November 18, 2020

Brickell Biotech Announces Launch Date for Sofpironium Bromide Gel, 5% (ECCLOCK®) in Japan by its Development Partner, Kaken Pharmaceutical

Kaken plans to launch ECCLOCK® for the treatment of primary axillary hyperhidrosis in Japan on November 26, 2020

\- - -

ECCLOCK® placed on Japan's National Health Insurance (NHI) drug reimbursement price list

BOULDER, Colo., Nov. 18, 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 its Japanese development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken") plans to launch sofpironium bromide gel, 5% under the brand name ECCLOCK® in Japan for the once daily treatment of primary axillary (underarm) hyperhidrosis on November 26, 2020. In addition, ECCLOCK® has been placed today on Japan's National Health Insurance (NHI) drug reimbursement price list. The NHI listed drug price for ECCLOCK® in Japan is ¥243.70 per gram, which is ¥4,874.00 (USD $46.47) for a 20 gram bottle or approximately a two-week supply.

"We are excited to announce the reimbursement and planned commercial launch of ECCLOCK® in Japan, which is the first topical prescription product to be approved and marketed there for the treatment of primary axillary hyperhidrosis," said Robert Brown, Chief Executive Officer of Brickell. "A key step to Kaken's moving forward with the planned commercial launch of ECCLOCK® in Japan was their receipt of the reimbursement price listing by the NHI. Kaken is now well-positioned to launch ECCLOCK® in Japan on November 26 as an important novel, first-in-class therapy for the millions of Japanese patients suffering with this debilitating medical condition."

On September 25, 2020, Kaken received approval from the Japanese Pharmaceuticals and Medical Devices Agency to manufacture and market ECCLOCK® for the once-daily treatment of primary axillary hyperhidrosis.

Under the sublicense agreement with Kaken, Brickell is entitled to receive sales-based milestone payments, as well as tiered royalties based on a percentage of net sales of ECCLOCK® in Japan. Furthermore, Kaken has rights to develop and commercialize sofpironium bromide in Korea, China and certain other Asian countries.

Sofpironium bromide is currently being developed by Brickell in the U.S. for the treatment of

primary axillary hyperhidrosis. Brickell recently initiated its pivotal Phase 3 clinical program in the U.S., which is comprised of two pivotal Phase 3 clinical trials (Cardigan I and II) to evaluate the safety and efficacy of sofpironium bromide gel, 15% compared to vehicle (placebo) in approximately 350 subjects (per trial) aged nine years and older with primary axillary hyperhidrosis. Brickell expects to report topline data from both the Cardigan I and II studies 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 topically 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[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 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 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, 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, AnGes 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, launch 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]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.

Brickell Investor Contact:
Dan Ferry
LifeSci Advisors
(617) 430-7576
daniel@lifesciadvisors.com

BrickellBio

Source: Brickell Biotech, Inc.