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Brickell Biotech Announces Final Patient Completed Second U.S. Phase 3 Pivotal Clinical Study of Sofpironium Bromide Gel, 15% for the Treatment of Primary Axillary Hyperhidrosis

Topline results for Phase 3 pivotal Cardigan I and Cardigan II studies expected to be reported in Q4 2021

NDA submission for sofpironium bromide gel, 15% anticipated in mid-2022 pending Phase 3 outcome

BOULDER, Colo., Aug. 16, 2021 (GLOBE NEWSWIRE) -- Brickell Biotech, Inc. (“Brickell” or the “Company”) (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 the final patient has completed the Phase 3 pivotal Cardigan II study, which is evaluating sofpironium bromide gel, 15% in patients with primary axillary (underarm) hyperhidrosis. The Company expects to announce topline results for the U.S. Phase 3 pivotal Cardigan I and Cardigan II studies concurrently in the fourth quarter of 2021. Pending the outcome of these studies, the Company expects to submit a New Drug Application (NDA) for sofpironium bromide gel, 15% to the U.S. FDA in mid-2022.

“We’re excited to announce that all patients have now completed their final visits in the Cardigan I and Cardigan II studies of sofpironium bromide gel, 15% in patients with primary axillary hyperhidrosis. Achieving this milestone positions us to report topline results from both studies in the fourth quarter of 2021,” said Deepak Chadha, Chief Research and Development Officer of Brickell. “We greatly appreciate the patients and investigators who participated in the Phase 3 program and look forward to receiving and releasing the results in due course.”

U.S. Phase 3 Cardigan I and Cardigan II Studies

Brickell’s U.S. Phase 3 clinical program for sofpironium bromide gel, 15% is comprised of two pivotal clinical studies, Cardigan I and Cardigan II. Each study has enrolled approximately 350 subjects nine years of age and older with primary axillary hyperhidrosis. The studies are multicenter, randomized, double-blinded, vehicle (placebo)-controlled studies evaluating the efficacy and safety of topically applied sofpironium bromide gel, 15%. Subjects applied sofpironium bromide gel, 15% or placebo to their underarms once daily at bedtime for 6 consecutive weeks, with a 2-week post-treatment follow-up. The co-primary efficacy endpoints of both studies include the proportion of subjects achieving at least a 2-point improvement on the Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax)

scale, a proprietary and validated patient-reported outcome measure, and change in gravimetric sweat production (GSP), each from baseline to end of treatment. Safety and tolerability assessments will be performed throughout the studies.

Additional details of the Cardigan I and II studies can be found onhttps://clinicaltrials.gov under identifiers NCT03836287 and NCT03948646, respectively.

About Sofpironium Bromide

Sofpironium bromide is Brickell's lead investigational product candidate and is a new chemical 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 intended to exert their action locally and are potentially rapidly metabolized into a less active metabolite once absorbed into the blood. Sofpironium bromide gel, 15% is currently being evaluated in a U.S. pivotal Phase 3 clinical program for the treatment of primary axillary hyperhidrosis, and sofpironium bromide gel, 5% is approved in Japan for the same indication under the brand name ECCLOCK®. 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 debilitating, life-altering medical condition where a person sweats beyond what is physiologically required for thermoregulation of the body. More than 15 million people, or 4.8% of the population of the United States, and 12.76% of the population in Japan, are believed to suffer from hyperhidrosis[1,2]. Primary 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. Additional information can be found on the International Hyperhidrosis Society website: https://www.sweathelp.org/.

About Brickell

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated prescription therapeutics for debilitating skin diseases with a focus on its lead asset sofpironium bromide for the treatment of hyperhidrosis. 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®. Brickell's strategy is to leverage this experience to in-license, acquire, develop and commercialize innovative and differentiated pharmaceutical products that Brickell believes can be successful in the marketplace and transform lives by solving currently unmet patient needs. For more information, visit https://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 ongoing and future clinical trials, intellectual property rights, including the validity, term and enforceability of such, the expected timing and/or results of regulatory approvals and prospects for commercializing any of Brickell's product candidates, or research collaborations with its partners, including in Japan, the United States or any other country, are forward-looking statements within the meaning of the U.S. 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," "potential," "look forward" and similar expressions and their variants, as they relate to Brickell, Kaken, or any of Brickell's partners, 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, ability to maintain and enforce intellectual property rights, potential delays for any reason in product development and clinical trial enrollment, regulatory changes, supply chain disruptions, unanticipated demands on cash resources, any disruption to its business caused by the current COVID-19 pandemic, interruptions, disruption or inability by Kaken to supply and commercialize the product in Japan, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's ongoing U.S. Phase 3 pivotal program on sofpironium bromide, and other risks associated with developing and obtaining regulatory approval for and commercializing product candidates.

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 https://www.sec.gov (or at https://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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1 Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.
2 Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J Dermatol 2013; 40: 886-90.

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