Brickell Biotech Announces Positive Phase 2b Study Results for BBI-4000 (Sofpironium Bromide) in Subjects with Primary Axillary Hyperhidrosis

Statistically significant outcomes guide plan for Phase 3 development of sofpironium bromide in 2018

More than 15 million Americans, or 4.8% of the U.S. population, live with excessive sweating[1]

Boulder, CO, October 24, 2017 – Brickell Biotech, Inc. ("Brickell"), a clinical-stage medical dermatology company, today announced positive results of its confirmatory Phase 2b study of sofpironium bromide for the topical treatment of primary axillary hyperhidrosis, or excessive underarm sweating.

The multicenter, randomized, double-blind, vehicle-controlled Phase 2b study was designed to evaluate the safety, tolerability and efficacy of three doses of sofpironium bromide delivered as a topically applied gel (5%, 10% and 15%) *vs.* vehicle in 227 subjects with primary axillary hyperhidrosis. Results from the study showed that all three doses of sofpironium bromide met the primary efficacy endpoints by successfully achieving statistical significance compared to vehicle for the Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax), a validated and proprietary patient-reported outcome [PRO] measure. Consistent with previous results, sofpironium bromide was well-tolerated at all three doses, with side effects that were primarily mild in severity.

"We are extremely pleased with these clinical trial results as they represent a significant milestone for sofpironium bromide and our company," said Patricia Walker, MD, PhD, President and Chief Scientific Officer of Brickell. "As a result of this Phase 2b study, we are well-positioned to move sofpironium bromide into Phase 3 development in 2018. We are optimistic that we will soon be able to provide clinically meaningful therapeutic relief to the millions of Americans living with this uncomfortable and embarrassing condition."

Phase 2b Results:

Primary Efficacy Endpoints: Sofpironium bromide demonstrated:

- Statistical significance for change in HDSM-Ax from baseline to end of therapy (EOT) as a continuous measure in all dose groups vs. vehicle ($p<0.0001$).
- Statistical significance for the proportion of subjects who achieved at least a one-grade improvement in HDSM-Ax from baseline to EOT in all dose groups vs. vehicle ($p<0.001$).

Secondary Efficacy Endpoints: Sofpironium bromide demonstrated:

- Statistical significance for the proportion of subjects who achieved at least a two-grade improvement in HDSM-Ax from baseline to EOT in all dose groups *vs.* vehicle ($p<0.001$).
- Statistical significance for change from baseline to EOT in gravimetric sweat production ("GSP") in 5% and 15% dose groups *vs.* vehicle ($p<0.002$).
- Statistical significance for the proportion of subjects achieving at least a 50% reduction in GSP from baseline to EOT in 5% and 15% dose groups *vs.* vehicle ($p<0.02$).
- Statistical significance for composite responder analysis, where an individual subject must have had a 50% reduction in GSP combined with a one or two-grade improvement in HDSM-Ax measure from baseline to EOT in all dose groups *vs.* vehicle ($p<0.0006$ for one-grade and $p<0.002$ for two-grade improvement, respectively).

[1] Doolittle, J., Walker, P., Mills, T. et al. Arch Dermatol Res (2016) 308:743. https://link.springer.com/article/10.1007%2Fs00403-016-1697-9

- Statistical significance for one and two-grade improvements in the Hyperhidrosis Disease Severity Scale (HDSS) from baseline to EOT in all dose groups *vs.* vehicle ($p<0.05$ for one-grade and $p<0.005$ for two-grade improvement, respectively).
- Statistical significance for the Dermatology Life Quality Index (DLQI) score from baseline to EOT in all dose groups *vs.* vehicle ($p<0.004$).

Sofpironium bromide was well-tolerated in all dose groups. No treatment-related serious adverse events were reported. Most anticholinergic Treatment Emergent Adverse Events (TEAEs) were mild or moderate in severity. TEAEs were reversible when treatment was discontinued.

David Pariser, MD, a leading expert on hyperhidrosis, a founding board member of the International Hyperhidrosis Society and an advisor to Brickell said, "These results are welcome news for the hyperhidrosis community, which has been frustrated by the lack of effective and convenient treatment options. The possibility of a new treatment in the future, especially one that is topical and well-tolerated, is an encouraging development for patients and their physicians."

In addition to Brickell's clinical development of sofpironium bromide in the United States, Kaken Pharmaceutical Co., Ltd. (Kaken) is currently conducting a multicenter, randomized, double-blind, vehicle-controlled Phase 2b study. Kaken has the exclusive rights to develop and commercialize sofpironium bromide in Japan, the second largest dermatology market in the world, and certain other Asian countries.

About Sofpironium Bromide

Sofpironium bromide, a new molecular entity and "soft" drug, 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 the activation of sweat glands. Soft drugs, such as sofpironium bromide, exert their action topically and are rapidly metabolized once absorbed into the blood. This mechanism of action allows for effective doses to be used while reducing the limiting systemic side effects associated with other drugs in this class.

About Hyperhidrosis

Hyperhidrosis is a medical condition that affects an estimated 15.3 million people – or 4.8% of the population – in the United States.[1] Of these, 70% report severe excessive sweating in at least one body area, the most common area being the underarms, followed by palms of hands, soles of feet, face and other areas.[1] Nearly half (49%) of people with hyperhidrosis have not discussed their condition with a healthcare professional, either because they believe that it is not a medical condition or that no treatment options exist.[1] Additionally, 75% of subjects with hyperhidrosis say that it has had negative impact on their social life, sense of well-being, and emotional and mental health.[1]

About Brickell Biotech

Brickell Biotech, Inc. is a clinical-stage pharmaceutical company focused on the development of innovative and differentiated therapeutics for the treatment of skin diseases. Its pipeline consists of potential novel therapeutics for hyperhidrosis (excessive sweating), allergic contact dermatitis, cutaneous t-cell lymphoma and psoriasis. Brickell's management team and board of directors have extensive experience in product development, having served in leadership roles at several pharmaceutical and successful start-up companies. Its strategy is to leverage this experience to in-license, acquire, develop and commercialize products that Brickell believes can be successful in the dermatology marketplace. For more information, visit www.brickellbio.com.

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About Kaken Pharmaceutical Co., Ltd.

Kaken (Tokyo Stock Exchange: 4521) is a Japanese specialty pharmaceutical company with a strong presence in the dermatology (antifungals) and orthopedics markets. The company's primary areas of research and development focus include inflammation, immunology (dermatitis, rheumatoid arthritis and osteoarthritis), pain and antifungals.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Words such as "believes" and "planning" or similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to the inherent uncertainties in predicting future results and conditions, many of which are beyond the control of Brickell. Brickell undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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[1] Doolittle, J., Walker, P., Mills, T. et al. Arch Dermatol Res (2016) 308:743.
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