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Brickell Biotech Acquires Exclusive Global Rights to Portfolio of Novel STING Inhibitors Targeting Autoimmune and Inflammatory Diseases from Carna Biosciences

Lead STING inhibitor candidate, BBI-10, demonstrated dose-dependent cytokine reduction in nonclinical in vitro and in vivo studies providing strong proof-of-mechanism

Agreement enhances Brickell's pipeline in immunology and inflammation and leverages its drug development capabilities to advance Carna's next-generation STING inhibitors

BOULDER, Colo. and KOBE, Japan, Feb. 02, 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, and Carna Biosciences, Inc. ("Carna") (JASDAQ: 4572), a clinical-stage biopharmaceutical company focusing on the discovery and development of innovative therapies to treat serious unmet medical needs, today announced that they have entered into a licensing agreement, whereby Brickell will have the exclusive, worldwide rights to develop and commercialize Carna's portfolio of novel, potent, and orally available Stimulator of Interferon Genes (STING) antagonists. STING is a well-known mediator of innate immune responses. Excessive signaling through STING is linked to a number of high unmet need diseases, ranging from autoimmune disorders, such as systemic lupus erythematosus and rheumatoid arthritis, to interferonopathies, which are a set of rare genetic conditions characterized by interferon overproduction.

"Inhibiting the STING pathway is a compelling and differentiated approach. In many chronic inflammatory conditions, persistent inflammation results in substantial tissue damage and release of DNA fragments into the extracellular space. The cGAS-STING pathway is the crucial sensor for these extracellular DNA fragments, which triggers release of interferons and other pro-inflammatory cytokines that further exacerbates the inflammation," states Dr. Monica Luchi, Chief Medical Officer of Brickell. "STING antagonists, especially those like the lead candidate, BBI-10, that inhibit the palmitoylation site and deactivate downstream kinase signaling have continued to attract the interest of many researchers, as well as pharmaceutical companies, because of their potential to target a broad spectrum of inflammatory diseases. We are particularly excited about the potential future opportunity of STING inhibitors in a precision medicine context, considering the cGAS-STING pathway has shown to be overactive in defined clinical subgroups of autoimmune and autoinflammatory conditions, as well as severe genetic disorders."

“Our acquisition of Carna’s next-generation STING inhibitors represents a tremendous opportunity to expand our presence in immunology and inflammation and bring forward new treatment options for patients in need,” commented Robert Brown, Chief Executive Officer of Brickell. “We believe that this portfolio of preclinical STING inhibitors is complementary to our current development-stage pipeline of NCEs, which includes BBI-02, a potential first-in-class DYRK1A inhibitor program that is expected to enter a Phase 1 clinical study in the coming months. These assets position us with two promising and novel immunology targets and we look forward to advancing them further throughout this year.”

“These STING antagonists have been identified from our first non-kinase target project, which we expect to become another cornerstone of the company's drug discovery research. Our compounds have demonstrated strong STING inhibitory potency in various settings, and we are thrilled that they will be further investigated by Brickell,” said Masaaki Sawa, Ph.D., Chief Scientific Officer and Head of Research and Development at Carna Biosciences.

“We are pleased to enter into this agreement with Brickell, as we are always looking for opportunities to accelerate the development of our drug candidates,” said Kohichiro Yoshino, Ph.D., President and Chief Executive Officer at Carna Biosciences. “We admire Brickell’s expertise in developing innovative therapies, and we look forward to Brickell leading the development of our STING antagonists to potentially deliver valuable new treatment options to patients with autoimmune and inflammatory diseases.”

Under the terms of the license agreement, Brickell will make a one-time cash payment to Carna of \$2.0 million. In addition, Brickell will pay Carna success-based development, regulatory, and sales milestone payments of up to \$258.0 million. Carna is also eligible to receive tiered royalty payments ranging from mid-single digits up to 10% of net sales. Brickell will be responsible for all future development activities and expenses related to the STING inhibitor platform.

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 combines several development-stage candidates and a cutting-edge platform with broad potential in autoimmune and inflammatory disorders with a potential best-in-class, late-stage program for the treatment of axillary 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[®], 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>.

About Carna Biosciences

Carna Biosciences is a biopharmaceutical company focused on the discovery and

development of kinase inhibitor drugs to treat serious unmet medical needs in oncology, autoimmune and neurological diseases by inhibiting kinases that are important drivers for those diseases. Carna Biosciences was founded in Kobe, Japan, in 2003 as a spinoff of Japan Organon (Nippon Organon KK). Carna's initial focus was to develop an extensive number of state-of-the-art, highest quality reagents for kinase drug discovery, and has since established a leading drug discovery program with a significant collection of proprietary chemical libraries. For more information, please visit <https://www.carnabio.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, our strategy; future operations; future financial position; future liquidity; future revenue; 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 validity, term, and enforceability of such; the expected timing and/or results of regulatory submissions and approvals; and prospects for commercializing any of Brickell's product candidates, or research collaborations with, or actions of, its partners, including in Japan, South 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," "should," "might," "anticipate," "believe," "estimate," "expect," "intend," "plan," "predict," "potential," "will," "evaluate," "advance," "excited," "aim," "help," "progress," "select," "initiate," "look forward," "promise," and similar expressions and their variants, as they relate to Brickell 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, expectations or regulatory approval requirements; ability to obtain adequate financing for product development, regulatory submissions, and any commercialization; ability to 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; regulatory agency feedback or requests; supply chain disruptions; unanticipated demands on cash resources; any disruption to our business caused by the current COVID-19 pandemic; interruptions, disruption, or inability by Brickell or its partners to obtain or supply research material, raw materials, and/or product anywhere in the world; efforts to obtain and retain adequate pricing and adequate reimbursement and other insurance coverage for our products; the outcome of Brickell's current and planned preclinical and clinical trials across our portfolio; 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. Brickell specifically disclaims any duty or obligation to update forward-looking statements.

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