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BioRestorative Therapies Announces Key Milestone of Dosing Completion in Safety Cohort of Phase 2 Trial Targeting Chronic Lumbar Disc Disease

--Clinical data expected to be reviewed by independent data safety monitoring board (DSMB) as to initial safety dosing profile of BRTX-100--

MELVILLE, N.Y., June 12, 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 the final subject in its BRTX-100 Phase 2 clinical trial safety cohort has been dosed. Four study participants were dosed at a 3:1 ratio with either BRTX-100 or control.

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. BRTX-100 is currently being evaluated in a Phase 2 clinical trial to treat chronic lumbar disc disease ("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 intradiscally injected into the nucleus of the lumbar disc. 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.

The initial safety run-in part of the study is intended to assess the initial safety of a dose of BRTX-100. If no dose limiting toxicity ("DLT") occurs among the four BRTX-100 treated subjects, enrollment will transition and expand to the 2:1 randomization scheme planned for the main component of the study. Establishing the safety profile and DLT of patients dosed with BRTX-100 will allow for open enrollment across all activated clinical sites participating in the clinical trial and accelerate patient recruitment.

"We are excited to announce this important clinical milestone as we continue to drive the development of BRTX-100 as a potential treatment for patients suffering from lower back pain," said Lance Alstodt, CEO of BioRestorative. "I am extremely impressed with the effort of our clinical and operational teams, working collectively throughout the early stages of the trial to coordinate and successfully complete dosing our safety cohort. Open enrollment will enable us to rapidly increase patient recruitment and allow us to work toward the completion of our Phase 2 trial."

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 degenerative disc disease. We are also investigating the expansion of the clinical application of *BRTX-100* to other indications within the body.

• 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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