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Brickell Biotech Announces Positive Preliminary Results of a Pilot Clinical Study of BBI-4000 for the Treatment of Hyperhidrosis

Well-tolerated novel topical drug demonstrates treatment effect on clinically meaningful endpoints in subjects with hyperhidrosis

Company also adds deep industry expertise to Board of Directors

MIAMI--(BUSINESS WIRE)-- Brickell Biotech, Inc. ("Brickell"), a clinical-stage pharmaceutical company focused on the development of differentiated, innovative therapeutics to satisfy current unmet human needs in the global dermatology markets, today announced the outcome of a pilot study of a new compound, BBI-4000, for the topical treatment of primary axillary hyperhidrosis, or excessive sweating. BBI-4000 is a new molecular entity that is different from other hyperhidrosis treatments in development or in current clinical practice. As a "soft anticholinergic", it is designed to be therapeutically active in the skin and rapidly metabolized if absorbed into the body, minimizing potential systemic side effects. The preliminary positive results support the potential for BBI-4000 to become a safe and effective treatment option for people suffering from excessive sweating.

Hyperhidrosis is a medical condition that affects an estimated 8 million people – or 3% of the population – in the U.S. It can affect the axillae (underarms), palms of hands, soles of feet, face and other areas. Hyperhidrosis can frequently and significantly impair social, occupational, and emotional well-being.

"This is an exciting day for our company. We are very encouraged by these clinical trial results, and look forward to rapidly continuing the development of BBI-4000, with plans to initiate a Phase 2 study during the first half of 2015," said Reginald Hardy, President of Brickell.

David Pariser, M.D., a leading expert on hyperhidrosis, a founding board member of the International Hyperhidrosis Society and an advisor to Brickell, said, "Hyperhidrosis can be an extremely frustrating and socially incapacitating disease. Given the currently available treatment options, these results are very promising news for the hyperhidrosis community and warrant further development."

In the parallel group part of this double-blind clinical study, 18 subjects with primary axillary hyperhidrosis were randomized to a high topical concentration of BBI-4000, a low topical concentration of BBI-4000, or to topical vehicle, with 6 subjects in each group. The preliminary data show that **75%** (9/12) of subjects receiving BBI-4000 achieved more than 50% sweat reduction compared to 33% (2/6) of the subjects in the vehicle group. In addition, **67%** (8/12) of subjects receiving BBI-4000 reported a substantial (≥ 2 point) improvement in

their score on the Hyperhidrosis Disease Severity Scale, in comparison with 33% (2/6) of subjects in the vehicle group. These endpoints are considered clinically relevant and have been used in the regulatory evaluation and product labeling of an approved product for hyperhidrosis. Additionally, there were no treatment-related adverse effects or discontinuations due to adverse events. This pilot trial, though not designed to demonstrate statistical significance, did meet its objectives of indicating preliminary efficacy, local tolerability, and systemic safety and for informing the design and conduct of clinical trial work that the company is planning for the future.

Brickell Expands Board of Directors

Brickell today also announced the addition to the Board of Directors of two industry veterans with deep expertise, Charles W. Stiefel and William D. Ju, M.D.

“We are delighted to welcome such distinguished industry experts to our board,” said Brickell Chairman George Abercrombie. “With their many years of experience in the dermatology industry, Charlie and Bill will be a valuable resource as we continue to build our pipeline of innovative drug therapies for the treatment of skin diseases.”

Mr. Stiefel has more than 30 years of experience in the pharmaceutical and dermatology industry. He served as Chairman and CEO of Stiefel Laboratories Inc. from 2001 until its acquisition by GlaxoSmithKline in 2009, at which time the company was the largest privately held dermatology company in the world. He joined Stiefel Laboratories as General Counsel in 1982. In 2003, the South Florida Dermatology Foundation awarded him the Lifetime Achievement Award, and he was named Ernst & Young's Entrepreneur of the Year in Health Sciences for the State of Florida in 2006.

Dr. Ju, a board-certified dermatologist, has over 20 years of biopharmaceutical experience in a wide variety of therapeutic areas, including dermatology. He is the President and a Founding Trustee of Advancing Innovation in Dermatology, Inc. He has been President and Chief Executive Officer of Follica, Inc. and Chief Operating Officer at PTC Therapeutics, Inc. In addition, he has held executive positions at Pharmacia Corporation/Pfizer, Inc. Merck & Co., Inc., and Hoffmann La Roche, Inc. in a broad spectrum of product development functions.

About Brickell Biotech

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on the development and commercialization of innovative pharmaceutical products for the treatment of skin diseases. Founded by a team of experienced pharmaceutical executives, Brickell's development strategy includes rapidly and cost effectively developing product candidates; executing strategic partnerships; maintaining a diversified product portfolio that addresses unmet medical needs; and leveraging professional relationships with thought leaders and contract research organizations in the pharmaceutical industry. For more information, visit www.brickellbio.com.

Media:

For Brickell Biotech, Inc.
Anne Granfield, 646-805-2033
Anne.granfield@finsbury.com

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