9 January 2023

Botanix attends JP Morgan Healthcare Conference

Key highlights

- **Botanix is attending the JP Morgan Healthcare Conference and related meetings being held this week in San Francisco**
- **The Conference attracts more than 50,000 attendees from around the world coming together for partnering and presentation opportunities with pharmaceutical companies and investors**
- **Botanix will be discussing the significant commercial potential of Sofpironium Bromide which remains on track to complete the important FDA mid-cycle review of the NDA this quarter**

Philadelphia and Phoenix US, 9 January 2023: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to advise that it is attending the JP Morgan Healthcare Conference and related meetings being held in San Francisco this week.

The Conference brings together more than 50,000 healthcare executives from around the world to participate in investor presentations, partnering discussions and industry engagement, in a return to in-person meetings in 2023. Botanix will be discussing the significant commercial potential of Sofpironium Bromide and sharing some of the independent market research recently completed by Triangle Insights.

With the formal filing of the Sofpironium Bromide NDA now accepted by FDA and a standard review period confirmed, a mid-cycle review remains on track for this quarter which is an important next milestone for Botanix. The mid-cycle review provides FDA management and review teams with an opportunity to identify any material issues relating to the NDA review which will be communicated to Botanix and will serve to substantially de-risk the ultimate approval of Sofpironium Bromide, which is on target for 3Q 2023.

A copy of the presentation being utilized by the Company for meetings is attached to this press release.

Release authorised by

Vince Ippolito
Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is committed to the development of novel treatments for a range of common skin diseases. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide, for the treatment of primary axillary hyperhidrosis, filed for FDA approval in Q3 CY2022 with approval expected in Q3 2023. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea (successful Phase 1b/2 study in 4Q 2022), dermatitis and acne respectively. Botanix is also developing a topical antimicrobial product for the eradication of bacteria on the skin surface, initially in patients who are undergoing hemodialysis.

Botanix leverages its proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which is utilised in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. To learn more please visit: http://www.botanixpharma.com/

For more information, please contact:

General enquiries
Corporate Communications
Botanix Pharmaceuticals
P: +61 8 6555 2945
investors@botanixpharma.com

Investor enquiries
Hannah Howlett
WE Communications
P: +61 450 648 064
hhowlett@we-worldwide.com

Media enquiries
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs, the Company's ability to obtain marketing approvals for is product candidates, the expected timing and/or results of regulatory approvals and the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Investor Update

JP Morgan Healthcare Conference
January 2023

Preparing for FDA mid-cycle review of Sofpironium Bromide in Q1 2023

botanix

Botanix: a leader in topical drug development

Preparing to file for FDA approval of first product in a $1.6 billion market

Dermatology focus

New treatments for common skin diseases - such as excessive sweating (hyperhidrosis), rosacea and acne – as well as life-threatening bacterial infections

Topically driven

Targeting key indications with topical (gel) treatments that are safe, well tolerated and validated with clinical efficacy

World class team

US based team that have been responsible for more than 30 dermatology drug developments and launches

Sofpironium Bromide (“SB”)

First and only new drug for “primary axillary hyperhidrosis” (medical condition which results in excessive underarm sweating) already approved in Japan and sales ramping up with partner[1]

Mid-cycle review catalyst

FDA mid-cycle review of SB scheduled for 1Q 2023, which will identify if there are any significant issues remaining for review

Source 1 : ASX release May 4 2022

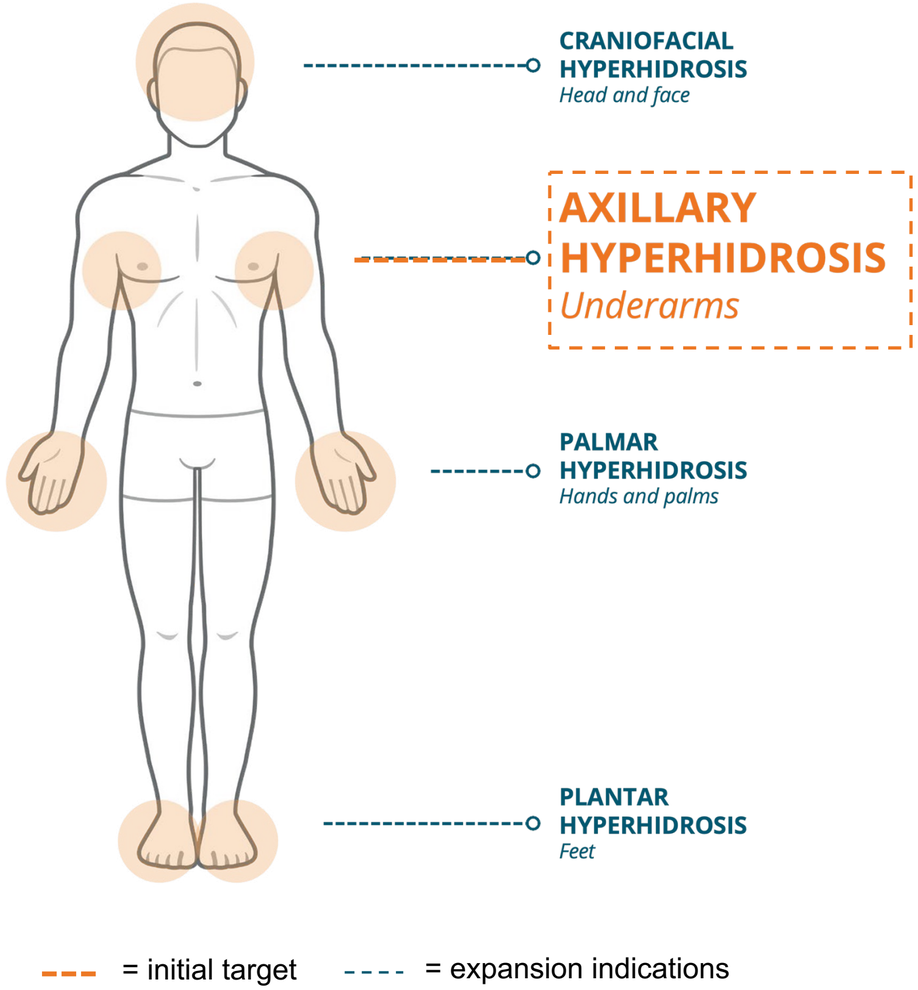
Hyperhidrosis

A medical condition where excessive sweating occurs beyond what is needed to maintain normal body temperature

Hyperhidrosis affects ~16M people in the US:[1]

- Results from overstimulation of the nervous system (a physiological not psychological condition)[1]
- 90% of axillary (underarm) patients also have it in a second region[1]
- The most common age of onset for axillary hyperhidrosis patients is 12-17[2]

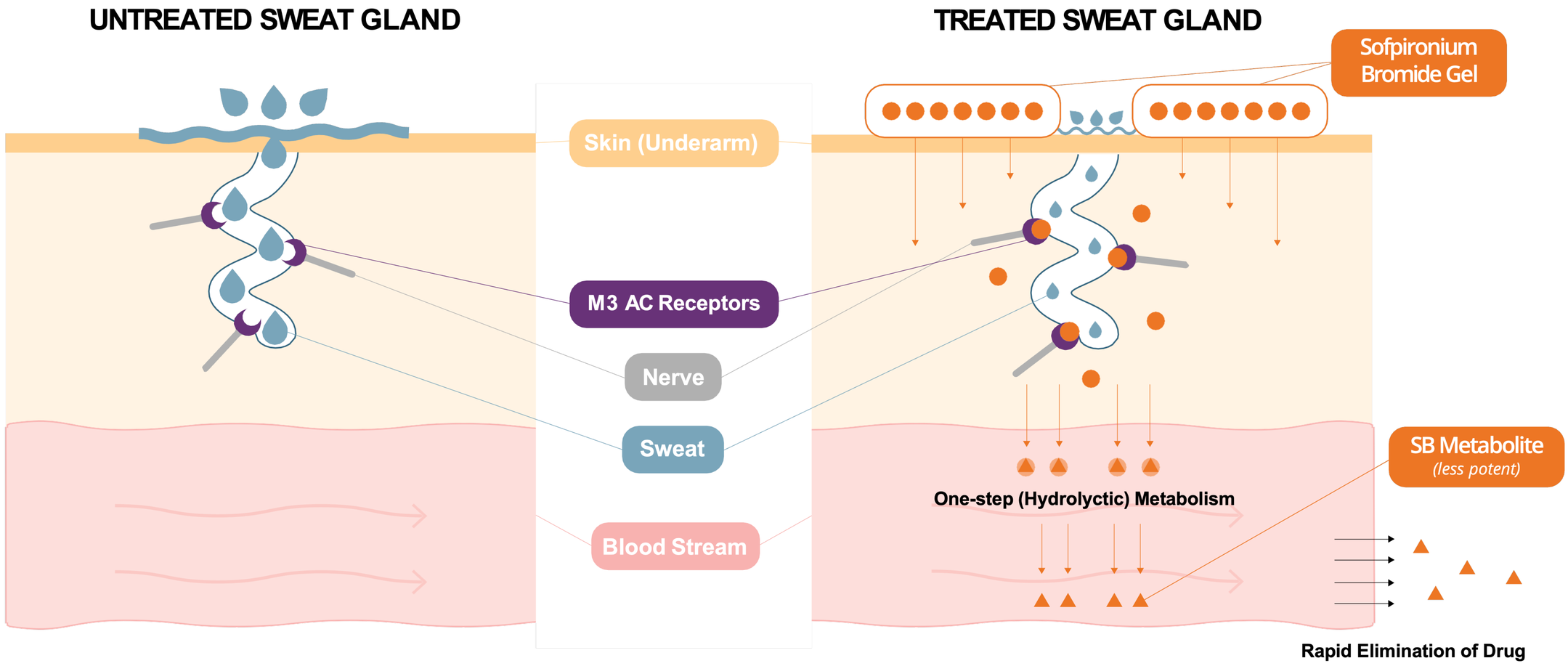
Market for treatments is ~$US1.6B per annum - projected to grow to $US2.8B by 2030



Source: 1. Doolittle, J. et al. Arch Dermatol Res, 2016. 2. Hamm H. et al. Dermatology. 2006.

Sofpironium Bromide mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion



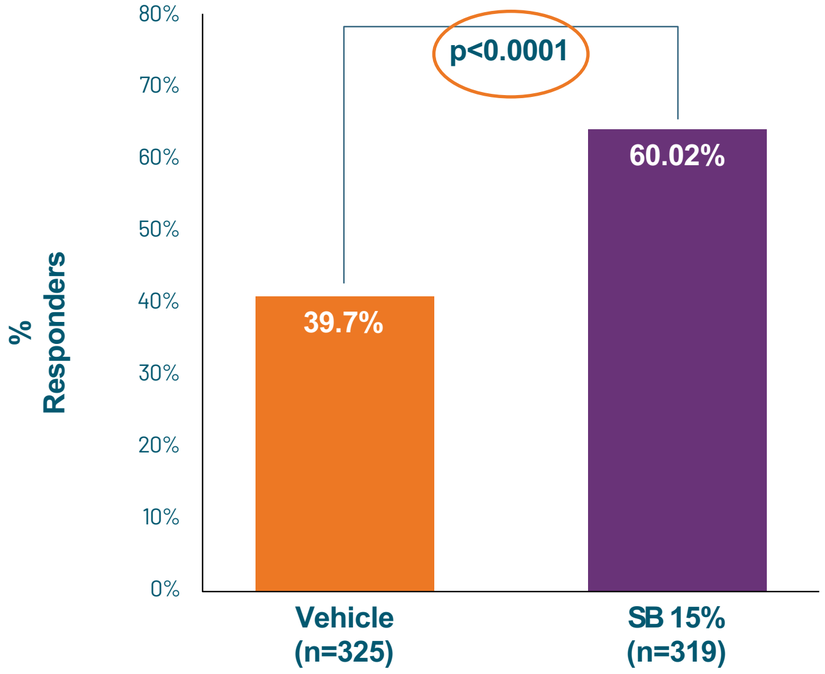
M3 AC Receptors = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

SB Metabolite = Sofpironium Bromide is converted into a less active form to help minimize side effects

Both Phase 3 clinical study co-primary endpoints were highly statistically significant

Pooled Data (Cardigan I and II)

≥2-point improvement in HDSM-Ax-7 from baseline to end of treatment[1]

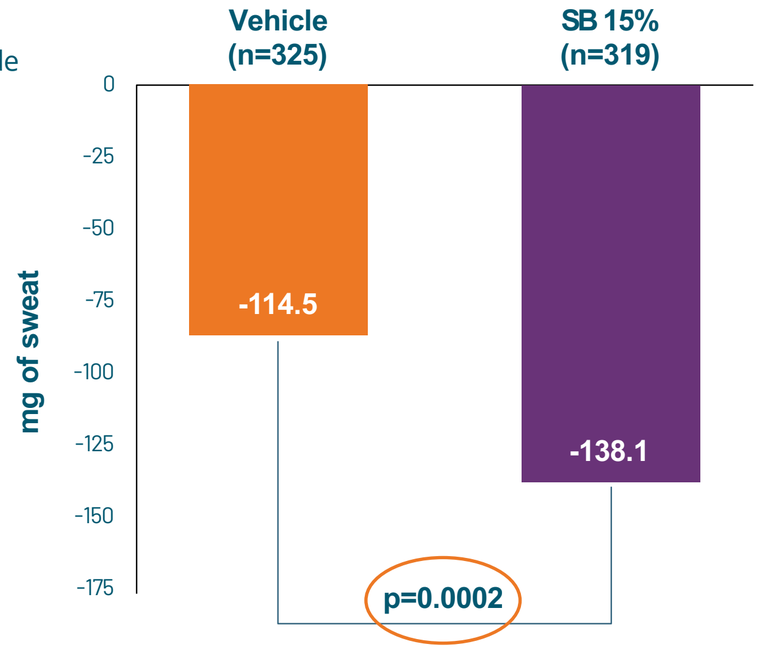


SB = Sofpironium Bromide

HDSM-Ax-7 scale measures patient reported severity of axillary (underarm) hyperhidrosis

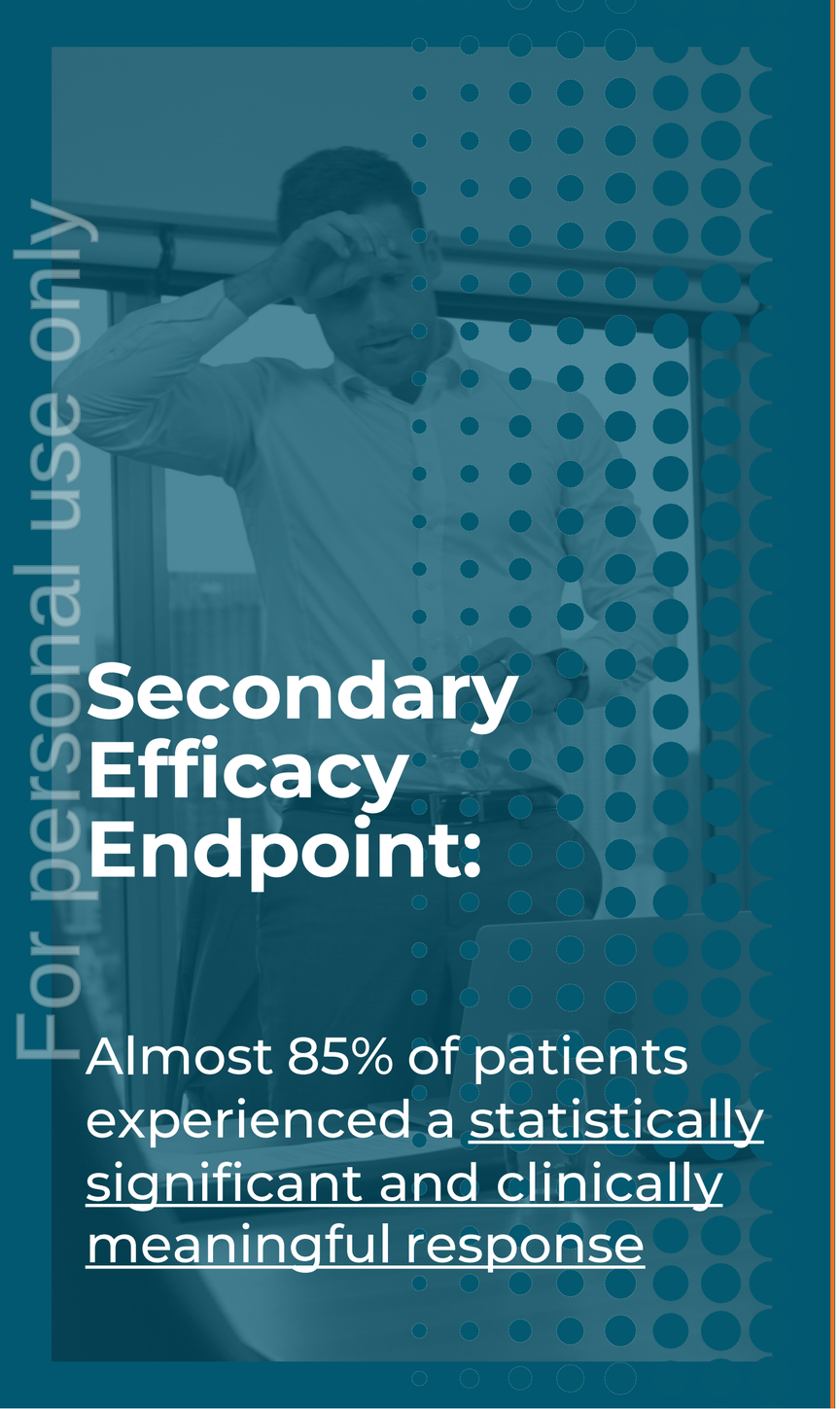
Pooled Data (Cardigan I and II)

GSP change from baseline to end of treatment[1]



GSP (Gravimetric Sweat Production) is an objective measurement of underarm sweat production over 5 minutes

Source: 1. Data on File

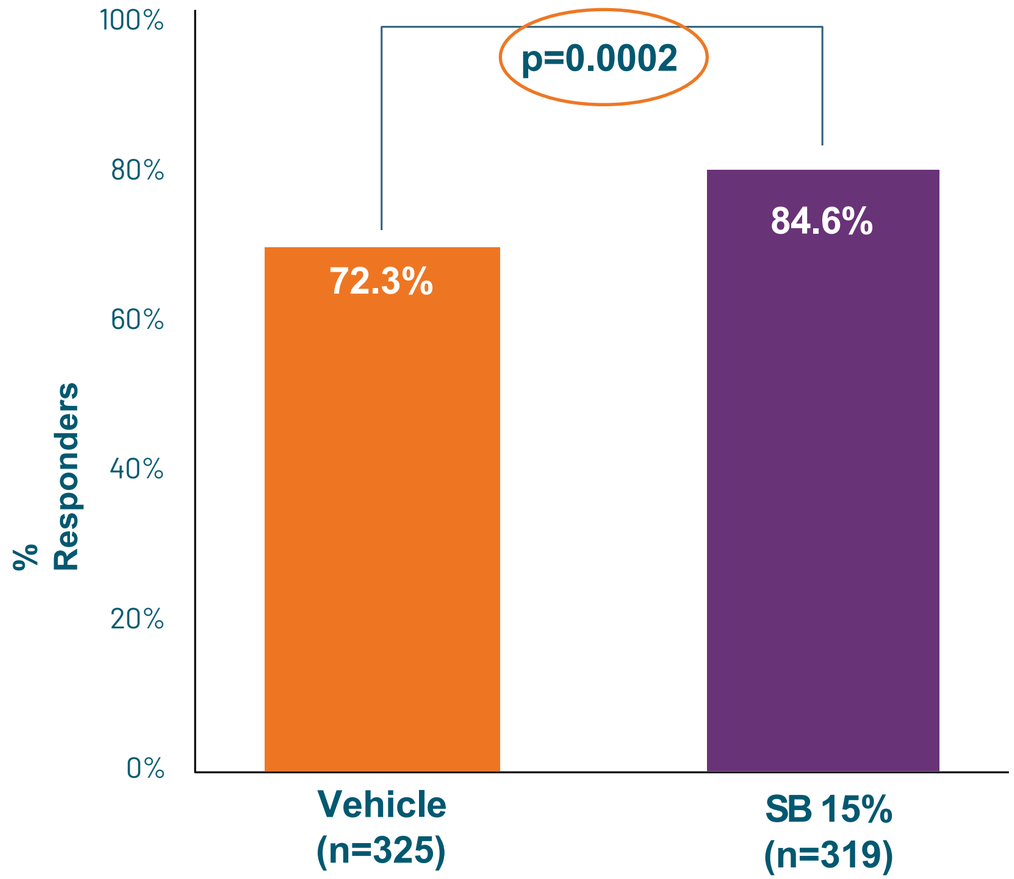


Secondary Efficacy Endpoint:

Almost 85% of patients experienced a statistically significant and clinically meaningful response

Pooled Data (Cardigan I and II)

HDSM-Ax-7 reduction (≥1-point improvement) from baseline to end of treatment[1]



SB = Sofpironium Bromide

Source: 1. Data on File

Stakeholder research shows a significant market opportunity for Sofpironium Bromide

TRIANGLE INSIGHTS GROUP
INSIGHTS THAT INSTILL CONFIDENCE
a trialcard company

Overview & Epidemiology

- Hyperhidrosis causes excessive sweat production, mostly in the underarms, and comes with associated psychological effects, including anxiety and embarrassment
- Hyperhidrosis impacts ~16M individuals in the US, though it is *under-diagnosed and under-treated*, with only ~2.4M patients currently treated for hyperhidrosis

Treatment & Unmet Need

- Current treatment regimens use OTC and Rx topicals before progressing to systemic orals, Botox, or more invasive procedures
- More effective treatment options typically carry high out of pocket patient costs
- Dermatologists and patients indicated a need for more effective treatment options without access/cost concerns

Stakeholder Receptivity

- Dermatologists rated SB favorably, citing improvements in efficacy, tolerability, and administration/convenience
- Payers viewed SB favorably, indicating that it would address a need for more treatments and suggested it would be covered if priced appropriately
- Patients viewed SB favorably, appreciating the limited side effect profile, administration convenience, and perceived efficacy

Opportunity for SB

- SB is expected to be the primary second line therapy, with potential to expand into the first line therapy space too
- US revenue expectations are strong with the base commercial launch alone, with significant upside potential driven by digital launch strategies and higher annual prescription fulfillment performance

Source: Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20) Q4 2022

Independent market research shows 85% of patients and dermatologists would use and prescribe Sofpironium Bromide

TRIANGLE INSIGHTS GROUP
INSIGHTS THAT INSTILL CONFIDENCE
a trialcard company

Stakeholders indicated the ***top two unmet needs*** are as follows:
1) New treatment options (i.e., limited options) and 2) and More efficacious treatments without access/cost concerns.

Unmet Need: ~6 out of 7

*"I can count on one hand my total armory for treating hyperhidrosis. I need **more tools in my toolbox** and a **convenient product** for my patients."*

– Dermatologist

A rating of 4 out of 7 is high based on our experience with payers across therapeutic areas

Unmet Need: ~4 out of 7

*"We are always looking for more **efficacious** therapies that are **easier to take**…"*

– Payer

Unmet Need: ~6 out of 7

*"The treatments that we have are **not very convenient** and are **pretty costly**. I just feel like there are **not enough options.**"*

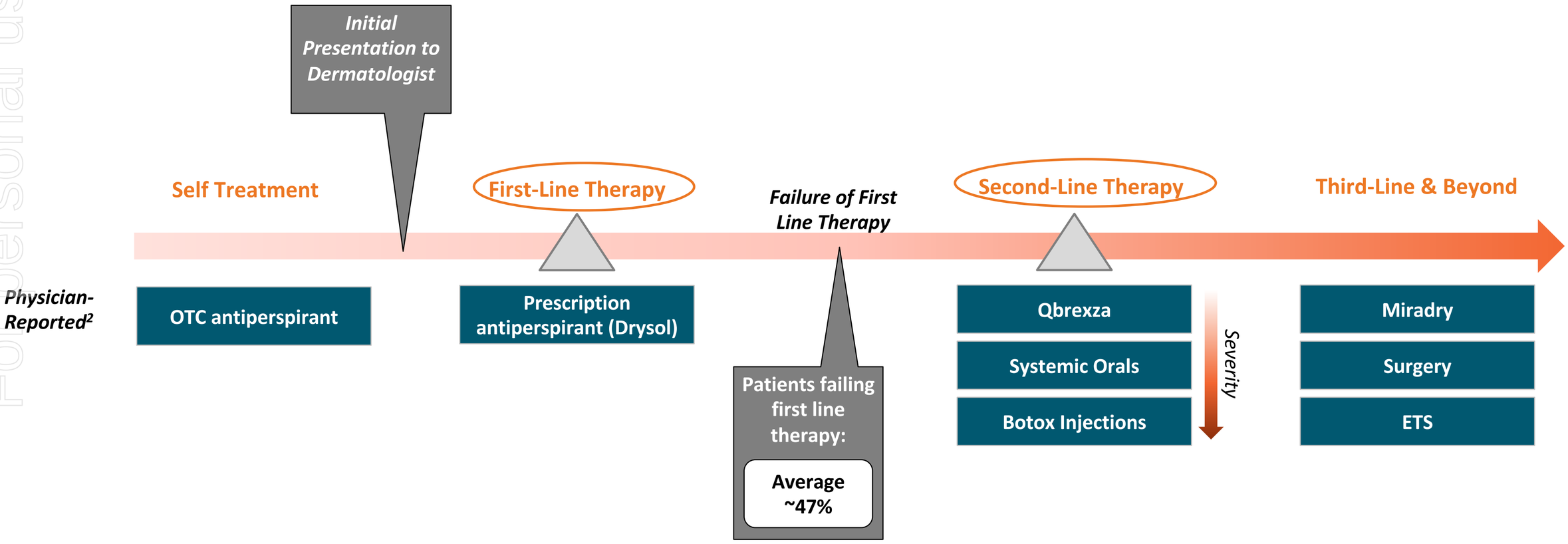
– Patient

With **~13M hyperhidrosis patients in the US, a significant opportunity exists for a new topical product** to address an unmet need if it is effective, convenient, and not priced prohibitively.

Source: Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20) Q4 2022

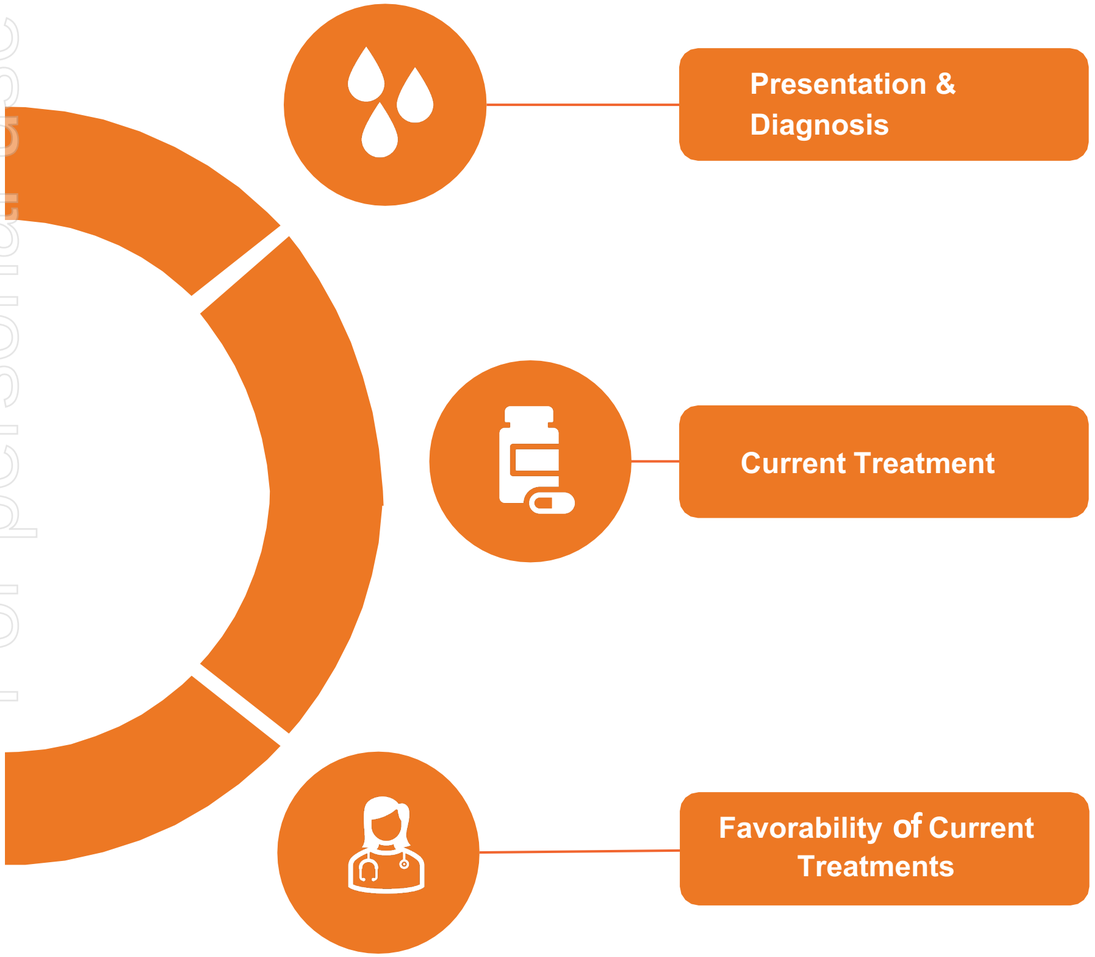
Research shows almost half of all patients fail first line prescription antiperspirants and progress to second line therapies

Hyperhidrosis Patient Journey and Treatment Paradigm



Sources: 1) International Hyperhidrosis Society Guidelines, 2) TIG Interviews with N=20 dermatologists, conducted September & October 2022

Physician interviews show that a new treatment is needed in the marketplace



Presentation & Diagnosis

- Patients will typically **deal with symptoms for several months to multiple years**, depending on severity and impact on QoL, **before presenting for care**
- Diagnosis involves qualitative symptom and history evaluation, rather than clinical (e.g weighing sweat production) measurement

Current Treatment

- Treatment pathways will **start with first line prescription topical antiperspirants** for several weeks before progressing to variable second-line treatments
  - Patients with milder symptoms are often managed by first line therapies, but up to **~60% of severe patients are unmanaged by their first line therapy**
  - Mild patients commonly progress to topical glycopyrrolate or a systemic oral agent
  - Moderate to severe patients will progress to topical glycopyrrolate or a systemic oral agent with only ~25-35% receiving injections between or other surgical interventions

Favorability of Current Treatments

- Physicians were generally positive with the existing limited range of second line therapies, but noted that access and co-pay costs can be preventative in using these treatments (even when the treatments are covered)
- Dermatologists suggested a willingness to work through prior authorization requirements for what they consider to be more effective treatments

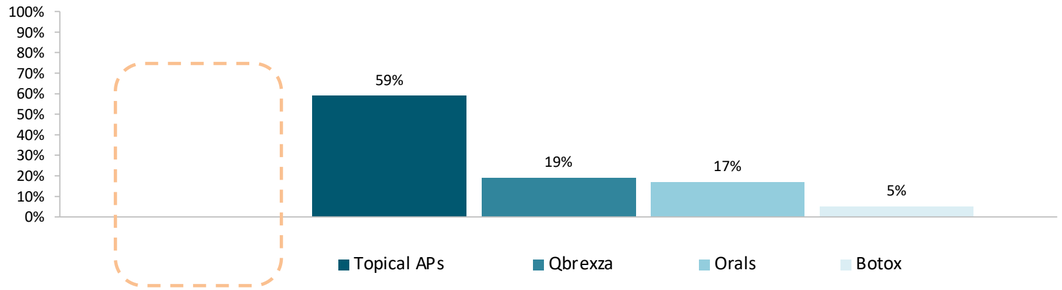
Source: Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20) Q4 2022

Research indicates dermatologists would start *new* patients on Sofpironium Bromide in addition to moving *existing* patients

Current Prescription Preferences

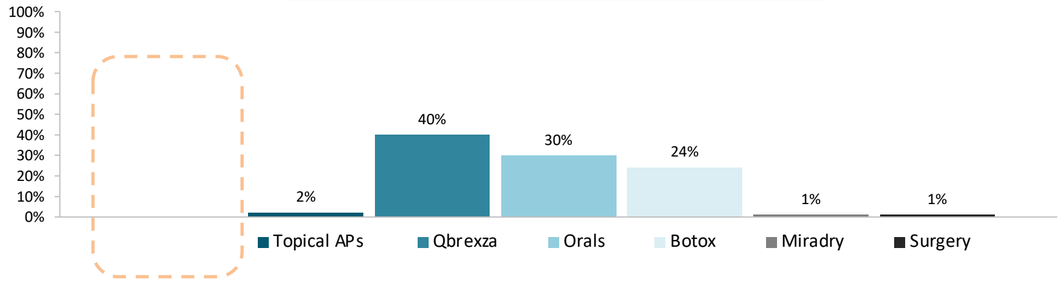
First Line

Share of Patients Receiving Treatments (1L)



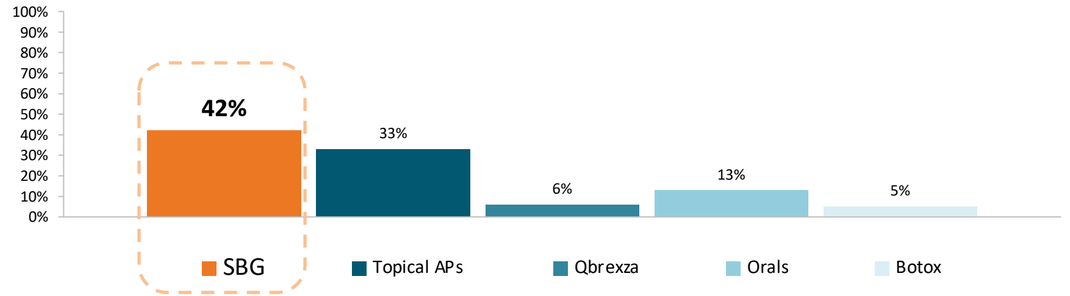
Second Line

Share of Patients Receiving Treatments (2L)

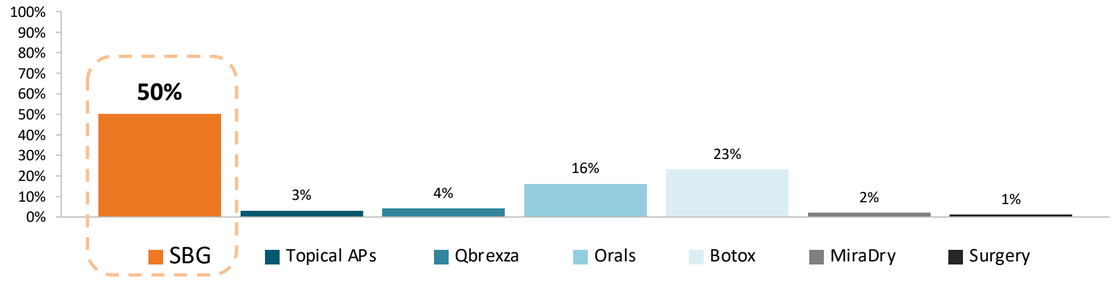


Prospective Prescription Preferences

Share of Patients Receiving Treatments (1L)



Share of Patients Receiving Treatments (2L)



*Share of patients by treatment type shows a weighted average across severities

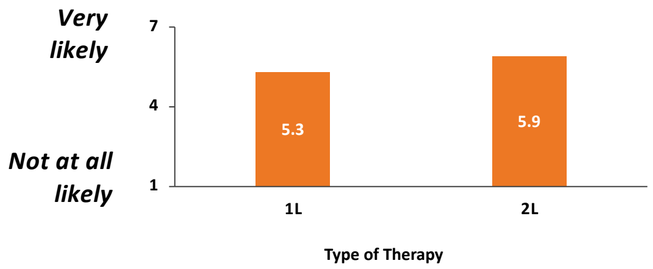
Source: Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20)

Patients would also use Sofpironium Bromide as a *new* first line therapy as well as in preference to *existing* second line therapies

Patients: SB Receptivity

On a scale of 1-7, where 1 = not at all favorable and 7 = very favorable, how would you rate the product overall?

How would you rate your likelihood to request this product from a doctor before other first or second line therapies?



Perceived Benefits

Key Perspectives

Safety and Efficacy

- Most patients stated that SB shows potential to treat hyperhidrosis due to its reported efficacy and significant reduction in measured sweat
- Patients highlighted the minimal side effects and no adverse events

Convenience

- Patients viewed SB as “easy to use”, noting its deodorant-like applicator and once-daily use (and highlighting the importance of this attribute)

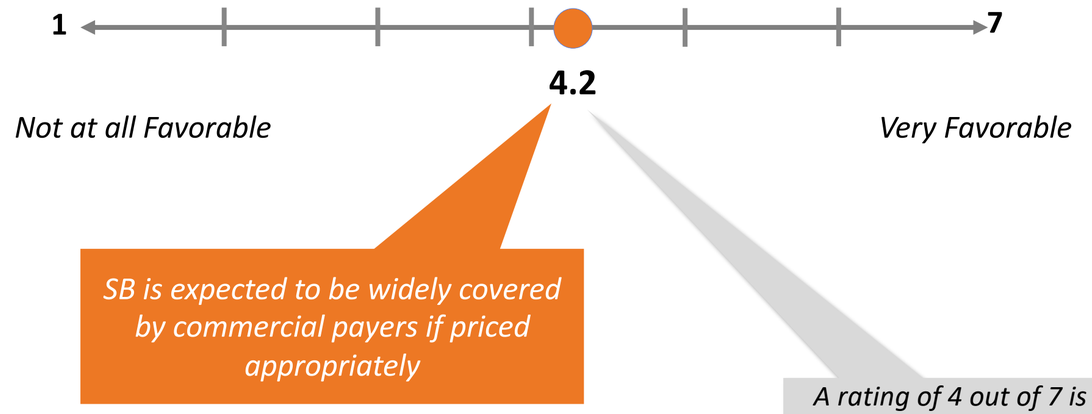
> *“It’s **nice that it comes with an applicator** as opposed to wipes…wipes as an application is just awkward and always wondering whether it's distributing correctly.”*
>
> – Patient

Source: Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20)

Payers were receptive to Sofpironium Bromide, noting favorable profile and high likelihood of coverage

Payers: SB Receptivity

On a scale of 1-7, where 1 = not at all favorable and 7 = very favorable, how would you rate the product overall?



SB is expected to be widely covered by commercial payers if priced appropriately

A rating of 4 out of 7 is high based on Triangle Insights experience with payers across therapeutic areas

Perceived Benefits

Key Perspectives

Efficacy

- Statistically-significant improvement over logical coprimary endpoints provided confidence to payers that SB was an effective treatment of hyperhidrosis

Safety Profile

- Minimal significant adverse effects, and a low trial discontinuation rate, validating the superiority in safety and tolerability relative to orals
- Low expected discontinuation rates were highlighted as a positive

Additional Treatment Option

- SB would provide an additional therapeutic option to patients with a novel route-of-administration; however, disagreement existed over whether the topical gel ROA was preferable to topical wipes

> *"This is **another tool** for the more severe patient…this **could meet the unmet need** [for more treatment options]. If it were me, I would try this first before treatments needing painful injections (e.g., Botox)…"*
>
> – Payer

Source: Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20)

Sofpironium Bromide approval in Japan de-risks FDA approval and supports commercial success

KAKEN

Approval Date	September 25, 2020 in Japan
Indication	Primary axillary hyperhidrosis
Launch Date	November 26, 2020
Application	An applicator allows for drug application without the need for the patient to touch the product
Name	Ecclock®

Mitigation of Commercial & Clinical Risk

Clinical & Regulatory

- Japanese approval paired with strong Phase 3 clinical trial results in the U.S. help to support safety and efficacy and de-risk SB from a regulatory standpoint

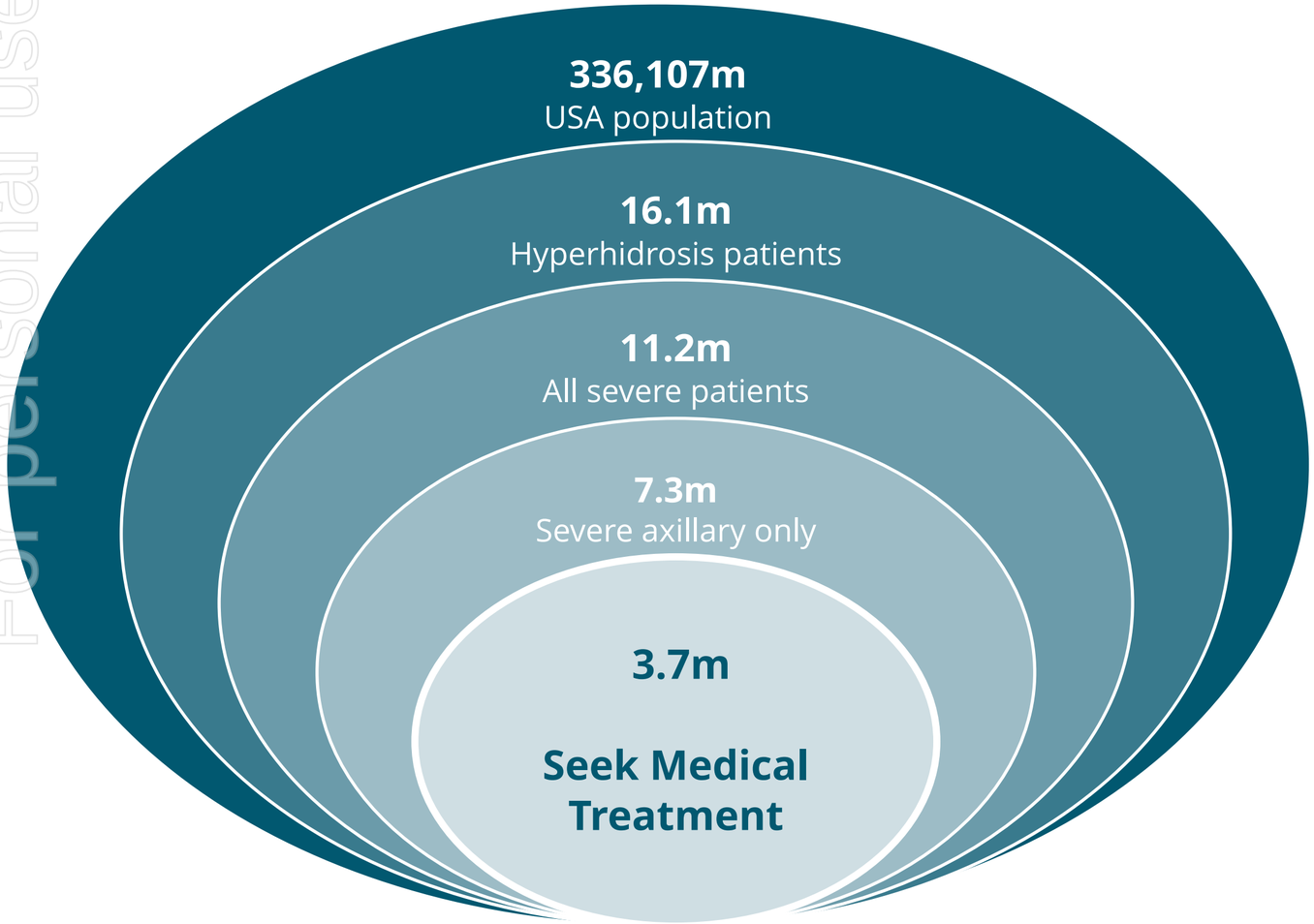
Commercial

- Inclusion on the National Health Insurance drug reimbursement price list supports the perceived need for the product from payers and suggests receptivity to Ecclock's (SBG) value proposition
- Initial performance in the Japanese market is promising, with year 2 sales estimated to reach ~300K units

Source: Kaken Company Website, Kaken Press Release November 18 2020, Kaken 2021 Corporate Report, FreshTracks Pharma (FKA Brickell Bio) Press Release June 24 2021

US market opportunity for hyperhidrosis[1]

Even a modest market share provides a significant financial opportunity



Share of patients already seeking treatment	Patients	Potential gross sales*
0.5%	18,500	$144,300,000
1.0%	36,700	$288,600,000
1.5%	55,500	$432,900,000
2.0%	74,000	$577,200,000
2.5%	92,500	$721,500,000
3.0%	111,000	$865,800,000

* Current yearly cost of topical treatment is ~US$7,800

Source. 1.Reports and Data, "Hyperhidrosis Treatment Market By Treatment Type, By Disease Type, By End-User, By Regional Outlook, and Segment Forecasts, 2022.

Value inflection points accrue as FDA review progresses

Critical mid-cycle review scheduled for 1Q 2023

✓	Phase 3 Clinical Studies	Positive efficacy data for both co-primary endpoints and positive extended safety
✓	NDA submission to FDA	Completion of NDA submission assembling all pre-clinical, clinical and manufacturing information for review
✓	Acceptance of NDA filing by FDA	Confirmation that the file is substantially complete and no advisory board required, with Q3 2023 approval target
1Q 2023	Mid-cycle review by FDA	**Feedback from FDA that there are no significant issues remaining for review**
	NDA Approval	Final approval

Sofpironium Bromide leads late-stage pipeline

Filed for FDA approval in 3Q 2022 with 12-month review period

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED
Axillary Hyperhidrosis (excessive underarm sweating)	Sofprionium Bromide					
Moderate to severe acne	BTX 1503					
Rosacea	BTX 1702					
Atopic Dermatitis	BTX 1204A					
Antimicrobial	BTX 1801					

Attractive late-stage pipeline with near term FDA approval expected for Sofpironium Bromide

Important Notice & Disclaimer

1. Summary information

This presentation has been prepared by Botanix Pharmaceuticals Ltd ("Botanix") and contains summary information about Botanix and the business conducted by it which is current as at the date of this presentation ("Presentation") (unless otherwise indicated).

The information in this Presentation is general in nature and does not purport to be accurate nor complete, nor does it contain all of the information that an investor may require in evaluating a possible investment in Botanix, nor does it contain all the information which would be required in a disclosure document or prospectus prepared in accordance with the requirements of the Corporations Act 2001 (Cth). It has been prepared by Botanix with due care but no representation or warranty, express or implied, is provided in relation to the accuracy, reliability, fairness or completeness of the information, opinions or conclusions in this Presentation by Botanix or any other party.

The information in this Presentation remains subject to change without notice. Reliance should not be placed on information or opinions contained in this Presentation, and Botanix does not have any obligation to finalise, correct or update the content of this Presentation. Certain data used in this Presentation has been obtained from research, surveys or studies conducted by third parties, including industry or general publications.

To the maximum extent permitted by law, Botanix is not responsible for updating, nor undertakes to update, this Presentation. It should be read in conjunction with Botanix's other periodic and continuous disclosure announcements lodged with the ASX, which are available at www2.asx.com.au or at https://botanixpharma.com/category/asx-releases/.

2. Not an offer

Neither this Presentation nor any of its contents will form the basis of any understanding, proposal, offer, invitation, contract or commitment.

3. Industry data

Certain market and industry data used in connection with or referenced in this Presentation has been obtained from public filings, research, surveys or studies made or conducted by third parties, including as published in industry-specific or general publications. Neither Botanix nor its advisers, or their respective representatives, have independently verified any such market or industry data.

4. Financial data

All dollar values are in United States dollars ($ or US$) unless otherwise stated. Amounts, totals and change percentages are calculated on whole numbers and not the rounded amounts presented.

5. Forward-looking statements and forecasts

This Presentation contains certain "forward-looking statements" and comments about future matters. Forward-looking statements can generally be identified by the use of forward-looking words such as, "expect", "anticipate", "likely", "intend", "should", "could", "may", "predict", "plan", "propose", "will", "believe", "forecast", "estimate", "target" "outlook", "guidance" and other similar expressions and include, but are not limited to, plans and prospects for the Company, the Company's strategy, future operations, the expected timing and/or results of regulatory approvals and prospects of commercialising product candidates or research collaborations with its partners, including in Japan, the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements. You are cautioned not to place undue reliance on forward-looking statements. Any such statements, opinions and estimates in this Presentation speak only as of the date hereof, are preliminary views and are based on assumptions and contingencies subject to change without notice, as are statements about market and industry trends, projections, guidance and estimates. Forward-looking statements are provided as a general guide only. The forward-looking statements contained in this Presentation are not indications, guarantees or predictions of future performance and involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Botanix, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct.

Any such forward looking statements are also based on assumptions and contingencies which are subject to change and which may ultimately prove to be materially incorrect, as are statements about market and industry trends, which are based on interpretations of current market conditions. Investors should consider the forward looking statements contained in this Presentation in light of those disclosures and not place undue reliance on such statements (particularly in light of the current economic climate and significant volatility, uncertainty and disruption caused by the COVID-19 pandemic). The forward looking statements in this Presentation are not guarantees or predictions of future performance and may involve significant elements of subjective judgment, assumptions as to future events that may not be correct, known and unknown risks, uncertainties and other factors, many of which are outside the control of Botanix.

Except as required by law or regulation, Botanix undertakes no obligation to finalise, check, supplement, revise or update forward-looking statements or to publish prospective financial information in the future, regardless of whether new information, future events or results or other factors affect the information contained in this Presentation.

6. No liability

The information contained in this document has been prepared in good faith by Botanix. Neither Botanix, nor any of its advisers or any of their respective affiliates, related bodies corporate, directors, officers, partners, advisers, employees and agents have authorised, permitted or caused the issue, lodgement, submission, dispatch or provision of this Presentation in a final form and none of them makes or purports to make any binding statement in this Presentation and there is no statement in this Presentation which is based on any statement by them.

To the maximum extent permitted by law, Botanix and its advisers, affiliates, related bodies corporate, directors, officers, partners, employees and agents:

expressly disclaims any and all liability, including, without limitation, any liability arising out of fault or negligence, for any loss arising from the use of or reliance on information contained in this document including representations or warranties or in relation to the accuracy or completeness of the information, statements, opinions, forecasts, reports or other matters, express or implied, contained in, arising out of or derived from, or for omissions from, this document including, without limitation, any estimates or projections and any other financial information derived therefrom, whether by way of negligence or otherwise; and

expressly exclude and disclaim all liabilities in respect of, make no representations regarding, any part of this Presentation and make no representation or warranty as to the currency, accuracy, adequacy, reliability or completeness or fairness of any statements, estimates, options, conclusions or other information contained in this Presentation.

Authorised for release by Vince Ippolito, Executive Chairman

Operations:
3602 Horizon Drive, Suite 160
King of Prussia PA 19406

Corporate Office:
Level 1, 50 Angove Street
North Perth W. Australia 6006

botanix