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# BioRestorative Therapies Announces Completion of Patient Enrollment for Safety Run-In Component of its Phase 2 Clinical Study of BRTX-100

***--Clinical data from safety run-in scheduled to be released in second half of 2023.--***

MELVILLE, N.Y., April 24, 2023 (GLOBE NEWSWIRE) -- [BioRestorative Therapies, Inc.](https://www.biorestorative.com) ("BioRestorative", "BRTX" or the "Company") (NASDAQ:[BRTX](https://www.biotxt.com)), a clinical stage company focused on stem cell-based therapies, today announced that it has completed enrollment for the safety run-in component of its Phase 2 clinical study of BRTX-100 targeting patients suffering from chronic lumbar disc disease (cLDD).

BRTX-100 is the Company's lead clinical candidate, a novel cell-based therapeutic engineered to target areas of the body that have little blood flow. BRTX-100 is currently being evaluated in connection with a Phase 2 clinical trial to treat 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. 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.

Lance Alstodt, Chief Executive Officer of BioRestorative Therapies, stated "The completion of patient recruitment and enrollment for the safety run-in component of our Phase 2 study of BRTX-100 is a very significant milestone for our company. Positive safety data would enable us to initiate unrestricted enrollment across all of our clinical sites and, of course, establish a strong safety profile for BRTX-100. In addition, we would be able to leverage the BRTX-100 platform across other indications within the body on an investigational basis with potentially a shorter timeline from a regulatory pathway perspective."

## **About BioRestorative Therapies, Inc.**

BioRestorative Therapies, Inc. ([www.biorestorative.com](https://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.

- **Metabolic Program (ThermoStem<sup>®</sup>):** 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.*

CONTACT:

Email: [ir@biorestorative.com](mailto:ir@biorestorative.com)



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