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BioRestorative Therapies Announces CRO Agreement with PRC Clinical for its BRTX-100 Phase 2 Clinical Trial to Treat Chronic Lumbar Disc Disease

MELVILLE, N.Y., Dec. 21, 2021 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. (the "Company" or "BioRestorative") (NASDAQ:[BRTX](#)), a life sciences company focused on adult stem cell-based therapies, today announced it has entered into a Master Service Agreement with PRC Clinical, a contract research organization (CRO) specializing in clinical trial management to conduct BioRestorative's Phase 2 clinical trial.

PRC Clinical is an all-inclusive CRO and has specialized expertise across regenerative medicine, CNS, ophthalmology, pulmonary and COVID-19, rare and orphan disease and more complex indications. Their innovative approach to executing studies for biotech and pharmaceutical companies combines high-touch human elements and cutting-edge technology with extensive experience and deep therapeutic knowledge. Pursuant to the agreement, PRC Clinical will manage BioRestorative's Phase 2 clinical study of BRTX-100, the Company's lead clinical product to treat chronic lumbar disc disease.

"This is a significant milestone in our mission to develop cell-based therapeutics and to become a clinical stage company. We believe that PRC's renowned expertise in conducting clinicals trials and their use of innovative technology makes them an excellent CRO to partner with," said Lance Alstodt, Chief Executive Officer of BioRestorative Therapies. "This is the most meaningful step the Company has taken to initiate our clinical trial. We should now expect a host of developments pertaining to the advancement of our clinical trial, ultimately leading to the read out of our primary endpoints."

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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Source: BioRestorative Therapies, Inc