February 11, 2026

BioRestorative Announces Positive Outcome from Type B Meeting with FDA

- *BioRestorative completed a Type B meeting with the U.S. Food and Drug Administration ("FDA") regarding a potential accelerated Biologics License Application ("BLA") approval pathway for the Fast-Track-Designated BRTX-100 program for the treatment of chronic lumbar disc disease ("cLDD")*
- *Consistent positive clinical safety endpoints from BioRestorative's ongoing 99 patient Phase 2 clinical trial of BRTX-100 in cLDD were discussed in the meeting and the FDA did not raise any clinical safety concerns*
- *FDA endorsed the proposed Phase 3 study design (i.e., outcome assessments, dosing strategy, and eligibility criteria), sample size, and powering assumptions pending final review of Phase 3 investigational new drug ("IND") application submission*
- *FDA feedback confirms alignment of the Company's ongoing Chemistry Manufacturing and Controls (CMC) activities prior to submission of an IND application for a Phase 3 trial*
- *Based on the positive final official summary of this Type B meeting, BioRestorative has initiated Phase 3 enabling activities, with the goal of submitting the Phase 3 IND application later this year*

MELVILLE, N.Y., Feb. 11, 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 provided an update following the positive feedback received from the FDA regarding a potential expedited Biologics License Application ("BLA") approval pathway for the Fast-Track-Designated BRTX-100 program for the treatment of chronic lumbar disc disease ("cLDD"), based on a Type B meeting requested by the Company.

"The positive outcome of our Type B meeting with the FDA provides the clarity needed to support a pathway to expedited BLA approval for our BRTX-100 program in cLDD," said Lance Alstodt, Chief Executive Officer of BioRestorative. "In addition, we believe the fact that we can prepare and submit the Phase 3 IND application ahead of unblinding the ongoing Phase 2 trial is a testament to the excellent safety profile and upward trend in efficacy endpoints demonstrated to-date."

Based on ongoing activities, the Company currently anticipates that the Phase 3 trial IND submission will be made in the second half of 2026.

About Fast Track Designation

The FDA granted Fast Track designation to the BRTX-100 Phase 2 clinical trial for the treatment of cLDD in February 2025. This FDA program is aimed to facilitate the development, and expedite the review, of investigational treatments that are designed to

treat serious conditions and have the potential to address significant unmet medical needs. Benefits of the program include early and frequent interactions with the FDA during the clinical development process, and stem cell product candidates with Fast Track designation may also be eligible for Priority Review and Accelerated BLA Approval.

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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