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BioRestorative Therapies Announces Notice of Allowance on Key Patent for its BRTX-100® Disc Program

Notice of Allowance Grants Protection for BioRestorative's Phase 2 Clinical Program to Treat Chronic Lumbar Disc Disease

MELVILLE, N.Y., Feb. 16, 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 the United States Patent and Trademark Office has issued a notice of allowance for a patent application related to the Company's *BRTX-100*® core clinical program.

Claims granted under the key patent cover a method of preparing *BRTX-100*®, a stem cell population derived from bone marrow, grown under hypoxic (low oxygen) conditions, and used to treat avascular zones, such as the intervertebral disc. The method of preparing stem cells under low oxygen conditions is designed to optimize the therapeutic potential of the cells once implanted in the low oxygen environment of the damaged disc.

"The issuance of this key patent is among the most significant milestones for the Company as the protection granted in the claims covers methodologies used in the manufacturing of our cell-based therapeutic," said Lance Alstodt, the Company's CEO. "We intend to continue expanding and fortifying our intellectual property portfolio for *BRTX-100*® in the U.S. and internationally as we advance our clinical development program to treat chronic lumbar disc disease, which we believe presents a significant potential market opportunity. Additionally, we believe this is in line with our promise to continue to build fundamental value to our business and for our shareholders."

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