapies Announces Activation of Northwell Health in the Company's Phase 2 Clinical Trial Targeting Chronic Lumbar Disc Disease

--Site activation allows for patients in the State of New York to participate in the BRTX-100 trial—

--15 Clinical Sites Identified, 12 of the 15 Activated and Recruiting Subjects

MELVILLE, N.Y., Sept. 08, 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 Northwell Health, New York State's largest health care provider, has been activated and can now start recruitment in the State of New York for BioRestorative's ongoing Phase 2 clinical trial targeting chronic lumbar disc disease ("cLDD"). BioRestorative and Northwell Health entered into a clinical trial agreement in May with regard to the Phase 2 trial. Much effort and collaboration have taken place and, now that site specific training is complete, the site can initiate patient recruitment and enrollment.

BRTX-100, the Company's lead clinical candidate, is a novel cell-based therapeutic engineered to target areas of the body that have little blood flow and limited oxygen supply. It is currently being evaluated in connection with the Company's ongoing Phase 2 clinical trial targeting cLDD. The trial is prospective, randomized, double-blinded and controlled. The trial will evaluate the safety and preliminary efficacy of a single dose of BRTX-100, with 40 million cells injected into the lumbar disc that is causing pain. A total of up to 99 eligible patients will be randomized at up to 15 clinical sites in the United States to receive either the investigational drug (BRTX-100) or control in a 2:1 fashion. BioRestorative recently completed its safety run-in phase of the Phase 2 trial and is now openly enrolling patients across all its clinical sites located throughout the United States.

"I'm pleased to report that, after several months of a deliberate and thoughtful collaboration with Northwell Health, the largest healthcare provider and employer in New York State, we have reached the point of initiating the patient enrollment process. Given the size of Northwell Health and its relative proximity to our facilities in Melville, New York, we look forward to significant benefits from working with Northwell Health in connection with our Phase 2 clinical trial. We hope that our partnership will result in a highly efficient recruitment / enrollment process among other significant benefits," stated Lance Alstodt, Chief Executive Officer of BioRestorative.

Dr. Sohrab Virk of Northwell Health stated, "Everyone at Northwell is laser focused on improving clinical outcomes related to the spine. The technology of BRTX-100 represents a

new hope for improving pain/functionality for our patients dealing with discogenic pain. We are eager to begin our investigation and hope to bring the extensive clinical volume and outstanding physician talent at Northwell to help with this trial.”

Dr. Virk is an orthopedic surgeon who specializes in the treatment of spine-related issues, specifically using minimally invasive surgical techniques and motion sparing technology. He is also an assistant professor of Orthopedic Surgery at the Donald and Barbara Zucker School of Medicine at Hofstra University.

Northwell Health is New York State's largest health care provider and private employer, with 21 hospitals, 850 outpatient facilities and more than 12,000 affiliated physicians. The partnership will enable Northwell Health to begin active recruitment and enrollment in BioRestorative's clinical trial targeting patients suffering from chronic lumbar disc disease.

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 chronic lumbar 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