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BioRestorative Therapies Partners with Galen Patient Recruitment to Accelerate Completion of Enrollment in Phase 2 Trial of BRTX-100 in Chronic Lumbar Disc Disease

— Collaboration follows recent manufacturing/clinical process enhancements that have tripled monthly trial capacity —

— Patient enrollment expected to be completed in 2024 —

MELVILLE, N.Y., April 08, 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 a collaboration with Galen Patient Recruitment, Inc. ("Galen") which, combined with the recent expansion of clinical trial capacity from approximately 10 to 30 participants per month, is expected to help accelerate the completion of patient enrollment in the ongoing Phase 2 study of BioRestorative's lead clinical candidate, BRTX-100, in chronic lumbar disc disease ("cLDD").

BRTX-100 is a novel cell-based therapeutic engineered to target areas of the body that have little blood flow. 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.

"The industry statistics can be sobering; around 80% of clinical trials fail to meet their initial enrollment targets and timelines, with patient recruitment being the single biggest cause of trial delays,"[1] said Lance Alstodt, Chief Executive Officer of BioRestorative. "With that in mind, we are confident that our partnership with an industry leader like Galen will help us achieve our 2024 enrollment goals by closing any gaps that may exist in our current recruitment process."

Reference

[1] Brøgger-Mikkelsen M, Ali Z, Zibert JR, Andersen AD, Thomsen SF. Online Patient Recruitment in Clinical Trials: Systematic Review and Meta-Analysis. J Med Internet Res. 2020 Nov 4;22(11):e22179. doi: 10.2196/22179. PMID: 33146627; PMCID: PMC7673977.

About Galen Patient Recruitment

Since 2006, Galen (www.galenrecruitment.com) has helped its clients bring new medical innovations to market through cost-effective patient recruitment solutions. Galen doesn't believe in one-size fits all. It approaches each study with a fresh perspective, and considers all of the variables in the study enrollment equation – the research sites, study coordinators and, most importantly, the patients. This leads to comprehensive yet flexible recruitment programs that take the guesswork out of achieving enrollment goals.

About BioRestorative Therapies

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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