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# BioRestorative Therapies Enhances Preclinical Metabolic Program with a Novel Exosome-Based Biologic Targeting Obesity

- *New therapeutic candidate developed using Company's patented ThermoStem<sup>®</sup> platform* —
- *Candidate has potential to serve as an adjuvant to existing pharmaceuticals that are FDA approved and marketed towards weight loss* —
- *DMF submission and commencement of first-in-human studies targeted for before the end of 2024* —
- *Expanding the use of ThermoStem<sup>®</sup> may open the door to big pharma partnership opportunities* —

MELVILLE, N.Y., May 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 its development of a novel exosome-based biologic program targeting obesity.

BioRestorative currently anticipates initiating the formal U.S. Food and Drug Administration ("FDA") process for this ThermoStem<sup>®</sup>-based therapeutic candidate by filing a Drug Master File ("DMF") in the third quarter of 2024. The Company aims to initiate first-in-human clinical studies before the end of the year.

Exosomes are small extracellular vesicles secreted by various cells, including stem cells. They are understood to be important mediators of intercellular communication, and have been found to play a role in adipose (fat) metabolism by transporting cargo, such as non-coding RNAs (ncRNA), proteins, and other factors that may impact weight loss. Previously [published](#) peer-reviewed preclinical data from a study conducted in collaboration with the University of Utah School of Medicine demonstrated that functional brown adipose derived stem cells, formulated using BioRestorative's proprietary ThermoStem<sup>®</sup> platform, produced significant reductions in weight (consistent with losses achieved by GLP1 drugs) and blood glucose levels in a diet induced obesity model in mice.

BioRestorative's ThermoStem<sup>®</sup> platform has a comprehensive portfolio of issued patents that cover both the U.S. and international markets. This broad intellectual property portfolio can be leveraged across drugs that are currently approved and marketed for weight loss, potentially opening the door to future big pharma partnership opportunities for the Company.

“We believe that our proprietary ThermoStem<sup>®</sup> technology platform has immense potential to develop both best-in-class and first-in-class therapies to treat obesity, such as this exosome-based biologic candidate,” said Lance Alstodt, BioRestorative’s Chief Executive Officer. “While tremendous progress has been made in the fight against obesity, there is no question that significant unmet need remains. As an adjuvant to approved and marketed weight loss drugs, we believe that our new therapeutic candidate may allow for lower dosing, as well as prevent or minimize potential of muscle mass loss and negative cardiovascular effects.”

### **About BioRestorative Therapies, Inc.**

BioRestorative ([www.biorestorative.com](http://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<sup>™</sup>):** 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<sup>®</sup>):** 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 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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