September 1, 2021

Brickell Biotech Acquires Exclusive Rights to Phase 1-Ready DYRK1A Inhibitor Program and Novel Platform Targeting Autoimmune and Inflammatory Diseases

Expect to initiate Phase 1 clinical study of lead DYRK1A inhibitor program, BBI-02, a potential first-in-class oral treatment for autoimmune and inflammatory diseases, in 2022

Acquisition includes rights to platform of DYRK1A inhibitors with potential to create next generation kinase inhibitors (NCEs) targeting neuroinflammatory and other autoimmune diseases

Newly appointed Chief Medical Officer to lead the development strategy for DYRK1A inhibitor pipeline

Management to host investor call today at 8:30 AM ET

BOULDER, Colo., Sept. 01, 2021 (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 dermatologic, autoimmune and other debilitating diseases, today announced it has entered into a definitive agreement with Voronoi Inc., a platform-based drug discovery company in South Korea dedicated to developing new kinase inhibitors, that grants Brickell exclusive, worldwide rights to research, develop and commercialize novel therapeutics generated from a proprietary DYRK1A inhibitor platform. These novel DYRK1A inhibitors aim to restore immune balance in patients whose immune system has become dysregulated, thus offering large potential across a wide array of autoimmune and inflammatory diseases.

“Recent studies linking DYRK1A to central pathways of inflammation, such as T_H17/T_{REG} differentiation, point to it being an important new druggable target in autoimmune diseases like atopic dermatitis and rheumatoid arthritis. Additional potential applications include type 1 diabetes, given DYRK1A also controls islet beta cell proliferation, as well as precision medicine strategies,” states 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. “Based on the promising preclinical efficacy data generated to date with Brickell’s novel DYRK1A inhibitor programs, this platform has the potential to offer first-in-class, new and potent therapies for many different types of autoimmunity and inflammation.”

The initial lead program that Brickell will be advancing is BBI-02, a Phase 1-ready, highly selective and orally bioavailable DYRK1A inhibitor that has demonstrated compelling results in various preclinical models, including of 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 JAK inhibitors and anti-TNF biologics. Notably, many current therapies for autoimmune disorders are broadly immunosuppressant, which may lead to severe side effects, such as increased infection risk. In contrast, preclinical data have shown BBI-02 to drive regulatory T-cell differentiation while dampening pro-inflammatory T_H17 cells and MyD88/IRAK4-related signaling pathways. Unlike many existing therapies, as well as those currently being investigated, BBI-02 has the ability to target both the adaptive and innate immune imbalance simultaneously, ultimately resulting in the potential restoration of immune homeostasis that would represent a paradigm shift in the treatment of certain autoimmune and inflammatory diseases.

“Today marks a pivotal day in the Company’s evolution, as we strengthen our position in dermatology while simultaneously broadening our strategic focus by expanding our pipeline with a Phase 1-ready DYRK1A inhibitor and cutting-edge platform. As we build out our long-term growth strategy, we believe this platform has the potential to create first-in-class therapeutics for the treatment of a wide array of autoimmune and neuroinflammatory disorders,” commented Robert Brown, Chief Executive Officer of Brickell. “We also announced today the appointment of a seasoned clinical executive and expert in immunologic disease, Dr. Monica Luchi, as our Chief Medical Officer to lead the development strategy of this exciting pipeline of DYRK1A inhibitors. With her guidance and the completion of this acquisition, we intend to progress BBI-02 into a Phase 1 clinical study in 2022. In addition, over the course of the next year, our team expects to conduct formulation development activities for BBI-03, a topically applied preclinical DYRK1A inhibitor, and to select and initiate development of a lead next generation DYRK1A inhibitor for the potential treatment of neuroinflammatory diseases. Ultimately, this acquisition allows us to enter an innovative emerging field of restoring immune balance with a novel and differentiated approach that we believe will enable Brickell to help improve millions of patient lives while building substantial value for our shareholders,” concluded Mr. Brown.

“We are excited to announce the partnering of our novel DYRK1A inhibitor platform with Brickell,” said Daekwon Kim, Chief Executive Officer of Voronoi. “We have the utmost confidence in the Brickell team’s broad clinical development and partnering experience. This is evidenced by Brickell’s advancement of sofpironium bromide in primary axillary hyperhidrosis from early preclinical through Phase 3 studies in the U.S., and the commercial launch in Japan via their current partnership with Kaken Pharmaceutical. Building on the significant investment we’ve made in the DYRK1A inhibitor programs to-date, we believe Brickell is the right company to maximize the global value of this platform in autoimmune and neuroinflammatory diseases, while we focus on the development of our other core kinase inhibitor programs in the field of precision oncology.”

Transaction Terms

Under the terms of the license agreement, in exchange for an exclusive, worldwide license to develop and commercialize compounds from Voronoi’s DYRK1A inhibitor platform, Brickell will make a one-time payment to Voronoi of $2.5 million in cash and $2.5 million in shares of Brickell common stock. The number of shares to be issued to Voronoi is based on a price of $0.89 per share, representing a premium of 35% to the trailing 10-day volume weighted average trading price. In addition, Brickell will pay Voronoi success-based development,

regulatory and sales milestone payments of up to $211.0 million with respect to BBI-02 and BBI-03. For the first next generation product arising from the DYRK1A inhibitor platform, Brickell will pay Voronoi success-based development, regulatory and sales milestone payments of up to $107.5 million. Brickell will also pay Voronoi tiered royalty payments ranging from low single digits up to 10% of net sales of products arising from the DYRK1A inhibitor platform. Brickell will be responsible for all future development activities and expenses related to the DYRK1A inhibitor platform. RM Global Partners LLC served as an advisor to Brickell on this transaction.

Conference Call and Webcast Information

Brickell's management will host a conference call today at 8:30 a.m. ET to discuss the license agreement with Voronoi Inc. and the Company's strategic expansion. The dial-in number for the conference call is 1-877-705-6003 for domestic participants and 1-201-493-6725 for international participants, with Conference ID #13722799. A live webcast of the conference call can be accessed at http://public.viavid.com/index.php?id=146441 or through the "Investors" tab on the Brickell Biotech website at https://www.brickellbio.com. A replay will be available on this website shortly after conclusion of the event for approximately 90 days.

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 dermatologic, autoimmune and other debilitating diseases. Brickell's pipeline combines a potential best-in-class, late clinical-stage program for hyperhidrosis with a novel, cutting-edge platform and development stage candidates with broad potential in autoimmune and neuroinflammatory 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 and differentiated 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.

About Voronoi

Voronoi Inc., located in Bio-Cluster in Incheon, South Korea, is a company with global competitiveness in the field of precision medicine targeted treatments. Voronoi has dramatically shortened the development timeline by combining proprietary artificial intelligence (AI) into the entire process of new drug development. The Company has eleven pipelines and is currently negotiating out-licensing arrangements with a number of domestic and overseas pharmaceutical companies regarding these core pipelines, of which the Brickell deal is one such priority. Voronoi has recently been recognized for its technology and business development capabilities through the recent out-licensing of an innovative non-small cell lung cancer investigational treatment to ORIC Pharmaceutical, a Nasdaq-listed

company, and global partnership with inno.N for its selective rearranged during transfection (RET) anti-cancer therapy, For more information, visit https://voronoi.io/ko/

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 pre-clinical and clinical trials, intellectual property rights, including the validity, term and enforceability of such, the expected timing and/or results of regulatory approvals and size and prospects for commercializing any of Brickell's product candidates, or research collaborations with its partners, including in Japan, Korea, 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," "would," "should," "might," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "look forward" and similar expressions and their variants, as they relate to Brickell, Kaken, Voronoi, 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, research results and data that do not meet targets or expectations, 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 or Voronoi to supply and commercialize research material and/or the product in Japan or Korea, as applicable, or obtain or retain adequate pricing or reimbursement, the outcome of Brickell's ongoing U.S. Phase 3 pivotal program on sofpironium bromide, and other current and planned preclinical and clinical trials, 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.

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Source: Brickell Biotech, Inc.