

May 31, 2023



# BioRestorative Therapies Receives License from New York State Department of Health to act as Tissue Bank for Mesenchymal Stem Cell Processing

***--License will enable expanded clinical operations for investigator-initiated trials and potential "right to try" uses of BRTX-100.—***

MELVILLE, N.Y., May 31, 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 it has received a license from the New York State Department of Health to act as a tissue bank for the processing of mesenchymal stem cells from autologous donors.

Licensure is an intensive and diligent process, and is required for all tissue and cell-related activities in New York, including collection, processing, storage, and distribution, as well as for any facility distributing tissues to other states. Holders of a New York State license are required to comply with regulations to ensure safe and ethical handling of tissues. Through a comprehensive on-site survey process, facilities are inspected and assessed for acceptable standards of practice and regulatory compliance.

"This is a significant milestone for BRTX as we now can further optimize our ISO 7 certified clean room and manufacturing facility. In addition, we are exploring the ability to do contract manufacturing on behalf of other regenerative medicine companies. Our state of the art facility along with our manufacturing capabilities could provide revenues and help us offset some cash burn related to our laboratory. Finally, what is most exciting about this license is the ability to act as a tissue bank. This will enable us to bank BRTX-100 on behalf of future patients and, if FDA approved, provide those patients with an "off the shelf" autologous cell therapy product once commercially available in the United States", said CEO Lance Alstodt

There are numerous entities that are licensed to operate tissue banks and non-transplant anatomic banks in New York State. The Blood and Tissue Resources Program oversees all human tissue banking activities and services provided in New York State, from donor solicitation to clinical use. The tissue bank regulatory program, being the first comprehensive oversight program for tissue banks in the country, has served as a model for the development of national and other state oversight programs. BioRestorative is the first facility in New York State to be licensed to process mesenchymal stem cells for clinical use.

BRTX-100, a novel cell-based therapeutic engineered to target areas of the body that have little blood flow, is the Company's lead clinical candidate. BRTX-100 is currently being evaluated in connection with 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. A total of up to 99 eligible patients will be randomized at up to 15 clinical sites in the United States. The patients will receive either the investigational drug (BRTX-100) or control in a 2:1 fashion.

BioRestorative's license may facilitate accelerated enrollment in the BRTX-100 cLDD trial. In addition, it potentially will allow for easier access to clinicians who are interested in investigator-initiated clinical studies or exploring "right to try" uses for patients who qualify.

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

BioRestorative Therapies, Inc. ([www.biorestorative.com](http://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<sup>™</sup>): 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)



Source: BioRestorative Therapies, Inc