November 13, 2024

BioRestorative Therapies Reports Positive Preliminary Phase 2 BRTX-100 Clinical Data

– Blinded preliminary data demonstrate a positive trend and clear signal in Primary and Secondary endpoints –

– Patient reported efficacy outcomes show a material decrease in pain and increase in function –

– If positive trends continue, Company confident that the Phase 2 trial will meet its Primary and Secondary end points -

– The blinded preliminary BRTX-100 data to be described in a podium presentation this morning at the ORS PSRS 7th International Spine Research Symposium –

– Webcasted conference call also scheduled for today at 4:30pm EST –

MELVILLE, N.Y., Nov. 13, 2024 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a clinical stage regenerative medicine innovator focused on stem cell-based therapies and products, today announced new preliminary 26–52 week blinded data from the first 10 patients with chronic lumbar disc disease ("cLDD") enrolled in the ongoing Phase 2 clinical trial of 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 placebo.

No serious adverse events (SAEs) were reported in any of the 10 safety run-in subjects. Notably, there was also no dose ($40X10^6$ cells) limiting toxicity at 26-52 weeks.

In addition to the aforementioned preliminary primary safety endpoint data, the Company reported blinded clinical data on the secondary efficacy endpoint of at least a 30% decrease in pain as measured on the Visual Analog Scale ("VAS") and at least a 30% increase in function based on the Oswestry Disability Index ("ODI") at week 52. The blinded preliminary efficacy endpoint data demonstrated:

- At 26 weeks, 70% of subjects (n=10) reported a >30% improvement in VAS versus baseline;

- At 52 weeks, 100% of subjects (n=4) reported a >30% improvement in VAS versus baseline (n=4);
- At 12 and 26 weeks, 70% of subjects (n=10) had a >30% improvement in ODI versus baseline;
- At 52 weeks, 100% of subjects (n=4) had a >30% improvement in ODI versus baseline; and
- At 26 weeks, 70% of subjects (n=10) reported a >30% decrease in pain (VAS) and a >30% increase in function (ODI).

“Blinded preliminary clinical data of safety and efficacy endpoints from the ongoing Phase 2 clinical trial of BRTX-100 in the treatment of cLDD are very encouraging, with patient reported pain and function outcomes demonstrating a positive trend,” said Lance Alstodt, Chief Executive Officer of BioRestorative. “Most importantly, at 26 weeks 70% of the patients are reporting a greater than 30% increase in function and a more than 30% decrease in pain. If data continues with this trend, we are confident that we will hit our efficacy end points for the Phase 2 trial.”

This new blinded preliminary safety and efficacy data from the ongoing Phase 2 clinical trial of BRTX-100 will be described in podium presentation later today at the Orthopaedic Research Society (ORS) Philadelphia Spine Research Society (PSRS) 7th International Spine Research Symposium, taking place in Skytop, Pennsylvania. BioRestorative management will also host a webcasted conference call with an associated slide presentation today at 4:30pm EST to review the BRTX-100 data, as well as review its third quarter 2024 financial results and provide a business update.

Conference Call & Webcast Details

To join the conference call via phone and participate in the live Q&A session, please dial 877-545-0320 (United States) or 973-528-0002 (International), participant access code 823128. The live webcast (with slides) 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 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 have also recently begun offering BioCosmeceutical products:

• 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 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 Investigational New Drug (IND)-enabling studies, with the aim of pioneering U.S. Food and Drug Administration (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, and Form 10-Q 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.

CONTACT:

Stephen Kilmer
Investor Relations
Direct: (646) 274-3580
Email: skilmer@biorestorative.com

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