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AnGes and Brickell Biotech Announce a Collaboration Agreement for the Development of a Novel DNA Vaccine Candidate for COVID-19 in the U.S.

Advancement of the U.S. based program will be dependent upon results generated from AnGes' ongoing and planned clinical studies in Japan

IBARAKI CITY, Osaka and BOULDER, Colo., Sept. 08, 2020 (GLOBE NEWSWIRE) -- AnGes, Inc. ("AnGes"), announced today a collaboration agreement with Brickell Biotech, Inc. ("Brickell") (Nasdaq: BBI), a clinical-stage pharmaceutical company, through which Brickell has the right to develop AnGes' proprietary investigational adjuvanted plasmid DNA vaccine intended to prevent SARS-CoV-2 (COVID-19) in the U.S., South America and certain emerging markets. AnGes is currently conducting Phase 1/2 clinical studies with its vaccine candidate in Japan, with data readouts expected through the first quarter of 2021. The results from these studies will guide AnGes' and Brickell's global development efforts of this novel vaccine candidate.

"We are pleased to enter into this collaboration agreement with Brickell in which we intend to leverage know-how, data and capabilities that Brickell acquired through its merger last year with another vaccine company," said Ei Yamada, President and Chief Executive Officer of AnGes. "This collaboration also provides the opportunity to expand our vaccine candidate into additional markets outside of Japan."

Under the terms of this agreement, AnGes will continue to lead the development of its vaccine candidate in Japan and Brickell will provide information and know-how that could be relevant to such development efforts. In exchange for this, Brickell has received the right to develop and, if approved, commercialize AnGes' DNA vaccine in the U.S. and certain underserved countries.

"We are excited by the opportunity to work with AnGes, a leading vaccine developer in Japan, to potentially bring a COVID-19 vaccine to the U.S. and other countries to help address the global pandemic. AnGes is at the forefront of developing a vaccine for COVID-19 and was the first company in Japan to initiate a COVID-19 vaccine clinical study," commented Robert Brown, Chief Executive Officer of Brickell. "While Brickell remains firmly focused on initiating its U.S. Phase 3 pivotal program for sofpironium bromide for the treatment of primary axillary hyperhidrosis later this year, we look forward to reviewing AnGes' clinical study results and then working together with them and the FDA to determine the best path forward."

About AnGes

AnGes, Inc. is a biopharmaceutical company founded in December 1999 based on an innovative discovery by researchers at Osaka University and focuses on the development of gene-based medicine. For our lead product, HGF Plasmid (gene therapy) for the treatment of critical limb ischemia, the company got the conditional and time-limited approval in March 2019. And its commercialization started in September 2019 in Japan. This is the world's first commercialization using the Plasmid DNA method. Development of NF-κB Decoy Oligonucleotide for diseases including low back pain, and DNA vaccines for high blood pressure is also under way. Furthermore, AnGes started co-development of the DNA vaccine with Osaka University from March 2020 for COVID-19 in Japan. The DNA vaccine for COVID-19 utilizes the method of Plasmid DNA. For more information, visit https://www.anges.co.jp/en/

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 lead product candidate is sofpironium bromide, a novel and potential best-in-class treatment for primary axillary hyperhidrosis. The Company expects to initiate its U.S. Phase 3 pivotal program for sofpironium bromide in the fourth quarter of 2020. In addition, Brickell's Japanese development partner for sofpironium bromide, Kaken Pharmaceutical Co., Ltd., expects to receive a regulatory decision for sofpironium bromide gel, 5% in Japan, later this year.

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, legal, 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 or 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" 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, ability to maintain and enforce intellectual property rights, potential delays for any reason in product development, regulatory changes unsuccessful clinical studies, unanticipated demands on cash resources, any disruption to our business caused by the current COVID-19 pandemic, interruptions, delays or negative determinations on Kaken's new drug application under current review, or on AnGes' development efforts for its lead COVID-19 vaccine candidate, including the outcome of ongoing and planned clinical trials in regard to this asset, 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 http://www.sec.gov (or a t 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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