February 5, 2024

BioRestorative Therapies Presents Preliminary Clinical Data from Phase 2 Study of BRTX-100 in Chronic Lumbar Disc Disease

— Preliminary data includes 26 and 52-week follow-up end points as part of ongoing Phase 2 trial —

— Company to host webcasted conference call today at 8:30am EST —

MELVILLE, N.Y., Feb. 05, 2024 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a clinical stage company focused on stem cell-based therapies, today announced the public availability of a poster, presented yesterday at the Orthopaedic Research Society (ORS) 2024 Annual Meeting, which describes preliminary 26 and 52 week blinded data from the ongoing Phase 2 clinical trial of the Company's lead clinical candidate, BRTX-100, in subjects with chronic lumbar disc disease ("cLDD").

The presented poster, titled "Autologous Stem Cell Therapy for Chronic Lumbar Disc Disease; Initial Phase 2 Clinical Safety and Feasibility Data of Intradiscal Injections of Hypoxic Cultured Mesenchymal Stem Cells" can be accessed on the Company's website at www.biorestorative.com under "Scientific Publications" in the Product Candidate section. During a webcasted conference call scheduled for 8:30am EST today, BioRestorative management will be available to discuss data from the presentation as well as provide a clinical update.

Previous clinical studies have demonstrated that the harsh microenvironment of the disc could impact cell dose viability and result in a non-efficacious or the worsening of clinical outcomes. Although this is blinded and early clinical data, it is important to note that the Visual Analog Scale, Oswestry Disability Index, Roland Morris Disability Questionnaire, and Functional Rating Index collected at weeks 26 and 52 post-injection demonstrated a positive trend compared to baseline. In addition to safety outcomes, changes to these pain and function scales compared to baseline are used by the U.S. Food and Drug Administration (FDA) to determine whether the trial will be allowed to proceed and ultimately gain Biologics License Application (BLA) approval.

"We are thrilled with the progress of our ongoing clinical development programs. With regard to the Phase 2 study investigating the use of BRTX-100 in the treatment of cLDD, we are strongly encouraged by the preliminary data presented at ORS 2024. The preliminary clinical data shows meaningful signals in patients enrolled in the study and, importantly, no notable safety signals," said Lance Alstodt, Chief Executive Officer of BioRestorative.

Conference Call & Webcast Information

BioRestorative management will host a webcasted conference call with an associated slide presentation today, February 5, at 8:30AM EST. To join the conference call via phone and participate in the live Q&A session, please dial 888-506-0062 (United States) or 973-528-0011 (International), participant access code 234972. The live webcast and audio archive of the presentation may be accessed on the investor section of the BioRestorative website at https://www.biorestorative.com/investor-relations/. An archived replay will be available for approximately 90 days following the event.

About BRTX-100

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. The safety and efficacy of BRTX-100 in treating cLDD is being evaluated in a Phase 2, prospective, randomized, double-blinded and controlled study. A total of up to 99 eligible subjects will be enrolled at up to 16 clinical sites in the United States. Subjects included in the trial will be randomized 2:1 to receive either *BRTX-100* or control.

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 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. 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