Sofpironium Bromide Demonstrates Promising Potential as a Safe and Effective First-Line Treatment for Primary Axillary Hyperhidrosis (Excessive Underarm Sweating)

Confirmatory Phase 2b Study Results Presented at the 76th American Academy of Dermatology Annual Meeting at the Late-Breaking Research Forum

SAN DIEGO, CA, February 20, 2018 – Brickell Biotech, Inc. ("Brickell"), a clinical-stage medical dermatology company, today announced that the positive confirmatory Phase 2b study (CL-203) results with sofpironium bromide for the topical treatment of primary axillary hyperhidrosis were presented at the 76th American Academy of Dermatology Annual Meeting in San Diego, CA. The study results were presented at the Late-Breaking Research Forum by Stacy Smith, M.D., a practicing dermatologist and participating investigator in the Phase 2b study.

The multicenter, randomized, double-blinded, vehicle-controlled Phase 2b study was designed to evaluate the safety and efficacy of three doses of sofpironium bromide delivered as a topically applied gel *vs.* vehicle in 227 subjects with primary axillary hyperhidrosis. The subjects were randomized evenly to apply sofpironium bromide, 5%, 10%, 15% or vehicle gel to their underarms once nightly for 42 days. At baseline, all subjects had Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) scores of $\geq$3 (scale, 0-4) and a combined axillary gravimetric sweat production (GSP) of $\geq$150mg/5min. The HDSM-Ax is a validated and proprietary patient-reported outcome measure. A one-point improvement in the HDSM-Ax has been established to be clinically meaningful.

Sofpironium bromide met its primary efficacy endpoint of achieving at least a 1-point improvement in the HDSM-Ax. Statistically significant treatment responses were observed as early as Day 8 for both the 5% dose group (p=0.0009) and 15% dose group (p=0.0003) and the response was maintained throughout the treatment period.[1] The proportion of subject responders at the end of treatment was 70.2% (p=0.0387) for the 5% dose group and 75.9% (p=0.0099) for the 15% dose group, compared to 54.4% for the vehicle group.

"This highly statistically significant and clinically meaningful data is very encouraging and consistent with Brickell's previous Phase 2 study (CL-201) results," said Patricia Walker, Chief Scientific Officer and President of Brickell. "We are extremely excited by these promising clinical trial results and are looking forward to the initiation our pivotal Phase 3 studies in the second half of the year."

In addition, sofpironium bromide treated subjects demonstrated statistically significant reductions in GSP when measured as a ranked variable over time for the 5% dose group (p=0.0024) and 15% dose group (p=0.0020). The reductions in rank were observed as early as Day 8 and remained consistent throughout the treatment period. A composite responder analysis also was performed in which, to be considered a treatment success, an individual subject had to achieve both $\geq$1-point improvement in HDSM-Ax and $\geq$50% reduction in GSP. The composite responder analysis demonstrated statistically significant improvement for the 5% dose group (59.6%, p=0.0154) and the 15% dose group (59.3%, p=0.0181) as compared to the vehicle group (38.6%). These statistically significant differences were observed as early as Day 8 for the 5% dose group (p<0.0001) and 15% dose group (p<0.0005) and remained consistent throughout the treatment period.

"Hyperhidrosis significantly impacts the social, occupational and emotional well-being of those affected, and there are currently very limited therapeutic options," said Dr. Smith. "What is most compelling about

[1] The 10% dose group treatment response observed was between the 5% and 15% dose groups, hence, for simplicity of the data presentation, this dose group was excluded.

these results is the potential they suggest for sofpironium bromide to address this unmet medical need. I am excited by the prospect of sofpironium bromide to offer my patients a well-tolerated, effective and convenient first-line treatment option."

Sofpironium bromide was well-tolerated at all three doses, with side effects that were transient and primarily mild to moderate in severity. Treatment-emergent adverse events occurred in 17 (29.8%) subjects in the 5% dose group, 28 (51.9%) subjects in the 15% dose group and 9 (15.8%) subjects in the vehicle group. The most common anticholinergic adverse event was dry mouth. No serious treatment-related adverse events were reported.

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. Brickell is planning to initiate pivotal Phase 3 studies in the second half of 2018.

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.[2] Of these, 70% report severe excessive sweating in at least one body area. The most common area is the underarms, followed by the palms of the hands, the soles of the feet, and the face.[2] 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.[2] 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.[2]

About Brickell Biotech, Inc.

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, 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.

Media Contact:
Stephanie Blank
646-805-2019
stephanie.blank@finsbury.com

[2] 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