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BioRestorative Therapies Announces cGMP Cell Manufacturing Facility Certification

Certification Gives BioRestorative Therapies Clinical Grade Manufacturing Capabilities

MELVILLE, N.Y., April 04, 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 completed testing and certification of its clinical grade cell therapy manufacturing facility.

The cGMP manufacturing facility is a three suite ISO 7 certified clean room environment. The facility will support BioRestorative's clinical manufacturing needs 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, its* lead cell therapy candidate. A total of up to 99 eligible patients will be randomized across 15 clinical sites in the United States to receive either the investigational drug (BRTX-100) or control. It is anticipated that the first patient will be treated during the second quarter of 2022.

"Possessing the capability to produce clinical grade therapeutics in-house provides us with valuable quality control and oversight in connection with our Phase 2 clinical trial manufacturing process. The importance of ensuring that *BRTX-100* is produced under the defined standards of quality and release criteria cannot be overly emphasized", said Lance Alstodt, the Company's CEO.

In addition to supporting the manufacturing needs for the *BRTX-100* Phase 2 trial, BioRestorative's facility will also provide clinical production of the Company's pipeline of clinical and investigational cell therapy candidates.

The new facility provides cGMP manufacturing according to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulations and guidelines to support clinical grade cell production.

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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