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BBI-4000 (Sofpironium Bromide) Demonstrates Promising Potential as a Safe and Effective First-line Treatment for Excessive Underarm Sweating

Phase 2b Study Presented at Late-breaking Research Forums during the 74th American Academy of Dermatology Annual Meeting

WASHINGTON--(BUSINESS WIRE)-- Positive Phase 2b study results with the new molecular entity, BBI-4000 (sofpironium bromide) for the topical treatment of primary axillary hyperhidrosis, or excessive underarm sweating, were presented on March 5, 2016 at the 74th American Academy of Dermatology Annual Meeting, in Washington, D.C. The study results were presented in a Late-Breaking Research Forum by David Pariser, M.D., a leading expert on hyperhidrosis and a founding board member of the International Hyperhidrosis Society.

The multicenter, randomized, double blind, placebo-controlled Phase 2b study was designed to evaluate the safety, tolerability and efficacy of three concentrations of BBI-4000 versus vehicle (placebo gel) in 189 people with primary axillary hyperhidrosis. The study participants were randomized to apply either 5%, 10%, or 15% of BBI-4000 or placebo gel to their underarms once daily for 28 days. At baseline, all subjects had Hyperhidrosis Disease Severity Scale (HDSS) scores of 3 or 4 (scale, 1-4) and ≥50mg/5min sweat per axilla (underarm).

Results from the study showed BBI-4000 met its primary endpoint (ITT analysis) by successfully achieving a statistically significant 2-grade improvement in the Hyperhidrosis Disease Severity Score (HDSS), in a dose-related fashion. At the maximum dose (15%), 38.3% of participants improved more than 2 points on HDSS at Day 29 versus 12.2% with vehicle ($p<0.01$).

Additionally, BBI-4000 achieved a statistically significant 1- and 2-grade improvement in a newly developed patient reported outcome measure, the Hyperhidrosis Disease Severity Measure Axillary (HDSM-Ax). Using this measure (ITT analysis), 44.7% achieved a greater than 2-point improvement at Day 29 in the 15% treatment group versus 19.5% for vehicle ($p=0.01$), while 72.3% for the 15% treatment group versus 43.9% vehicle achieved a greater than 1-point improvement ($p=0.01$). The BBI-4000 15% treatment group demonstrated a trend in reduction of gravimetrically measured sweat production versus vehicle. In a composite measure (ITT analysis) of subjects who achieved at least a 1-grade improvement in their HDSM-Ax and a 50% reduction in gravimetric sweat production, 48.9% of subjects in the 15% group achieved a statistically significant improvement compared to 26.8% of vehicle-treated subjects ($p=0.03$). The BBI-4000 15% treatment group also demonstrated an improvement in the subjects' quality of life as measured by the Daily Quality of Life Index

(DLQI) modified for sweating.

BBI-4000 was well-tolerated at all three concentrations studied. The incidence of local tolerability signs was low throughout the study, and were predominantly mild to moderate in severity and resolved spontaneously. Treatment-related anticholinergic side effects were predominantly mild and transient and occurred in 16 (11.2%) of study subjects randomized to BBI-4000.

“This Phase 2b study demonstrates promising potential for a new first-line, safe and efficacious topical hyperhidrosis treatment,” said Patricia Walker, M.D., PhD, President and Chief Scientific Officer of Brickell Biotech, which is developing BBI-4000. “The possibility of a new treatment alternative for hyperhidrosis – one that is topical, well-tolerated, effective and non-invasive – is truly exciting and would address the current unmet need for patients and physicians.”

Hyperhidrosis can affect the underarms as well as the palms of hands, soles of feet, face and other areas. Current treatments, which include injections of botulinum toxin, are expensive, painful and not effective long-term.

“These data are extremely encouraging for the estimated 15+ million Americans – or 4.8% of the population – who are affected by this medical condition,” said Dr. Pariser. “Hyperhidrosis can significantly impair social, occupational and emotional well-being, and the current treatment standard is lacking in many ways. I’m very encouraged by these study results and look forward to participating in the future clinical development of BBI-4000.”

About BBI-4000 (Sofpironium Bromide)

Sofpironium bromide, a new molecular entity, belongs to a class of drugs called ‘anticholinergics,’ which exert their effect by blocking the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including the activation of sweat glands. Soft-anticholinergics, such as sofpironium bromide, exert their action topically and are rapidly metabolized into a considerably less active metabolite when they reach the blood system, thus potentially allowing for effective doses to be used while reducing the limiting systemic side effects associated with other drugs in this class.

About Brickell Biotech

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated therapeutics for the treatment of skin diseases. Its pipeline consists of five product candidates, including potential novel therapeutics for hyperhidrosis (excessive sweating), atopic dermatitis, allergic contact dermatitis, acne and psoriasis. Brickell’s management team and board of directors have extensive experience in product development, having served in leadership roles at several pharmaceutical and successful start-up companies. Its strategy is to leverage this experience to in-license, acquire, develop and commercialize products that Brickell believes can be successful in the dermatology marketplace. For more information, visit www.brickellbio.com.

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