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Brickell Biotech Announces Publication of its U.S. Phase 2b Study Results for Sofpironium Bromide in Patients with Primary Axillary Hyperhidrosis in the Journal of the American Academy of Dermatology

BOULDER, Colo., Feb. 20, 2020 (GLOBE NEWSWIRE) -- Brickell Biotech, Inc. (“Brickell”) (Nasdaq: BBI), a clinical-stage pharmaceutical company focused on developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases, today announced that positive results from its Phase 2b study with sofpironium bromide in patients with primary axillary hyperhidrosis were published in the peer-reviewed *Journal of the American Academy of Dermatology* (JAAD).

The paper, entitled “Efficacy and Safety of Topical Sofpironium Bromide Gel for the Treatment of Axillary Hyperhidrosis: A Phase 2, Randomized, Controlled, Double-Blinded Trial,” is now available online (Journal Pre-proof) at (https://doi.org/10.1016/j.jaad.2020.02.016) and will be published in a future print edition of JAAD.

Sofpironium bromide is an innovative, retro-metabolically designed, anticholinergic new molecular entity under investigation for the topical treatment of primary axillary hyperhidrosis. In this Phase 2b dose-finding study, sofpironium bromide elicited clinically and statistically significant sustained reductions in sweating severity and was well tolerated, suggesting that pivotal Phase 3 studies in the U.S. of this investigational drug are warranted. Brickell and its Japanese partner, Kaken Pharmaceutical Co., Ltd. (“Kaken”) have conducted a range of clinical studies with sofpironium bromide in over 1,300 subjects, including a Phase 3 registration trial in Japan.

“We are encouraged by these Phase 2b study results and are pleased by the publication of these data in such a prestigious academic peer-reviewed journal,” said Deepak Chadha, M.S. M.B.A., Brickell’s Chief Research & Development Officer. “These study results give us the confidence to continue to advance the development of sofpironium bromide.”

Stacy Smith, MD, an author, study investigator, and head of the California Dermatology and Clinical Research Institute, said, “The publication of these results are important to the millions of hyperhidrosis sufferers in the U.S. The dermatology community needs new treatment options to effectively manage hyperhidrosis patients and give them the quality of life they seek.”

Key findings from this study include:

- Topically applied sofpironium bromide gel, at concentrations of 5%, 10% and 15%, showed statistically significant differences relative to vehicle in axillary hyperhidrosis severity as demonstrated by improvement in Hyperhidrosis Disease Severity Measure–Axillary (HDSM-Ax; a proprietary validated patient report outcome measure), Hyperhidrosis Disease Severity Scale (HDSS), and modified Dermatology Life Quality Index-Axilla (DLQI-Ax). The HDSM-Ax and HDSS assessments showed improvements as early as the first post-baseline visit on day 8 and were sustained during the treatment period. The DLQI-Ax was assessed at the baseline and end of treatment only.

- Although the Phase 2b study was not designed to detect treatment differences in Gravimetric Sweat Production (GSP), an objective measure of reduction in sweat production. sofpironium bromide gel, 15%, demonstrated a statistically significant result over vehicle.

- Across all dose groups, adverse events were predominantly mild or moderate in severity and transient in nature. Safety and tolerability assessments exhibited dose-related trends. The most common adverse events with sofpironium bromide were dry mouth and blurred vision, which are expected anticholinergic side effects.

About Sofpironium Bromide

Sofpironium bromide, is a proprietary new molecular entity that belongs to a class of medications called anticholinergics. Anticholinergics block the action of acetylcholine, a chemical that transmits signals within the nervous system that are responsible for a range of bodily functions, including activation of the sweat glands. Sofpironium bromide was retrometabolically designed. Retrometabolic drugs are designed to exert their action topically and are potentially rapidly metabolized into a considerably less active metabolite once absorbed into the blood. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. Sofpironium bromide was discovered at Bodor Laboratories, Inc. by Dr. Nicholas Bodor D.Sc., d.h.c. (multi), HoF, Graduate Research Professor Emeritus, University of Florida.

About Hyperhidrosis

Hyperhidrosis is a life-altering medical condition where a person sweats more than the body requires to regulate its temperature. More than 15 million people, or 4.8% of the population of the United States, are believed to suffer from hyperhidrosis. Axillary (underarm) hyperhidrosis is the targeted first indication for sofpironium bromide and is the most common site of occurrence of hyperhidrosis, affecting an estimated 65% of patients with hyperhidrosis in the United States or 10 million individuals. Doolittle et al. Arch Dermatol Res (2016).

About Brickell

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. Brickell's pipeline consists of potential novel therapeutics for hyperhidrosis, cutaneous T-cell lymphoma, psoriasis, and other prevalent dermatological conditions. Brickell's executive management team and board of directors bring extensive experience in

product development and global commercialization, having served in leadership roles at large global pharmaceutical companies and biotechs that have developed and/or launched successful products, including several that were first-in-class and/or achieved iconic status, such as Cialis®, Taltz®, Gemzar®, Prozac®, Cymbalta® and Juvederm®. For more information, visit www.brickellbio.com.

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, business and/or research and clinical performance, conditions, plans, prospects, trends, or strategies and other such matters, including without limitation, the anticipated timing, scope, design and/or results of future clinical trials and prospects for commercializing any of Brickell's product candidates are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this press release, the words "may," "could," "should," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict" and similar expressions and their variants, as they relate to Brickell, may identify forward-looking statements. Brickell cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time, often quickly and in unanticipated ways. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including without limitation, ability to obtain adequate financing to advance product development, potential delays for any reason in product development, regulatory or law changes, unanticipated demands on cash resources, risks associated with developing, and obtaining regulatory approval for, and commercializing novel prescription therapeutics.

Further information on the factors and risks that could cause actual results to differ from any forward-looking statements are contained in Brickell's filings with the United States Securities and Exchange Commission (SEC), which are available at www.sec.gov (or at www.brickellbio.com). The forward-looking statements represent the estimates of Brickell as of the date hereof only, and Brickell specifically disclaims any duty or obligation to update forward-looking statements.

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