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# Brickell Biotech Announces Publication of its HDSM-Ax Patient Reported Outcome Scale Validation Results in the Journal of Drugs in Dermatology

**HDSM-Ax scale is a well-defined and reliable measure of primary axillary hyperhidrosis severity and a 1-point change is clinically meaningful**

BOULDER, Colo., April 15, 2021 (GLOBE NEWSWIRE) -- Brickell Biotech, Inc. ("Brickell" or the "Company") (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 results from a Phase 2b study evaluating the use of Hyperhidrosis Disease Severity Measure-Axillary<sup>®</sup> (HDSM-Ax), Brickell's proprietary patient reported outcome (PRO) scale, to measure primary axillary hyperhidrosis (AHH) severity were published in the peer-reviewed *Journal of Drugs in Dermatology*. The article, entitled "Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax): Evaluation of Measurement Performance," can be accessed online [here](#).

The psychometric analyses conclude that HDSM-Ax is a well-defined and reliable measure of primary AHH severity that is expected to improve the assessment of axillary hyperhidrosis treatment effects compared to pre-existing scales, such as the Hyperhidrosis Disease Severity Scale (HDSS). The analyses determine that a 1-point change in HDSM-Ax severity score (on a 0-4 scale) represents a clinically meaningful change in AHH severity.

"We are pleased to publish the evaluation of measurement performance results of the HDSM-Ax scale, which further confirm its ability to more reliably, consistently, and effectively assess the severity of primary AHH as compared to previously used PROs," said Deepak Chadha, M.S. M.B.A., Brickell's Chief Research & Development Officer. "We developed and validated this PRO scale to assess the efficacy of sofpironium bromide gel in reducing sweating severity in patients with primary AHH. The results of the published study demonstrate that the HDSM-Ax is a robust, validated and fit-for-purpose PRO measure of AHH severity. Furthermore, the HDSM-Ax scale forms the basis for one of the co-primary efficacy endpoints in our ongoing U.S. Phase 3 pivotal clinical studies of sofpironium bromide gel for the treatment of primary AHH."

## 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. Retrometabolic

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 sofipironium bromide gel, 5% is approved in Japan for the same indication under the brand name ECCLOCK<sup>®</sup>. 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<sup>1,2</sup>. Primary axillary (underarm) hyperhidrosis is the targeted first indication for sofipironium 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 sofipironium 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<sup>®</sup>, Taltz<sup>®</sup>, Gemzar<sup>®</sup>, Prozac<sup>®</sup>, Cymbalta<sup>®</sup> and Juvederm<sup>®</sup>. 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 sofipironium bromide, 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.

<sup>1</sup> Doolittle et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 2016; 308: 743-749.

<sup>2</sup> Fujimoto et al. Epidemiological study and considerations of focal hyperhidrosis in Japan. J Dermatol 2013; 40: 886-90.

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