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BioRestorative Reports Compelling Preliminary Data for FDA-Fast-Tracked BRTX-100 – an Autologous Stem Cell Therapy to Treat Chronic Lumbar Disc Disease

– The International Society for Stem Cell Research ("ISSCR") 2025 Annual Meeting is the world's foremost gathering of stem cell and regenerative medicine leaders –

– Updated data presented at ISSCR 2025 demonstrates >50% improvement in pain and function in a significant portion of cLDD subjects –

– Number of evaluated subjects increases by more than two-fold since last update —

MELVILLE, N.Y., June 13, 2025 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative," "BRTX" or the "Company") (NASDAQ: BRTX), a clinical-stage regenerative medicine company developing stem cell-based therapies for serious musculoskeletal conditions, today announced the presentation of promising preliminary blinded data from the first 36 subjects in its ongoing Phase 2 clinical trial of BRTX-100, an autologous stem cell therapy for chronic lumbar disc disease (cLDD). This data was shared at the prestigious ISSCR 2025 Annual Meeting in Hong Kong by Francisco Silva, Vice President of Research and Development.

The U.S. Food and Drug Administration ("FDA") is requiring at least 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") in determining whether the clinical trial will be allowed to proceed and ultimately gain Biologics License Application (BLA) approval.

Key Highlights:

- **Patient Numbers Growing:** The number of subjects evaluated has increased from 15 to 36 since the Company's last press release — an important milestone toward full Phase 2 enrollment (up to 99 subjects).
- **Compelling Clinical Signals:**
  - Over 74% of subjects showed >50% improvement in function (ODI) by 52 weeks;
  - Over 72% of subjects reported >50% reduction in pain (VAS) by 52 weeks;
  - Combined >50% improvement in both ODI and VAS measures was achieved by a meaningful portion of subjects across all timepoints.
- **Excellent Safety Profile:** No serious adverse events (SAEs) or dose-limiting toxicities reported between 26 and 104 weeks at the target dose (40 million cells).

- **Strengthening Data:** Each new data analysis has outperformed prior releases, highlighting an upward trend in efficacy markers.

The following is a detailed breakdown of the subjects that had greater than 50% improvement in function, as measured by ODI, greater than 50% decrease in pain, as measured by VAS, and greater than 50% improvement in both ODI and VAS:

Week	Percentage of Subjects With >50% Average Improvement in ODI	Percentage of Subjects With >50% Average Improvement in VAS	Number of Subjects With >50% Average Improvement in Both ODI and VAS
Baseline	0.00%	0.00%	0/36
12	67.57%	73.82%	5/25
26	74.04%	76.94%	6/15
52	74.63%	72.35%	8/10
104	75.13%	68.54%	2/4

“With every new analysis, our confidence grows that BRTX-100 is positioned to meet and potentially exceed the FDA’s functional and pain reduction thresholds,” said Lance Alstodt, Chief Executive Officer of BioRestorative. “We are excited by the trajectory of this material milestone and its potential to address a massive unmet need in chronic lower back pain — one of the largest global healthcare burdens. We believe this data moves us one step closer to bringing a much-needed, non-surgical therapeutic option to market and should add to further value enhancing inflection points in the near-term.”

The data were presented as part of the Clinical Innovations track at ISSCR 2025, an event that attracts the world’s top stem cell and regenerative medicine researchers, clinicians, and investors.

About the BRTX-100 Phase 2 Trial

BRTX-100 is a novel, autologous cell-based therapy designed to treat patients suffering from painful lumbosacral disc degeneration. The Phase 2 trial is a randomized, double-blinded, placebo-controlled study that will enroll up to 99 subjects at 16 leading U.S. sites. Subjects are randomized 2:1 to receive either BRTX-100 or placebo via a minimally invasive outpatient procedure.

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, 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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