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Brickell Bio's Development Partner, Kaken Pharmaceutical, Submits New Drug Application for Sofpironium Bromide in Japan for Primary Axillary Hyperhidrosis

BOULDER, Colo., Jan. 10, 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 development partner, Kaken Pharmaceutical Co. Ltd. ("Kaken") submitted a new drug application for approval of manufacturing and marketing for sofpironium bromide in Japan for primary axillary hyperhidrosis. The application for sofpironium bromide in Japan involves data from the Phase 3 study in Japan, targeting patients with primary axillary hyperhidrosis, in which positive results were obtained.

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.

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 occurrence of hyperhidrosis, affecting an estimated 65% of patients 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®. 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 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, whether Brickell prevails in arbitration and/or litigation relating to its license agreement with Bodor, the costs associated with, and the management time associated with arbitration and/or litigation, potential delays in product development, regulatory or law changes, unanticipated demands on cash resources, risks associated with developing, and obtaining regulatory approval for and commercializing novel 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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