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Brickell Biotech Doses First Subject in Phase 1 Study of DYRK1A Inhibitor BBI-02

– BBI-02 is a potential first-in-class, oral DYRK1A inhibitor with strong preclinical validation and broad potential to treat debilitating autoimmune and inflammatory diseases –

– Topline results from the SAD and MAD parts of the Phase 1 study expected to be announced by early 2023 –

BOULDER, Colo., May 19, 2022 (GLOBE NEWSWIRE) -- Brickell Biotech, Inc. ("Brickell" or the "Company") (Nasdaq: BBI), a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of autoimmune, inflammatory, and other debilitating diseases, today announced that the first subjects were dosed in the single ascending dose ("SAD") portion of the Company's Phase 1 clinical trial evaluating BBI-02 in healthy adult subjects and patients with atopic dermatitis ("AD"). BBI-02 is a potential first-in-class, highly selective, orally bioavailable small molecule DYRK1A inhibitor that aims to restore immune balance through modulating adaptive and innate immune responses in patients with autoimmune and inflammatory diseases.

"I am thrilled to see BBI-02 move into the clinic, which will expand our understanding of DYRK1A's potential as a promising, novel mechanism in autoimmunity and inflammation," commented Dr. Bernard Khor, MD, PhD, Principal Investigator and Assistant Member at the Benaroya Research Institute for Translational Medicine and Affiliated Assistant Professor at the University of Washington. "Since reporting DYRK1A as a potential novel target to regulate immune homeostasis, encouraging data have been generated exploring DYRK1A inhibition across several autoimmune conditions. Brickell's trial marks an important step forward for the field, and I look forward to keeping a close eye on the progress and results from this study."

The first-in-human Phase 1 trial of BBI-02 ("BBI-02-101") is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, pharmacokinetics ("PK"), and pharmacodynamics ("PD") of BBI-02 capsules in both healthy adult subjects and patients with AD. Part 1A of the study is a SAD assessment of BBI-02 or placebo in healthy adult subjects, and Part 1B of the study will be a multiple ascending dose ("MAD") assessment of BBI-02 or placebo administered once daily for 14 days in healthy adult subjects. After completing the SAD and MAD cohorts, Brickell plans to enroll Part 2 of the study, which will compare BBI-02 to placebo in patients with moderate-to-severe AD over 28 days of dosing and will include a preliminary assessment of efficacy. Topline results from the SAD and MAD parts of the Phase 1 trial are expected to be announced by early 2023. Additional information on this clinical trial can be found on www.clinicaltrials.gov under identifier NCT05382819.

"We are excited to announce initiation of the BBI-02-101 study for our lead DYRK1A inhibitor

candidate, BBI-02, which marks the first time a DYRK1A inhibitor intended for patients with autoimmune diseases has been administered in humans," commented Dr. Monica Luchi, Chief Medical Officer of Brickell. "I am proud of Brickell's efforts to quickly progress BBI-02 into the clinic following our acquisition of this program in the third quarter of last year. We look forward to building on the promising preclinical results generated to-date by evaluating the clinical safety, tolerability, PK, and PD of BBI-02 throughout this year."

About BBI-02

BBI-02 is a highly selective and orally bioavailable DYRK1A (dual specificity tyrosine-phosphorylation-regulated kinase 1A) inhibitor that has demonstrated promising results in various preclinical models, including atopic dermatitis and rheumatoid arthritis. In these models, BBI-02 showed encouraging decreases in disease severity and reduction of pro-inflammatory cytokines compared to current standard-of-care agents, such as Janus kinase (JAK) inhibitors and anti-tumor necrosis factor (TNF) biologics. Notably, many current therapies for autoimmune disorders are broadly immunosuppressant, which may lead to severe side effects, such as increased infection risk. Preclinical data have shown BBI-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory T_H17 cells and myeloid differentiation primary response 88 ("MyD88")/IRAK4-related signaling pathways. Regulatory T-cells serve to maintain tolerance and keep the autoreactive, pro-inflammatory T-cells in check, thus inhibiting autoimmune disease and limiting chronic inflammation. The MyD88 protein is normally spliced into a long form and a short form. DYRK1A inhibition shifts the balance to produce more MyD88 short form, which leads to IRAK4, a protein kinase involved in signaling immune responses from toll-like receptors, not being phosphorylated and so appears to deactivate downstream cascades of certain pro-inflammatory cytokines. Based on current understanding, this inhibition of the release of excess cytokines can be achieved by re-establishing the role of MyD88 short form as a negative regulator of this pathway. Unlike many existing therapies for autoimmune diseases, as well as those currently being investigated, BBI-02 may have the ability to target both the adaptive and innate immune imbalance simultaneously, potentially resulting in, or substantially achieving, restoration of immune homeostasis that, if proven, would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

About Brickell

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company striving to transform patient lives by developing innovative and differentiated prescription therapeutics for the treatment of autoimmune, inflammatory, and other debilitating diseases. Brickell's pipeline consists of several development-stage candidates and a cutting-edge platform with broad potential in autoimmune and inflammatory disorders. 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 pharmaceutical products that Brickell believes can meaningfully benefit patients who are suffering from chronic, debilitating diseases that are underserved by available therapies. 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, Brickell's strategy; future operations; future financial position; future liquidity; future revenue; territorial focus; projected expenses; results of operations; the anticipated timing, scope, design, progress, results, and/or reporting of data of ongoing and future non-clinical and clinical trials; intellectual property rights, including the acquisition, validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for commercializing any product candidates of Brickell or third parties, or research and/or licensing collaborations with, or actions of, its partners, including in the United States, Japan, South Korea, 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," "might," "anticipate," "reflects," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," "evaluate," "advance," "excited," "aim," "strive," "help," "progress," "select," "initiate," "look forward," "promise," "provide," "commit" "best-in-class," "first-in-class," and similar expressions and their variants, as they relate to Brickell or any of Brickell's partners or third parties, 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, research results and data that do not meet targets, expectations or regulatory approval requirements; ability to obtain adequate financing for product development, regulatory submissions, and any commercialization; ability to acquire, maintain and enforce intellectual property rights; potential delays or alterations in product development, trials of any type, and regulatory submission and reviews; changes in law or policy; litigation, regulatory agency feedback or requests; supply chain disruptions; unanticipated demands on cash resources; disruptions and negative effects related to the COVID-19 pandemic and the conflict in Ukraine; interruptions, disruption, or inability by Brickell, its partners or third parties to obtain or supply research material, raw materials, and/or product anywhere, or secure essential services, in the world; efforts to obtain and retain adequate pricing and adequate reimbursement and other insurance coverage for Brickell's products; the outcome of Brickell's current and planned preclinical and clinical trials across its portfolio of assets; the inability of third parties to achieve regulatory and sales-based events, resulting in Brickell not receiving any additional payments under its agreement with them; 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, 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. Brickell specifically disclaims any duty or obligation to update forward-looking statements.

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