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BioRestorative Therapies Enters Agreement with Regenexx, Granting BRTX Exclusive License Rights for Intellectual Property Related to the Development and Commercialization of its BRTX-100® Disc Program to Treat Chronic Lumbar Disc Disease

-- Intellectual Property Provides a Cell-Based Therapeutic Platform Designed to Target All Avascular Zones--

MELVILLE, N.Y., Dec. 05, 2022 (GLOBE NEWSWIRE) -- [BioRestorative Therapies, Inc.](#) ("BioRestorative" or the "Company") (NASDAQ: [BRTX](#)), a clinical stage company focused on stem cell-based therapies, today announced an agreement with [Regenexx, LLC](#) pursuant to which the license rights granted by Regenexx to the Company for intellectual property developed to address chronic lumbar disc disease have been made exclusive. The intellectual property now exclusively licensed to the Company represents important technological framework for BRTX's disc/spine technology related to the Company's BRTX-100® lead clinical program, currently in a Phase 2 trial with approximately 15 sites selected across the United States. The intellectual property was developed in the lab of [Dr. Christopher Centeno](#). Dr. Centeno has been a leader in the field of cellular therapy for musculoskeletal indications for over 17 years.

"This is an important event for BioRestorative. We are thrilled to now have through this agreement an exclusive license with regard to Regenexx's technology," said [Lance Alstodt](#), Chief Executive Officer at BioRestorative. "With this agreement, coupled with our unique in-house research and manufacturing capabilities, we aim to create a new generation of cell-based products to induce long-term and sustained pain relief for patients suffering from musculoskeletal indications. Approximately \$40 billion is spent annually on invasive surgical procedures. With BRTX-100, the Company is seeking to provide a paradigm shifting, non-invasive solution to millions of patients worldwide."

The BRTX-100 platform is a cell-based technology that utilizes low oxygen (hypoxia) to engineer the cells' modulation strategy to repress or activate transcription of target genes related to tissue remodeling. Data from early investigator-initiated human studies suggest a potential for this platform to regulate target hypoxia-dependent gene expression as a means to improve upon both the efficacy and safety of first-generation cell-based therapies.

“Regenexx is excited to have granted exclusive license rights to BioRestorative and support their efforts as they continue to develop the technology through the regulatory pathway. We have a great deal of clinical experience with positive clinical outcomes using this technology. We are grateful that BioRestorative is working to provide access to this product to the many patients who are currently left with minimal options that are less effective and more economically inefficient.” said Christopher Centeno MD, Founder and Chief Medical Officer for Regenexx, LLC.

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. Pursuant to authorization received from the Food and Drug Administration, 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 [®]): 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 and other public filings. 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