Brickell Biotech Announces Publication of Japan Phase 3 Long-Term Safety and Efficacy Study Results for Sofpironium Bromide Gel, 5% (ECCLOCK®) in the Journal of Dermatology

BOULDER, Colo., June 01, 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 results from the Phase 3 long-term safety and efficacy study conducted in Japan by its development partner, Kaken Pharmaceutical Co., Ltd. (“Kaken”) were published in the peer-reviewed Journal of Dermatology.

The paper, entitled “A phase III, 52-week, open-label study to evaluate the safety and efficacy of 5% sofpironium bromide (BBI-4000) gel in Japanese patients with primary axillary hyperhidrosis,” is available online in English at the Wiley Online Library.

Kaken and Brickell first announced the release of the Japan pivotal Phase 3 study results in June 2020 and this is the first release of these long-term safety and efficacy results. 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 announce the publication of these data from Kaken’s Phase 3 long-term safety and efficacy study in the highly regarded peer-reviewed Journal of Dermatology. Publications such as this are a valuable clinical experience resource for Kaken during its commercialization of ECCLOCK® in Japan, as it further aids in acquainting Japanese physicians and healthcare professionals on prescribing sofpironium bromide, 5% as a potential best-in-class treatment for patients with primary axillary hyperhidrosis, a chronic medical condition,” said Deepak Chadha, Chief Research and Development Officer of Brickell.

In addition, Brickell announced in its quarterly update on May 13, 2021 that it had completed enrollment in the U.S. Phase 3 Cardigan I study and exceeded 70% enrollment in the U.S. Phase 3 Cardigan II study. Both randomized, double-blinded, placebo-controlled pivotal studies are evaluating sofpironium bromide gel, 15% vs. placebo (1:1 ratio) in approximately 350 subjects (per study) aged nine and older with primary axillary hyperhidrosis. Brickell expects to report topline results from the Cardigan I and II pivotal studies in the fourth quarter of 2021.
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. Retrometabolically designed 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. 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 gel, 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.
3 Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J

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