

18 November 2022

## Webinar – initial market research Sofpironium Bromide

### Key highlights

- Botanix has completed an initial market research project for its advanced Sofpironium Bromide product, that was recently submitted for FDA approval
- Primary research with physicians, payers (insurance companies) and patients was conducted by the leading independent research company, *Triangle Insights*
- Outputs from the market research suggest a significant market opportunity for Sofpironium Bromide and positive feedback from key stakeholders that were introduced to the product on a blinded basis
- Botanix will be conducting a webinar with participation from Triangle Insights staff, on Friday morning at 8.30am Perth time – details outlined below

**Philadelphia and Phoenix US, 18 November 2022:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or “the Company”), is pleased to advise that it has completed an initial market research project for its Sofpironium Bromide product (“the Market Research Study”) with leading independent consultants, *Triangle Insights*.

A summary of the Market Research Study project outputs is included in a presentation attached to this press release. A webinar to discuss the Market Research Study outputs will be held at 8.30am Perth time this morning and the [Zoom details are at the end of this release](#).

The Market Research Study involved primary research with 20 independent dermatologists, 10 different insurance companies (payers) and 10 patients who were introduced to the Sofpironium Bromide product characteristics, but blinded to the identity of the drug for the purposes of the survey. The Study was conducted by Triangle Insights, a leading consulting company who have conducted more than 100 similar projects for clients and have worked with the majority of the dermatology companies that have launched products in the USA over the last 5 years.

**Botanix Chief Operating Officer Howie McKibbon said:** *“We are very pleased with the work conducted by Triangle and the conclusions drawn from this initial Market Research Study, that highlight the significant market potential for Sofpironium Bromide and the unmet need that patients have for effective and accessible treatments.*

*“We believe that Sofpironium Bromide provides a unique solution to patients suffering from axillary hyperhidrosis and the feedback from physicians, payers and patients certainly confirms that positioning.”*

Interested parties can join Mr McKibbon and representatives of Triangle Insights for a webinar to review the output from the Market Research Study at 8.30am Perth time today (Friday 17 November) as follows:

#### Zoom Call Details:

**When:** Nov 18, 2022 08:30 AM Perth time

**Topic:** Botanix SB Market Research with Triangle Insights

**Register in advance for this webinar:**

[https://us02web.zoom.us/webinar/register/WN\\_31a55F4IRU6X26zz6w81FA](https://us02web.zoom.us/webinar/register/WN_31a55F4IRU6X26zz6w81FA)

**After registering, you will receive a confirmation email containing information about joining the webinar.**

Release authorised by

**Vince Ippolito**

President and 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

##### Investor enquiries

Hannah Howlett  
WE Communications  
P: +61 450 648 064

##### Media enquiries

Haley Chartres  
H^CK  
P: +61 423 139 163

[investors@botanixpharma.com](mailto:investors@botanixpharma.com)

[hhowlett@we-worldwide.com](mailto:hhowlett@we-worldwide.com)

[haley@hck.digital](mailto: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 its 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.

### **Not an offer in the United States**

This announcement has been prepared for publication in Australia and may not be released to US wire services or distributed in the United States. This announcement does not constitute an offer to sell, or a solicitation of an offer to buy, securities in the United States or any other jurisdiction. Any securities described in this announcement have not been, and will not be, registered under the US Securities Act of 1933 and may not be offered or sold in the United States except in transactions exempt from, or not subject to, the registration requirements under the US Securities Act and applicable US state securities laws.

# Sofpironium Bromide

November 2022

Summary of initial market  
research program





# Recap – NDA filed for Sofpironium Bromide in 3Q 2022

Positive Phase 3 data, Japanese approval and rapidly growing Japanese sales help de-risk FDA approval and launch



## Addressing unmet needs

First and only new chemical entity for “primary axillary hyperhidrosis”



## Positive Phase 3 Data

All co-primary and secondary endpoints were statistically significant with no treatment-related serious adverse events



## Significant Market

More than 16 million people suffer from hyperhidrosis in the US - market is ~\$US1.6B per annum and projected to grow to \$US2.8B by 2030<sup>1,2</sup>



## NDA submitted and milestones upcoming

NDA submitted in 3Q 2022, with Day 74 letter expected in December 2022, mid-cycle review in March 2023 and approval in 3Q 2023



## De-risked Asset

Molecule already approved by Japanese equivalent of the FDA with partner Kaken Pharmaceuticals and recently launched in Japan

# Hyperhidrosis and Sofpironium Bromide Gel Market Research

---

November 17<sup>th</sup> 2022



**TRIANGLE**  
INSIGHTS GROUP  
INSIGHTS THAT INSTILL CONFIDENCE  
a trialcard<sup>®</sup> company

## Triangle Insights Group – Legacy of Strategy Consulting with US-focused Dermatology Clients

*Triangle Insights has helped clients with valuations and go to market strategies*

Previous experience with dermatology & immunology companies and portfolios.



# Triangle Insights conducted market research to capture receptivity from key stakeholders regarding use of sofpironium bromide gel (SBG) to treat axillary hyperhidrosis

## Market Research Cohort

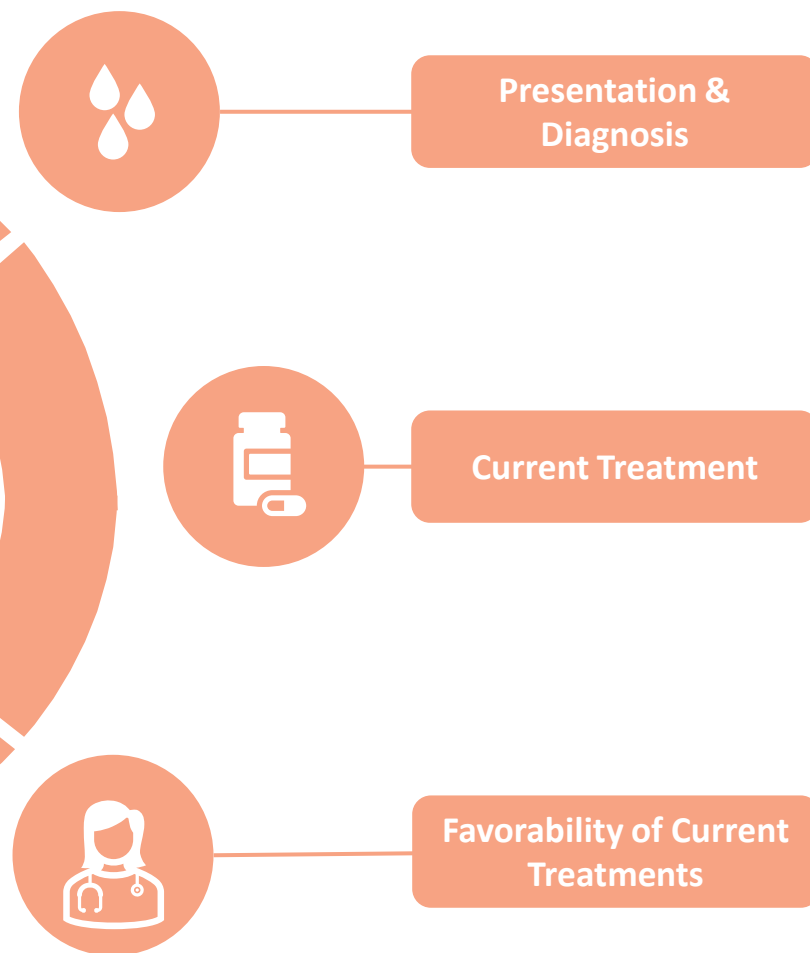


US Dermatologist (N=20)	US Insurance Companies (Payer) (N=10)	US Patient (N=20)
<ul style="list-style-type: none"><li>Interviews were conducted with dermatologists with experience treating patients with hyperhidrosis</li><li>Discussions focused on current treatment paradigm, unmet need, and receptivity to SBG as a novel treatment</li></ul>	<ul style="list-style-type: none"><li>Interviews were conducted with pharmacy directors at US payer organizations</li><li>Discussions focused on current hyperhidrosis therapies, evaluation of new treatments, and receptivity / potential coverage of SBG as a novel treatment</li></ul>	<ul style="list-style-type: none"><li>Interviews were conducted with patients with axillary hyperhidrosis</li><li>Discussions focused on the patient journey, treatment landscape, and receptivity to SBG as a novel treatment</li></ul>

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



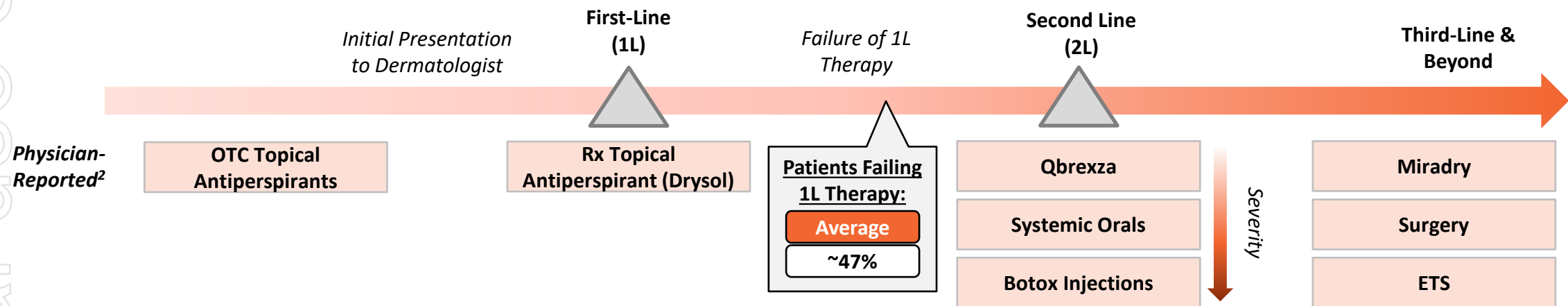
# Key Physician Findings: Current State of Care



- Patients will typically **deal with symptoms for several months to multiple years**, depending on severity and impact on QoL, before presenting for care
  - When presenting for care, **~80% of hyperhidrosis patients will go directly to dermatologists** who are widely known as the primary providers for hyperhidrosis
  - **Diagnosis involves qualitative symptom & history evaluation**, rather than clinical measurement
- Treatment pathways will typically **begin with prescription topical antiperspirants** for several weeks before progressing to variable second-line treatments
  - Patients with milder symptoms are often managed by first line therapies, with only ~20% progressing, while up to ~60% of severe patients are unmanaged by their first line therapy
  - **Mild patients most commonly progress to either Qbrexza or a systemic oral agent** (i.e., oral glycopyrrolate)
  - **Moderate to severe patients will progress to Botox injections between ~25-35% of the time**, with other patients receiving oral medication or, less commonly, Qbrexza
- Physicians held positive views of both Qbrexza (average ~5 out of 7) and Botox (average ~5 out of 7), but noted that insurance costs and access challenges can be preventative in using these treatments (even when the treatments are covered)
  - Despite insurance restrictions, dermatologists suggested a willingness to work through prior authorization requirements for what they consider to be more effective treatments

# Beyond the use of topical antiperspirants, there are variations in second-line therapies amongst hyperhidrosis patients of varying severities

## Hyperhidrosis Current Treatment



(ETS) Endoscopic thoracic sympathectomy

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



# Despite current options, there remains a moderate-to-high degree of unmet medical need for hyperhidrosis, primarily driven by few options being both effective and affordable to patients

## Unmet Need

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

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



Unmet Need: ~4 out of 7



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

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

– Payer

*"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.

# SBG profile was well-received by dermatologists, who noted that, barring insurance issues, it could provide a viable and welcomed alternative to current first and second line treatments

## Physicians: SBG (called “Product X” in blinded surveys) Receptivity

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



Not at all Favorable

Very Favorable

Physicians, on average, rated SBG more favorably than Qbrexza (~5/7), Botox (~4.9/7), and Drysol (~4.6/7)

“Expected range” displayed is based on Triangle Insights’ extensive experience with market research in dermatology

**“I’m very interested.** I am excited to try it. I’d need to review Qbrexza’s stats, but I think this is going to be stronger because there is more penetration of the active ingredient with this type of application”  
— Dermatologist

**“Why didn’t the Dermira people think to make the treatments more similar to what people are familiar with using the active ingredients? This is great.”**  
— Dermatologist

### Key Perspectives

#### Route of administration

- Targeted rather than systemic medication
- Familiar topical application supported confidence in patient compliance

#### Safety profile

- Minimal significant adverse effects, and relative non-concern with listed mild-to-moderate side effects

#### Tolerability

- Limited patient discontinuation instilled confidence in patient tolerability

#### Addition of another treatment option

- Appreciation for a new treatment option amidst a limited arsenal

#### Potential insurance concerns for branded dermatological products

- Noted concern around non-coverage for expensive branded products and potential restrictions
  - However, dermatologists noted that restrictions would be unlikely to impact prescribing



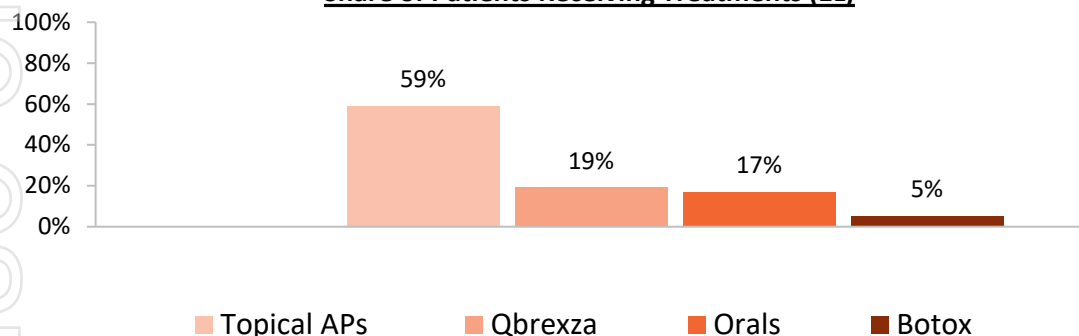


# Dermatologists indicated they would consider prescribing SBG to ~40-50% of axillary hyperhidrosis patients, largely displacing other topicals and some orals

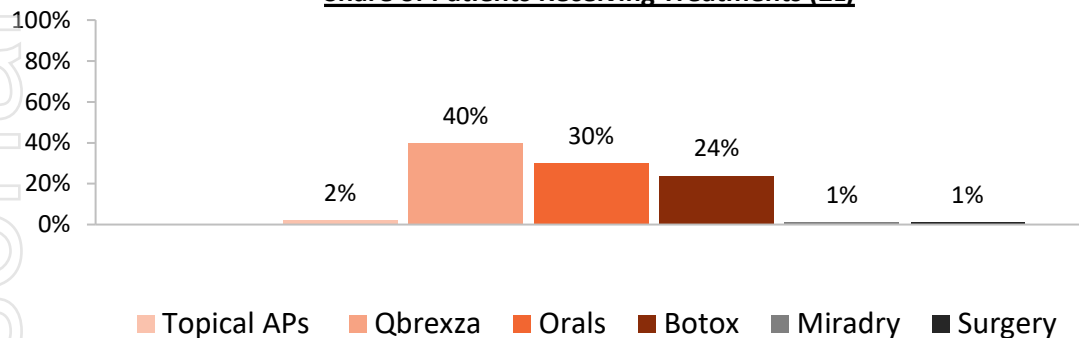
## Dermatologist Treatment Preferences and Anticipated Future SBG Prescribing

### Current Prescription Preferences

#### Share of Patients Receiving Treatments (1L)

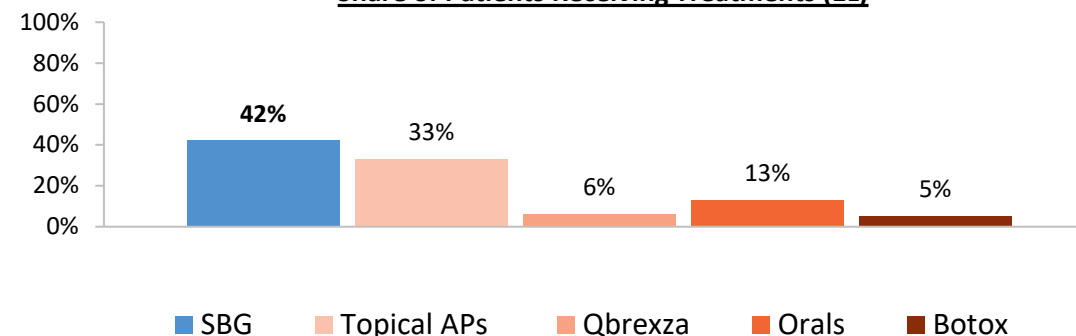


#### Share of Patients Receiving Treatments (2L)

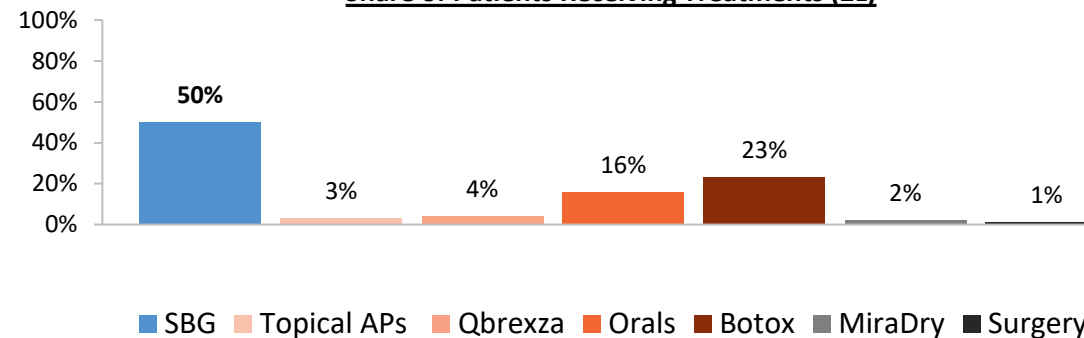


### Prospective Prescription Preferences

#### 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)

Overall, payers were receptive to SBG, noting a favorable efficacy and safety profile, and indicating a high likelihood of commercial coverage.

## Payers: SBG (called “Product X” in blinded surveys) Receptivity

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



Not at all Favorable

Very Favorable

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

“Expected range” displayed is based on Triangle Insights’ extensive experience with market research in dermatology

“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

“[Product X] looks like it works, and it helps **provide options**...”

– Payer

### Key Perspectives

#### Efficacy

- Statistically-significant improvement over logical coprimary endpoints provided confidence to payers that Product X 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

- Product X, if approved, 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

#### Degree of Improvement Vs. Vehicle

- While Product X was clearly impacting the condition, the difference between treatment and vehicle was considered as moderate, and not a “transformative improvement”

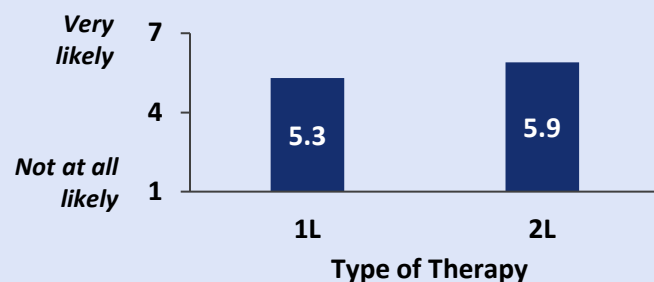
# Patients perceived SBG favorably, indicating a moderate-to-high likelihood of requesting SBG from a doctor before other first and second line therapies in the future

## Patients: SBG (called “Product X” in blinded surveys) 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?



### Key Perspectives

#### Safety and Efficacy

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

#### Convenience

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

#### Tolerability

- A minority of patients indicated that they would want to learn more about the potential for SBG to cause dry mouth and dry eyes

*“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



# Market research highlighted favorable receptivity across key stakeholders, further emphasizing SBG's value story and ability to address an unmet need in the hyperhidrosis space

## SBG Value Proposition: Stakeholder Receptivity



### Physicians

5.9 / 7

Favorable response due to **improved efficacy & tolerability over other topicals**



SBG's **roll-on applicator** seen as an improvement to current Rx topicals (wipe, spray)



**Anticipated use** in ~50% of 2L patients, with potential use as a first line if no payer restrictions

Ultimately, physicians will use SBG if it is easily accessible and affordable, as it is viewed as an improvement over SoC



### Payers

4.2 / 7

Favorable response due to **perceived safety and efficacy**

\$\$

Payers felt SBG addresses an unmet need for more therapeutics



Commercial payers indicated **high likelihood to cover SBG** if priced appropriately

Payers recognize a need for more treatment options, and expect coverage for SBG at appropriate price points



### Patients

5.3 / 7

Positive response, with note that **reducing symptoms enough to lessen daily impact** of sweat is the most important product attribute



**Ease of application** cited as another key driver of potential SBG use



Highlighted importance of **avoiding side effects** which impact QoL (i.e., irritation, dry eyes)

Target patients (18-35 y/o) are motivated to try new treatments, particularly those with promise of being effective without impacting their daily routines & lives



# Executing on planned commercial and regulatory milestones

Calendar year

**NDA  
submission  
complete**

3Q 2022

**Day 74  
letter**

December 2022

**Mid-cycle  
review**

March 2023

**FDA  
approval**

3Q 2023