February 10, 2026

BioRestorative Completes Patient Enrollment in Landmark Phase 2 Trial of BRTX-100 for Chronic Lumbar Disc Disease

- *Largest FDA-authorized Phase 2 cell therapy trial conducted in chronic lumbar disc disease*
- *The study has enrolled a total of 99 participants, each of whom was randomized to receive either BRTX-100 or placebo*
- *Prospective, randomized, double-blind, sham-controlled single-disc study — gold-standard clinical design*
- *Enrollment completion strengthens regulatory pathway toward Phase 3 and potential BLA filing*

MELVILLE, N.Y., Feb. 10, 2026 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a late stage clinical regenerative medicine innovator focused on stem cell-based therapies and products, today announced completion of patient enrollment in its Phase 2 clinical trial evaluating the safety and efficacy of BRTX-100 for the treatment of chronic lumbar disc disease ("cLDD").

BRTX-100 is BioRestorative's lead clinical candidate — an autologous, hypoxically cultured mesenchymal stem cell therapy engineered for delivery into low-oxygen, low-nutrient disc environments.

With 99 patients enrolled across 15 leading U.S. clinical sites, the BRTX-100 Phase 2 study represents, the Company believes, the largest Phase 2 cell-therapy trial conducted in cLDD under a Food and Drug Administration ("FDA") Investigational New Drug (IND) application and ranks among the largest controlled cell-therapy trials in spine medicine to date.

The trial utilizes a prospective, randomized, double-blind, sham-controlled design focused on single-disc disease, widely considered the gold standard for clinical rigor in spine intervention studies. Participants were randomized 2:1 to receive either BRTX-100 or placebo through a minimally invasive outpatient intradiscal procedure.

The primary safety endpoint for the Phase 2 clinical trial of BRTX-100 in cLDD is the frequency and severity of adverse events (AEs). The primary efficacy endpoints of the trial are a greater than 30% improvement in function in the Oswestry Disability Index (ODI) and a greater than 30% reduction in pain on the Visual Analog Scale (VAS) vs. baseline at week 52.

Single-disc enrollment criteria are notably restrictive and historically challenging, underscoring the significance of completing full enrollment at this scale.

“Our manufacturing, quality control and clinical teams executed exceptionally well in completing enrollment in a highly selective, technically demanding study design,” said Francisco Silva, Vice President of Research and Development. “Interest from both investigators and patients was driven in part by the preliminary blinded data we presented at multiple leading scientific conferences, including ISSCR, ISCT, ORS, and the International Spine Research Symposium. We are deeply grateful to the patients and investigators whose participation made this milestone possible.”

Approximately 40% of total enrollment occurred within the past six months, reflecting accelerating site productivity and investigator engagement.

“This is a defining operational and clinical milestone for BioRestorative,” said Lance Alstodt, Chief Executive Officer. “Completing enrollment in what we believe is the largest and most rigorously designed Phase 2 cell-therapy trial in chronic lumbar disc disease represents years of disciplined execution and scientific focus.”

“This is not only a scale milestone — it is a quality milestone. A randomized, double-blind, sham-controlled, single-disc trial sets a high evidentiary bar and positions the program for meaningful regulatory dialogue and advancement,” added Mr. Alstodt. “Indeed, based on the compelling preliminary blinded Phase 2 data we have reported to date, together with constructive feedback from our recent FDA Type B meeting, we believe we have a clear and actionable pathway toward Phase 3 development and a potential BLA submission. We look forward to providing additional updates as we advance the program in the very near future.”

About Chronic Lumbar Disc Disease

cLDD is a common, often confounding problem for patients and physicians. In the United States, at least 80% of adults experience at least one episode of lower back pain during their lifetime. Low back pain is the most common cause of disability among Americans between 45 and 65 years of age and imposes the highest economic burden on the U.S. healthcare system. The standard of care for treating cLDD involves conservative non-surgical approaches or surgical interventions that target symptomatic relief and musculoskeletal stabilization. Currently, there is no clinical therapy targeting the reversal of disc degeneration or that addresses intervertebral disc cell homeostasis.

About BRTX-100

BRTX-100, a novel cell-based therapeutic engineered to target areas of the body that have little blood flow, is BioRestorative’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 99 eligible subjects have been enrolled at 15 clinical sites in the United States. Subjects included in the trial were randomized 2:1 to receive either BRTX-100 or placebo. Further details of the trial can be found at www.clinicaltrials.gov under NCT identifier: NCT04042844.

About BioRestorative Therapies, Inc.

BioRestorative (www.biorestorative.com) develops therapeutic products using cell and tissue protocols, primarily involving adult stem cells. As described below, our two core clinical development programs relate to the treatment of disc/spine disease and metabolic disorders, and we also operate a commercial BioCosmeceutical platform:

• 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. We have also obtained U.S. Food and Drug Administration ("FDA") Investigational New Drug ("IND") clearance to evaluate BRTX-100 in the treatment of chronic cervical discogenic pain.

• Metabolic Program (ThermoStem®): We are developing cell-based therapy candidates to target obesity and metabolic disorders using brown adipose (fat) derived stem cells ("BADSC") to generate brown adipose tissue ("BAT"), as well as exosomes secreted by BADSC. 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. BADSC secreted exosomes may also impact weight loss.

• BioCosmeceuticals: We operate a commercial BioCosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-based biologic aesthetic products and therapeutics via IND-enabling studies, with the aim of pioneering FDA approvals in the emerging BioCosmeceuticals space.

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, as amended, 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