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Brickell Biotech Announces Positive Phase 3 Pivotal Study Results for Sofpironium Bromide in Japan Released by Development Partner, Kaken Pharmaceutical

Data based on registration study in Japan of sofipronium bromide gel, 5% in patients with primary axillary hyperhidrosis

All primary and secondary endpoints were met and achieved statistical significance

BOULDER, Colo., June 15, 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 the release of positive Phase 3 pivotal study results from its development partner, Kaken Pharmaceutical Co. Ltd., in Japan. All primary and secondary efficacy endpoints of the study were met. The results were presented as part of the Late-Breaking Research Program during the American Academy of Dermatology (AAD) Virtual Meeting Experience. The presentation is titled "A Phase 3, Randomized, Double-Blinded, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied Sofpironium Bromide Gel, 5% in Japanese Patients with Primary Axillary Hyperhidrosis." Earlier this year, Kaken announced submission of a new drug application for approval in Japan of manufacturing and marketing of sofipronium bromide gel for primary axillary hyperhidrosis based on these data.

"We are encouraged by these positive results and are pleased by the filing of the Japanese New Drug Application based on this Phase 3 study by Kaken," said Deepak Chadha, Brickell's Chief Research & Development Officer. "We believe there is growing interest from the global medical community for novel therapeutic options for the treatment of primary axillary hyperhidrosis and think these data provide additional clinical support for sofipronium bromide to be a potential best-in-class treatment."

The Phase 3 pivotal study evaluated a total of 281 Japanese subjects randomized 1:1 to apply sofipronium bromide gel, 5% ("SB") or vehicle gel (placebo) to the axillae for 42 days. All subjects had Hyperhidrosis Disease Severity Scale (HDSS) scores ≥ 3 and ≥ 50 mg/5 min gravimetric sweat production (GSP) in each axilla at baseline.

All primary and secondary efficacy endpoints demonstrated statistically significant differences between sofipronium bromide and vehicle, with safety and tolerability, as follows:

Primary Endpoint:

- Proportion of subjects whose HDSS was improved to a score of 1 or 2 at the end of treatment (EOT) and > 50% reduction in GSP at EOT was 53.9% (SB) versus 36.4% (vehicle); p-value = 0.003

Key Secondary Endpoints:

- Proportion of subjects whose HDSS was improved to a score of 1 or 2 at the EOT was 60.3% (SB) versus 47.9% (vehicle); p=0.036
- Change in the total GSP mean value for both axillae from baseline to EOT was -157.6 mg (SB) versus -127.6 mg (vehicle); p=0.015¹
- Change in the HDSM-Ax score from baseline to EOT was -1.41 (SB) versus -0.93 (vehicle); p=0.001
- Proportion of subjects with ≥50% reduction in the rate of GSP from baseline to EOT was 77.3% (SB) versus 66.4% (vehicle); p=0.042

Safety and Tolerability:

- Common adverse events (incidence ≥5%) in SB group were nasopharyngitis (14.2%), dermatitis at the application site (8.5%), and erythema at the application site (5.7%). The severity of adverse events was predominantly mild.
- 2.8% of SB-treated subjects experienced any anticholinergic-class side effects; dry mouth (1.4%), constipation (0.7%) and mydriasis (0.7%).
- No serious adverse events related to SB were reported in the study

In addition to Japan, Kaken has rights to develop and commercialize sofipironium bromide in Korea, China and certain other Asian countries. Under the sublicense agreement with Kaken there are royalties and sales-based milestone payments due to Brickell.

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 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 D.Sc., d.h.c. (multi), HoF, Graduate Research Professor Emeritus, University of Florida. Sofpironium 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^{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 or 10 million individuals and an estimated 45% of patients with hyperhidrosis in Japan or 7.2 million individuals^{2,3}. 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, 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, 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, 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, and 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.

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¹ Change in the total GSP mean value for both axillae from baseline to EOT is one of the co-primary efficacy endpoints required by FDA for Brickell's prospective U.S. Phase 3 pivotal trials.

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.



Source: Brickell Biotech, Inc.