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# BioRestorative Therapies Announces Notice of Allowance for Patent Covering Fundamental Aspect of ThermoStem® Metabolic Disease Program

*– Adds to comprehensive patent portfolio underlying novel ThermoStem® technology platform –*

*– Expanding intellectual property estate expected to help drive ThermoStem® licensing opportunities –*

*– Substantive discussions continue with commercial stage regenerative medicine company with regard to a license of ThermoStem® IP –*

MELVILLE, N.Y., June 27, 2024 (GLOBE NEWSWIRE) -- BioRestorative Therapies, Inc. ("BioRestorative", "BRTX" or the "Company") (NASDAQ:BRTX), a clinical stage company focused on stem cell-based therapies, is pleased to announce that it has received a notice of allowance from the Japanese Patent Office for patent application No. 2021-564135 related to the Company's allogeneic, off-the-shelf ThermoStem® platform.

Previously published peer-reviewed preclinical data from a study conducted in collaboration with the University of Utah School of Medicine ("UUSOM") demonstrated a clonogenic population of metabolically active brown adipose tissue ("BAT") stem cells residing in adult humans that: (i) can be expanded *in vitro*; (ii) exhibit multilineage differentiation potential (osteogenetic, chondrogenic and adipogenic); and (iii), functionally differentiate into metabolically active brown adipocytes. In addition, the preclinical results confirmed that multipotent brown adipose derived stem cells ("BADSCs") induced to differentiate into brown adipocytes exhibit the mature functional properties of these cells, including increased mitochondrial activity, an important functional characteristic of BAT.

In the UUSOM study, data obtained in high-fat fed NOD-SCID mice transplanted with differentiated BADSCs supported by a BioRestorative-developed 3D Porous Extracellular Matrix-Derived Scaffold showed significant reductions in weight (consistent with losses achieved by GLP1 drugs), triglyceride and blood glucose levels compared to saline-only injected controls. The study also demonstrated that BioRestorative's 3D scaffold was capable of retaining viable transplanted cells for at least five weeks post-implantation.

This, the fifth Japanese patent to issue for BioRestorative's ThermoStem® technology platform, covers a method of making three-dimensional brown adipose derived stem cell aggregates in the absence of differentiation medium.

“As awareness of the promise that our ThermoStem®-based BADSCs hold for the treatment of obesity and related metabolic disorders continues to grow, it is important that this potentially game-changing opportunity is well protected, both for us and any current and/or future potential licensing partners,” said Lance Alstodt, BioRestorative’s Chief Executive Officer. “To that end, and as demonstrated by this new patent allowance, we are proactively expanding the already formidable ThermoStem® intellectual property estate to help ensure long-term market exclusivity.”

Substantive discussions with an undisclosed commercial stage regenerative medicine company with regard to a license of BioRestorative’s ThermoStem® metabolic intellectual property, as previously reported, are continuing. No assurances can be given that a license agreement will be entered into whether on commercially reasonable terms or otherwise.

**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, 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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