

November 24, 2014



# BioRestorative Therapies Schedules Pre-IND Meeting with FDA

***Company Submits Pre-IND Package for brtxDISC™***

***Clinical Development Meeting with FDA***

JUPITER, Fla.--(BUSINESS WIRE)-- **BioRestorative Therapies, Inc. ("BRT" or the "Company") (OTCBB:BRTX)**, a life sciences company focused on adult stem cell-based therapies for various personal medical applications, announced that a Pre-IND (Investigational New Drug) meeting with the Center for Biologics Evaluation and Research ("CBER") of the U.S. Food and Drug Administration ("FDA") has been scheduled for December 19, 2014.

The purpose of the meeting is to obtain FDA's input regarding BRT's plans for the development of *brtxDISC™*, the Company's novel autologous stem cell product for the treatment of chronic lumbar disc disease ("cLDD"). In preparation for the meeting, the Company has submitted a Pre-IND Package to the FDA that describes the information BRT proposes to include in the *brtxDISC™* IND planned for submission in 2015. The IND is the regulatory vehicle that will allow for the initiation of clinical trials with *brtxDISC™* for the treatment of cLDD.

Prior to the meeting, FDA will specifically review BRT's manufacturing, preclinical pharmacology and toxicology, and clinical plans for *brtxDISC™* and provide comments to the Company. At the meeting, BRT management and its advisors will discuss with FDA any follow-up questions or clarifications relative to FDA's comments on the Pre-IND Package.

"This is an exciting milestone for BRT, and we are pleased to have achieved our goal of submitting our Pre-IND Information Package and being granted a meeting with the FDA prior to the end of the year," said Mark Weinreb, BioRestorative Therapies' Chief Executive Officer. "Our submission summarizes the proposed nonclinical efficacy and safety studies of *brtxDISC™* to support an IND, the proposed manufacturing process and controls, and a synopsis of the first proposed clinical study on subjects with cLDD. We look forward to reporting on further regulatory progress for this important program."

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

BioRestorative Therapies, Inc. ([www.biorestorative.com](http://www.biorestorative.com)) develops products and medical procedures using cell and tissue protocols, primarily involving adult stem cells, including:

- ***brtxDISC™* (Disc Implanted Stem Cells)** is an investigational non-surgical treatment for protruding and bulging lumbar discs that is intended for patients who have failed non-invasive procedures and face the prospect of surgery. The treatment involves culturing a patient's own stem cells and then delivering them via a proprietary medical device to the damaged region of the disc in an outpatient procedure.

- **ThermoStem®** is a treatment using brown fat stem cells that is under development for metabolic disorders including diabetes and obesity. Initial preclinical research indicates that increased amounts of brown fat in the body may be responsible for additional caloric burning as well as reduced glucose and lipid levels.
- **brtx-C Cosmetic** is based on the development of a human cellular extract that has been demonstrated in *in vitro* skin studies to increase the production of collagen and fibronectin, which are proteins that are essential to combating the aging of skin. Potential cosmetic uses are being explored with third parties.

The Company also offers plant stem cell-based facial creams and beauty products under the **Stem Pearls®** brand at [www.stempearls.com](http://www.stempearls.com).

### 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 those set forth in the Company's 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.*

Investor Contacts:

**LHA**

Kim Sutton Golodetz, 212-838-3777

[kgolodetz@lhai.com](mailto:kgolodetz@lhai.com)

or

Bruce Voss, 310-691-7100

[bvoss@lhai.com](mailto:bvoss@lhai.com)

Source: BioRestorative Therapies, Inc.