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Brickell Biotech Announces Issuance of New Composition of Matter Patent on Sofpironium Bromide by the Japanese Patent Office

Claims directed to novel crystalline forms of sofpiroonium bromide

Patent protection in Japan granted through 2040

BOULDER, Colo., Aug. 31, 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, announced today that Brickell and its Japanese development partner, Kaken Pharmaceutical Co., Ltd. ("Kaken"), were granted by the Japanese Patent Office a composition of matter patent with claims directed to the novel polymorphic, or crystalline, forms of sofpiroonium bromide, a retrometabolically designed new chemical entity, currently under development in the United States and Japan as a potential best-in-class treatment for primary axillary hyperhidrosis. This patent is expected to provide additional protection in Japan through 2040 for these newly developed and distinct characterized crystalline forms of sofpiroonium bromide. Patent protection for these crystalline forms of sofpiroonium bromide currently is being pursued worldwide, including in the United States.

"The issuance of this new composition of matter patent is a key accomplishment in protecting and expanding upon our intellectual property portfolio," commented Robert Brown, Chief Executive Officer of Brickell. "We are pleased by this important new patent issuance in Japan, as well as the continued progress Kaken is making in their commercial planning for sofpiroonium bromide in Japan. Kaken expects to receive a regulatory decision for sofpiroonium bromide gel, 5% in Japan, later this year."

About Sofpiroonium Bromide

Sofpiroonium bromide is a proprietary 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. Sofpiroonium 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. This proposed mechanism of action may allow for highly effective doses to be used while limiting systemic side effects. Sofpiroonium 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. Sofpiroonium bromide is not approved for use in any country at this time.

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 more than 16 million people, or 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 or 10 million individuals and an estimated 45% of patients with hyperhidrosis in Japan or 7.2 million individuals^{1,2}. 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 <http://www.brickellbio.com>.

Cautionary Note Regarding Forward-Looking Statements

Any statements made in this press release relating to future financial, legal, 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, 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, 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" 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, 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, unanticipated demands on cash resources, any disruption to our business caused by the current COVID-19 pandemic, interruptions, delays or negative determinations on Kaken's new drug application under current review, and other 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 <http://www.sec.gov> (or at <http://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.

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