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Brickell Biotech Announces Publication of Japan Pivotal Phase 3 Study Results for Sofpironium Bromide Gel, 5% (ECCLOCK®) in the Journal of Dermatology

Commercial launch of ECCLOCK® in Japan currently underway by Development Partner, Kaken Pharmaceutical

BOULDER, Colo., Jan. 19, 2021 (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 the efficacy and safety results from the pivotal Phase 3 study conducted in Japan by its development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken") were published in the peer-reviewed Journal of Dermatology[1].

The paper, entitled "A phase 3, multicenter, randomized, double-blind, vehicle-controlled, parallel-group study of 5% sofpironium bromide (BBI-4000) gel in Japanese patients with primary axillary hyperhidrosis," is available online in English at the Wiley Online Library (click here).

Kaken and Brickell first announced the release of the Japan pivotal Phase 3 study results in June 2020. Subsequently, Kaken received regulatory approval to manufacture and market ECCLOCK® in Japan for the treatment of primary axillary hyperhidrosis in September 2020 and launched commercial sales in November 2020. Japan is the first country to approve sofpironium bromide, which also marks the first approval of a topical prescription product for the treatment of primary axillary hyperhidrosis in Japan.

"We are pleased to see Kaken continue to advance the commercialization of ECCLOCK® in Japan, as a potential best-in-class treatment for patients with primary axillary hyperhidrosis," said Deepak Chadha, Chief Research and Development Officer of Brickell. "The publication of Kaken's pivotal Phase 3 study results in the highly regarded peer-reviewed Journal of Dermatology provides additional clinical support for sofpironium bromide and will be an important reference tool for treating dermatologists and physicians across Japan."

In addition, Brickell recently initiated its U.S. pivotal Phase 3 clinical program evaluating sofpironium bromide gel, 15% for the treatment of primary axillary hyperhidrosis. Brickell expects to report topline data from the U.S. pivotal Phase 3 program in the fourth quarter of 2021.

About Sofpironium Bromide

Sofpironium bromide is a proprietary investigational 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 designed to exert their action locally and are potentially rapidly metabolized into a less active metabolite once absorbed into the blood. 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, and 12.76% of the population in Japan, are believed to suffer from hyperhidrosis[2,3]. 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 developing innovative and differentiated prescription therapeutics for the treatment of debilitating skin diseases. Brickell's pipeline consists of potential novel therapeutics for hyperhidrosis 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®. Brickell's strategy is to leverage this experience to in-license, acquire, develop and commercialize innovative products that Brickell believes can be successful in the currently underserved dermatology global marketplace. 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, progress 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 submissions and approvals, and prospects for commercializing any of Brickell's product candidates, or research collaborations with, or actions of, 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, 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, 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.

[1] The Journal of Dermatology is the official peer-reviewed publication of the Japanese Dermatological Association and the Asian Dermatological Association.

[2] Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.

[3] Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J Dermatol 2013; 40: 886-90.

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