BrickellBio

NASDAQ: BBI

Company Overview Presentation

Making Fresh Tracks in Dermatology®

July 2021

Forward-Looking Statements

- This presentation contains forward-looking statements that involve substantial risk and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation other than statements of historical fact, including, but not limited to, statements regarding our strategy; our ongoing and future clinical and non-clinical trials including timing and ability to complete and later report data therefrom; future operations and attendant results; ability to supply material and products; future financial position; liquidity; future revenue; projected expenses; prospects; and staffing, plans and objectives of management are forward-looking statements. The words "believe," "could," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "look forward," "opportunity," "goals," or "should," and similar expressions and their variants, as they relate to Brickell Biotech, Inc., or any of our business partners, are intended to identify forward-looking statements. Such statements are based on Brickell's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors.

- Statements regarding the following subjects, among others, may be forward-looking: Expectations regarding the successful development, regulatory approval and commercialization of sofpironium bromide and our other product candidates; expectations regarding our intellectual property rights and that of our partners; expectations regarding the results and timing of results of clinical trials for sofpironium bromide and our other product candidates; expectations regarding the potential market size, opportunity and growth potential for sofpironium bromide and our other product candidates; expectations regarding the degree of physician and patient adoption and reimbursement, funding and use of sofpironium bromide following regulatory approval in countries like Japan where it has been obtained and in other countries, if received; our relationship with, and expectations of, our product development partners; our cash (and equity) position and ability to obtain adequate financing in the future on satisfactory terms or at all; our expenses and capital requirements; the timing or likelihood of regulatory filings and approvals; the implementation of our business model, strategic plans for our business, product candidates and technology; the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; and developments relating to our competitors; and our business development efforts to enhance the Brickell product pipeline.

- These forward-looking statements are based largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, legal compliance, business strategy, short-term and long-term operations and objectives. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2020, and under a similar heading in any other periodic or current report we may file with the U.S. Securities and Exchange Commission (the "SEC"), in the future. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge quickly and from time to time. It is not possible for our Company to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

Brickell Biotech, Inc. (NASDAQ: BBI)

Striving to be best-in-class in dermatology with a new chemical entity in Phase 3 in the U.S. (and approved in Japan) for the treatment of primary axillary (underarm) hyperhidrosis

PHASE 3 PRODUCT CANDIDATE

- Sofpironium bromide (SB), a novel topical treatment being developed for **primary axillary hyperhidrosis**
- Large estimated market opportunity of **>15 million people in U.S. with hyperhidrosis**
- **U.S. P3 program for SB gel, 15% fully enrolled; topline results expected in Q4 2021**

STRONG ASIA PARTNERSHIP

- SB has been developed & **is being commercialized by Kaken Pharmaceutical** in Japan
- **Commercial launch of SB gel, 5% (ECCLOCK®) underway in Japan** for the once daily treatment of primary axillary hyperhidrosis
- Large estimated market opportunity; **~12.7% of Japanese population has hyperhidrosis**

EXPERIENCED LEADERSHIP

- **Executive team with proven track record**
- **History of successful development and launch** of numerous products achieving first-in-class and/or iconic status

Executing Strategy with Experienced Leadership Team

Brickell executives have successfully developed and launched numerous novel products achieving first-in-class and/or iconic status

Cialis® tadalafil · taltz® (ixekizumab) injection 80 mg/mL · Humalog® KwikPen® insulin lispro injection 100 units/mL · PROZAC® fluoxetine hydrochloride · Cymbalta™ duloxetine · EVISTA® raloxifene HCl · GEMZAR® (gemcitabine) · Dysport® (abobotulinumtoxinA) · Juvéderm® · kybella™ (deoxycholic acid) injection

Robert Brown
Chief Executive Officer

Lilly

Andy Sklawer
Co-Founder & COO

Concordia Pharmaceuticals · Verid

Deepak Chadha
Chief R&D Officer

Allergan · INAMED AESTHETICS · KYTHERA biopharmaceuticals

Gary Walker
Chief Marketing Officer

Lilly · DOW

Albert Marchio II
Chief Financial Officer

CytomX · EDGE Therapeutics, Inc. · Three Fields Capital

David McAvoy
General Counsel & CCO

Lilly · Elanco · ENDOCYTE · NOVARTIS

Why We're Excited About The Sofpironium Bromide Opportunity

Significant Market Opportunity

- Hyperhidrosis (HH) impacts >15M people in U.S
- ~10M with axillary HH in U.S.
- Broad reimbursement potential

Potential Best-In-Class

- Retrometabolically-designed investigational New Chemical Entity
- Multiple ways to differentiate (efficacy, formulation, device)
- First-to-market outside U.S.

Robust Clinical Data

- Statistically significant results in U.S. P2 & JP Pivotal P3
- Completed U.S. & JP P3 long-term safety studies
- U.S. P3 program underway
- Exposure in >1,600 patients for NDA

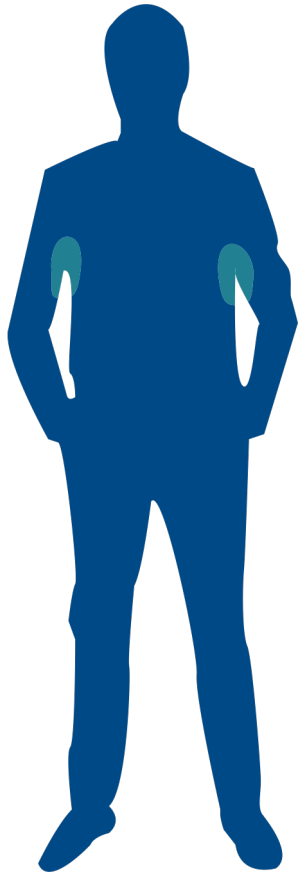
Launched in Japan

- SB gel, 5% (ECCLOCK®) approved & launched in JP for primary axillary HH
- BBI entitled to sales-based milestones and tiered royalties
- Phase 1 PK study in palmoplantar HH patients ongoing in Japan

Global IP Protection

- Comprehensive IP in U.S. and other countries
- Patent protection may extend through 2040

Significant U.S. Market Opportunity in Hyperhidrosis



Hyperhidrosis affects approximately 4.8% of the U.S. population or 15.3M individuals with a reported negative impact on quality of life

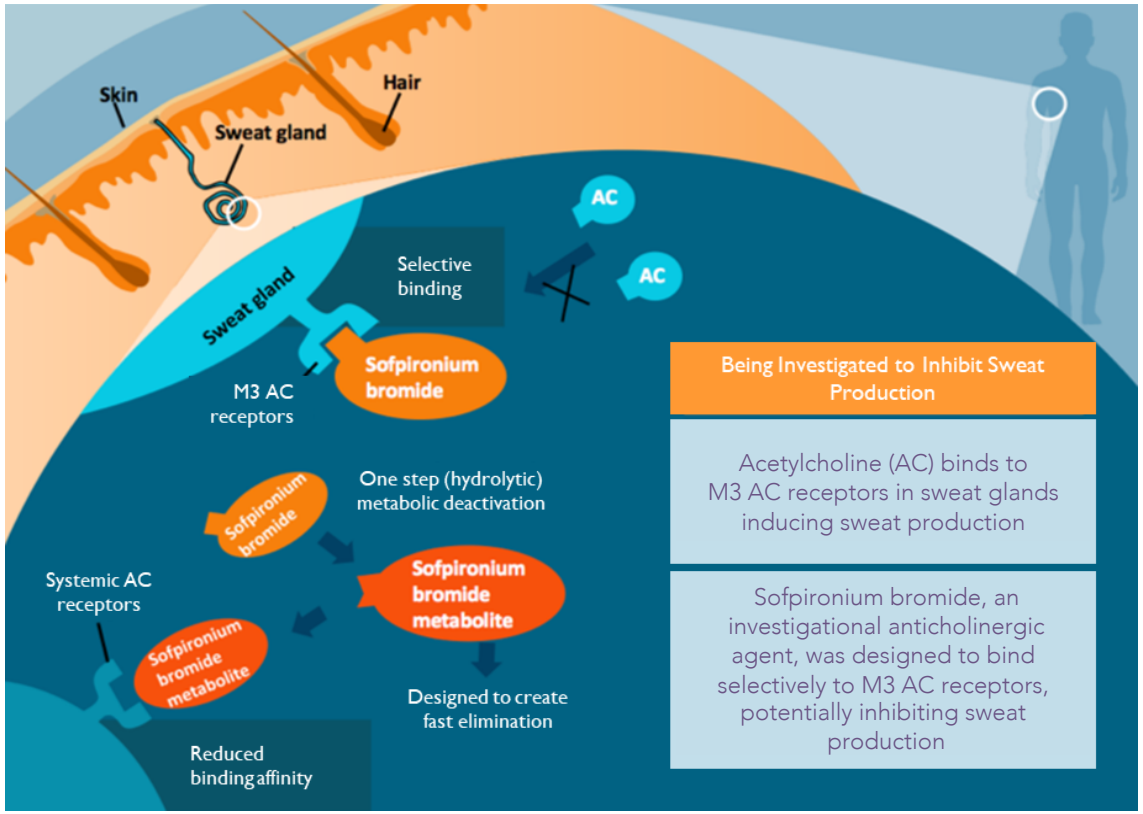
- HH affects **8.8% ages 18–39** and **17.1% ages 12-17** of the U.S. population[1,2]
- Over **10 million individuals in the U.S. suffer from primary axillary HH** and ~80% have multifocal HH (3 or more body areas) [1,3]
- Only **51%** of U.S. HH sufferers have seen a healthcare professional regarding their HH, with approx. **23%** currently receiving treatment[1]
- **75%** of U.S. HH sufferers report a negative impact on their social life, wellbeing, emotional and mental health[1]
- **95%** of HH sufferers say their HH is not resolved[4]

1. Hyperhidrosis: An update on prevalence and severity of hyperhidrosis in the United States, Doolittle, James, October 2016
2. Prevalence of primary focal hyperhidrosis among teens 12-17 in US Population, Glaser, Ballard, Pieretti, Pariser, March 2017
3. Prevalence of multifocal primary hyperhidrosis and symptom severity over time…, Glaser, Ballard, Pieretti, Pariser, 2016
4. Hebert AA, Glaser DA, Ballard AM, Pieretti LJ, Pariser DM. Voice of the hyperhidrosis patient: symptoms, impacts and treatments. Insights from large, open, FDA-attended meeting. Poster presented at the 77th Annual Meeting of the American Academy of Dermatology; March 1-5, 2019; Washington, DC.

Sequence of Currently Available Therapeutic Options for Hyperhidrosis in U.S.

Representative products shown for some therapeutic classes.

Sofpironium Bromide: Retrometabolic Anticholinergic Investigational Agent



- **Sofpironium bromide** is a NCE and analog of glycopyrrolate (an anticholinergic agent)
- **Retrometabolic** molecules are designed such that they undergo rapid metabolism into less active moieties following absorption after topical application and therefore have a short systemic half-life

U.S. Phase 2b Study: Design Overview

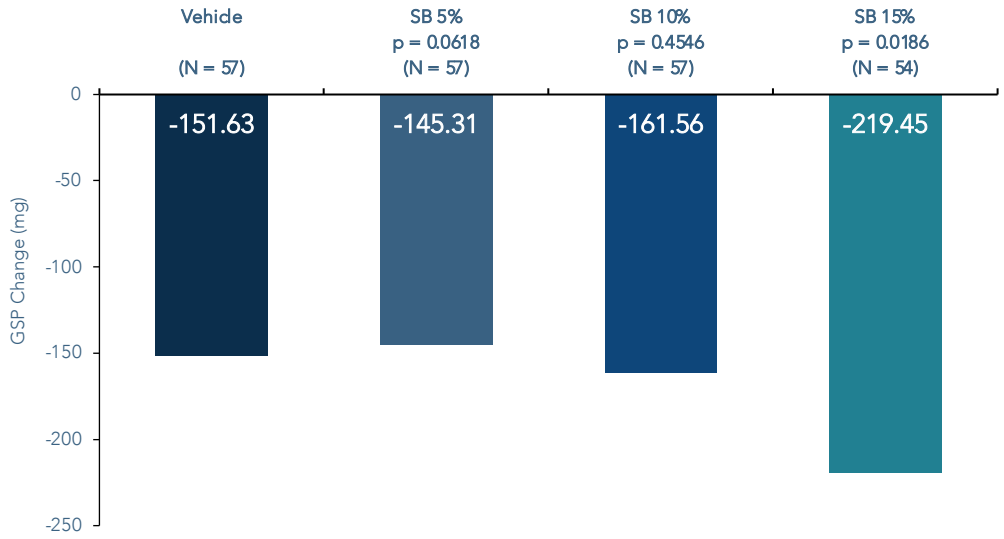
STUDY TITLE	A multicenter, randomized, double-blinded, vehicle (placebo)-controlled study to evaluate the safety and efficacy 5%, 10% and 15% topically applied sofpironium bromide gel in subjects with axillary hyperhidrosis (AH)
STUDY DURATION	6-week treatment with 2-week follow-up
NUMBER OF SUBJECTS & RANDOMIZATION	227 subjects were randomized to either sofpironium bromide, 5%, 10%, 15%, or 0% (1:1:1:1)
KEY INCLUSION CRITERIA	Subjects aged ≥18 diagnosed with primary AH with symptoms for at least 6 months duration, a Hyperhidrosis Disease Severity Measure-Axillary (HDMS-Ax) score of ≥3 and a total Gravimetric Sweat Production (GSP) of ≥150 mg in 5 minutes (both axillae combined, minimum 50 mg / axilla)
PRIMARY EFFICACY ENDPOINTS	Proportion of subjects achieving at least a 1-point improvement in HDSM-Ax from baseline to end of treatment (EOT) Change of HDSM-Ax from baseline to EOT as a continuous measure
KEY SECONDARY EFFICACY ENDPOINTS[1]	Proportion of subjects achieving at least a 2-point improvement in HDSM-Ax from baseline to EOT Change in GSP from baseline to EOT

1. These endpoints are the co-primary efficacy endpoints required by the US FDA for Brickell's prospective U.S. Phase 3 pivotal trials.

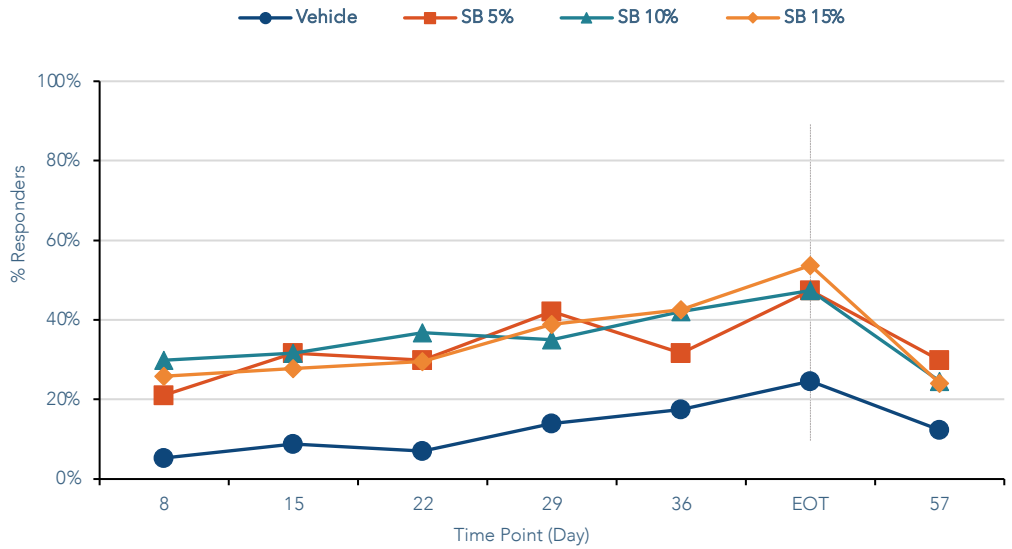
U.S. Phase 2b Study: Phase 3 Co-Primary Efficacy Endpoints Results

Sofpironium bromide (SB) gel, 15% demonstrated statistically significant response for change in GSP and all doses demonstrated statistically significant responses for HDSM-Ax[1]

GRAVIMETRIC SWEAT PRODUCTION (GSP) CHANGE FROM BASELINE TO END OF TREATMENT (EOT) – IMPUTED[1]



HDSM-AX REDUCTION FROM BASELINE (≥2 POINT SHIFT) TO END OF TREATMENT (EOT)[2,3]



1. EOT Imputed includes subjects missing all EOT values, where data is imputed by the mean of the last three available post-baseline visits. Change in GSP - Table 14.2.3.5; Rank value analysis p-values – Table 14.2.3.7
2. ANCOVA model, p-values: 0.0122 (5%); 0.0169 (10%), 0.0025 (15%).
3. Post-hoc analysis with the (7-Item HDSM-Ax Scale), Table 14.2.1.7

U.S. Phase 2b Study: Safety Results

Sofpironium bromide gel was observed to be safe and generally well tolerated; AEs were predominantly mild or moderate in severity with a trend toward dose-dependency

Preferred Term[1]	Sofpironium Bromide Gel			Vehicle (Placebo) Gel
	5%	10%	15%	
	(N = 57)	(N = 57)	(N = 54)	(N = 57)
Subjects Reporting at Least One Adverse Event	17 (29.8%)	19 (33.3%)	28 (51.9%)	9 (15.8%)
Anticholinergic AEs				
Dry Mouth	9 (15.8%)	10 (17.5%)	12 (22.2%)	1 (1.8%)
Blurred Vision	2 (3.5%)	6 (10.5%)	5 (9.3%)	0 (0.0%)
Urinary Hesitation	0 (0.0%)	2 (3.5%)	4 (7.4%)	0 (0.0%)
Nasopharyngitis	3 (5.3%)	1 (1.8%)	3 (5.6%)	0 (0.0%)
Application Site AEs				
Pain	1 (1.8%)	3 (5.3%)	5 (9.3%)	0 (0.0%)
Pruritis	0 (0.0%)	3 (5.3%)	3 (5.6%)	0 (0.0%)
Dermatitis	3 (5.3%)	1 (1.8%)	0 (0.0%)	0 (0.0%)

Twelve subjects discontinued from the study due to TEAEs (7 subjects at 15%, 4 subjects at 10%, 1 subject at 5%).

1. Adverse events depicted here were present in at least one treatment group at >5%.

U.S. Phase 3 Long-Term Safety Study: Design Overview

In this open-label trial, the long-term safety, tolerability and efficacy of SB gel was evaluated in adult and pediatric subjects (300 total) with primary axillary hyperhidrosis*

OBJECTIVES	➢ To evaluate the long-term safety, local tolerability and efficacy of sofpironium bromide gel, 5% and 15% when applied topically to subjects with AHH
STUDY DURATION	➢ 48-weeks of treatment with a 4-week follow-up
RANDOMIZATION	➢ Subjects were randomized 1:2 to receive either sofpironium bromide gel, 5% or 15%
KEY INCLUSION CRITERIA	➢ Subjects ≥9 year of age with AHH of ≥6 months duration ➢ Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) scores of 3 or 4 (scale, 0 - 4)
STUDY ASSESSMENTS	➢ Efficacy Assessments: HDSM-Ax, DLQI, PGI-S, PGI-C, HidroQOL; GSP was not measured ➢ Safety Assessments: Physical Exams, Adverse Events, Local Tolerability, Clinical Laboratories

*This was NOT a rollover study

U.S. Phase 3 Long-Term Safety Study: Incidence of Treatment-Related TEAEs[1]

Daily topical application of SB gel over 48 weeks was generally well tolerated and consistent with prior clinical experience; majority of AEs were mild or moderate and transient in nature

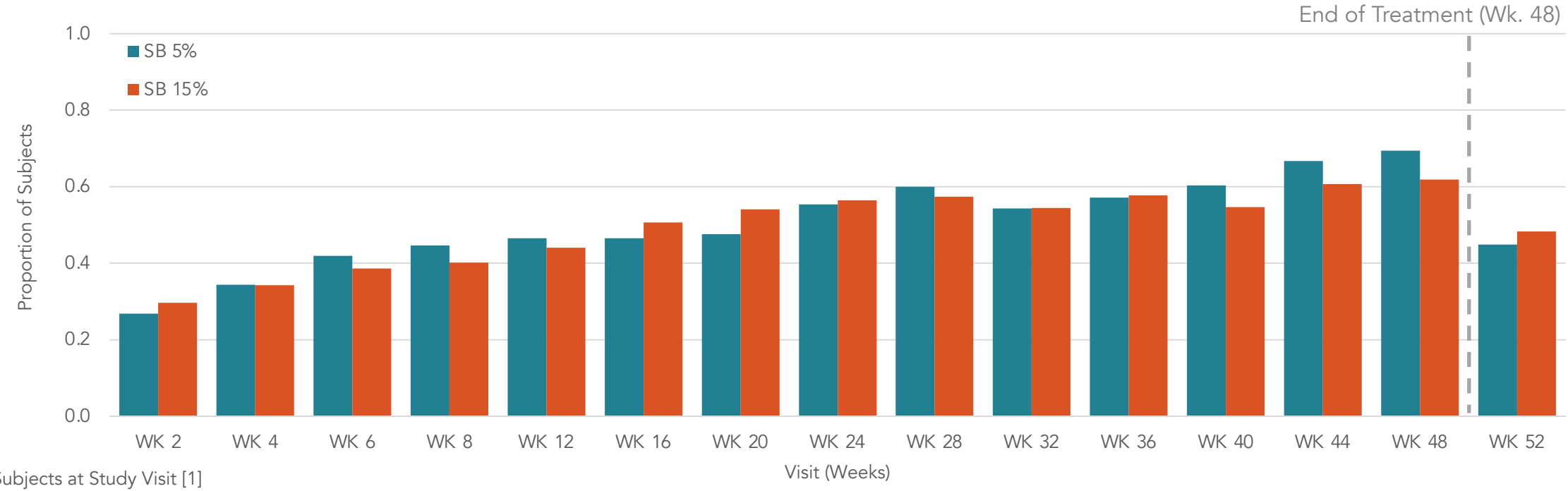
Preferred Term[1]	SB gel, 5% (N = 102)	SB gel, 15% (N=197)
Anticholinergic AEs		
Blurred Vision	4.9%	18.8%
Dry Mouth	8.8%	16.8%
Mydriasis	1.0%	5.1%
Application Site AEs		
Pruritis	5.9%	14.7%
Pain	3.9%	14.7%
Dermatitis	5.9%	9.1%
Erythema	4.9%	7.6%
Irritation	4.9%	5.6%
Infections and Infestations		
Upper respiratory tract infection	8.8%	4.1%

Thirty-seven subjects discontinued from the study due to treatment-related TEAEs (5 subjects at 5%, 32 subjects at 15%).

[1]Adverse events depicted here were present in at least one treatment group at ≥5%

U.S. Phase 3 Long-Term Safety Study: HDSM-Ax Response Over Time

There appears to be efficacy over 48 weeks of treatment as measured by ≥2-point improvement in HDSM-Ax



Subjects at Study Visit [1]	WK 2	WK 4	WK 6	WK 8	WK 12	WK 16	WK 20	WK 24	WK 28	WK 32	WK 36	WK 40	WK 44	WK 48	WK 52
SB 5%	97	96	93	92	86	86	84	83	80	81	77	73	72	72	69
SB 15%	186	178	166	167	152	140	133	133	129	125	123	117	112	113	116

[1] Subjects at Study Visit are subjects with a visit corresponding to the week shown (i.e., still enrolled and receiving treatment at a given timepoint).

Note: The proportions shown are the number of subjects in each treatment group meeting the criteria at each visit out of the number of subjects in each treatment group at each visit. The denominator is defined as the number of subjects in each treatment group at each visit, is displayed

Japan Pivotal Phase 3 Study (Kaken): Design Overview

STUDY DESIGN	➢ Randomized, vehicle-controlled, double-blind, parallel-group trial
NUMBER OF SUBJECTS & RANDOMIZATION	➢ 281 subjects randomized to either vehicle or sofpironium bromide gel, 5% (1:1)
STUDY DURATION	➢ 6-week treatment (applied once a day) with a 2-week follow-up
PRIMARY ENDPOINT	➢ Proportion of subjects achieving BOTH a Hyperhidrosis Disease Severity Scale (HDSS) score of 1 or 2 AND at least a 50% reduction in GSP from baseline to end of therapy
KEY INCLUSION CRITERIA	➢ Subjects who have a diagnosis of primary axillary hyperhidrosis, a HDSS score of 3 or 4, and a total GSP of ≥50 mg / 5 minutes / axilla in at least two of three baseline visits

Japan Pivotal Phase 3 Study (Kaken): Efficacy Results

Kaken achieved statistically significant results (5% concentration) for the primary and secondary efficacy endpoints

	Efficacy Endpoints		SB Gel, 5% n=141	Vehicle Gel n=140	p value
Brickell's U.S. Phase 3 Co-Primary Endpoints[3]	Primary Endpoint	HDSS 1 or 2 at EOT & ≥50% reduction in GSP from Baseline to End of Treatment (EOT) [n (%)]	76 (53.9)	51 (36.4)	0.003[1]
	Secondary Endpoint	Absolute change in GSP (mg) from Baseline to EOT [mean (SD)][4]	-157.6 (149.32)	-127.6 (121.05)	0.015[2]
	Exploratory Endpoint	≥2 point reduction in HDSM-Ax-7 from Baseline to EOT [n (%)][5]	38 (27.0)	16 (11.4)	0.001[1]

[1] χ^2 test; [2] ANCOVA; [3] While the Kaken Phase 3 pivotal study met each of its efficacy endpoints (some of which are not included in this presentation), no inference should be drawn with respect to the efficacy outcomes of our prospective U.S. Phase 3 pivotal studies due to differences in the design, patient population and product utilized in the studies; [4] GSP Inclusion criteria of total GSP ≥50 mg / 5 minutes / axilla in at least two of three baseline visits; [5] HDSM-Ax ≥2 at all three baseline visits were used for this study.

Japan Pivotal Phase 3 Study (Kaken): Safety Results

Anticholinergic and application site adverse events related to study drug were reported to be **mild** and **transient** in nature

Preferred Term[1]	Sofpironium Bromide Gel 5% (N = 141)	Vehicle (Placebo) Gel (N = 140)
Subjects Reporting at Least One Adverse Event	62 (44.0%)	43 (30.7%)
Nasopharyngitis	20 (14.2%)	8 (5.7%)
Anticholinergic AEs		
Dry Mouth	2 (1.4%)	0 (0.0%)
Constipation	1 (0.7%)	0 (0.0%)
Mydriasis	1 (0.7%)	0 (0.0%)
Headache	0 (0.0%)	1 (0.7%)
Vision Blurred	0 (0.0%)	1 (0.7%)
Application Site AEs		
Application Site Dermatitis	12 (8.5%)	3 (2.1%)
Application Site Erythema	8 (5.7%)	1 (0.7%)
Application Site Pruritis	3 (2.1%)	0 (0.0%)
Application Site Eczema	3 (2.1%)	1 (0.7%)

One subject in the 5% dose group discontinued from the study due to a TEAE: mild erythema.

1. This table depicts all anticholinergic TEAEs, all application site TEAEs and all TEAEs at a prevalence of ≥5%.

U.S. Phase 3 Pivotal Study Overview (Cardigan I & Cardigan II)

STUDY TITLE	A multicenter, randomized, double-blinded, vehicle-controlled study to evaluate the safety and efficacy of topically applied sofpironium bromide gel, 15% in subjects with axillary hyperhidrosis
STUDY DURATION	6-week treatment with a 2-week follow-up
NUMBER OF SUBJECTS & RANDOMIZATION	~350 subjects (per study) aged 9 or older will be randomized to sofpironium bromide gel, 15% or vehicle (1:1)
CO-PRIMARY EFFICACY ENDPOINTS AGREED WITH FDA	The proportion of subjects achieving at least a 2-point improvement in HDSM-Ax from baseline to end of treatment The change in GSP from baseline to end of treatment
STUDY POWER CALCULATIONS	The overall study power to demonstrate a statistically significant treatment effect ($p<0.05$) for both co-primary endpoints is ~0.90 (>0.95 for HDSM-Ax and 0.95 for GSP)

Key Achieved & Anticipated Milestones for Sofpironium Bromide

✓	Completion of Phase 3 open-label, long-term safety study in U.S.
✓	Initiation of Phase 3 pivotal clinical program in U.S.
✓	Commercial launch of sofpironium bromide gel, 5% (ECCLOCK®) for the once-daily treatment of primary axillary hyperhidrosis in Japan
✓	Enrollment complete for both Phase 3 pivotal studies in U.S.
Q4 2021	Topline results of Phase 3 pivotal studies in U.S.

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Thank you

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Making Fresh Tracks in Dermatology®

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