

9 March 2023

## Webinar – updated commercial research for Sofpironium Bromide

### Key highlights

- Botanix has completed commercial research for its Sofpironium Bromide product
- Primary research was conducted by the leading independent research company, *Triangle Insights Group*
- Outputs from the research provide new insights into competitive and market situation and opportunities to access patients through digital outreach in addition to traditional dermatology channels
- Botanix will be conducting a webinar with participation from Triangle Insights Group personnel, on Thursday morning at 9.00am Perth time – details outlined below

**Philadelphia and Phoenix US, 9 March 2023:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or “the Company”), is pleased to advise that it has completed further commercial research project for its Sofpironium Bromide product (“the Commercial Study”) with leading independent consultants, *Triangle Insights Group*.

A summary of the Commercial Study project outputs is included in a presentation attached to this press release. A webinar to discuss the Commercial Study outputs will be held at 9.00am Perth time this morning and the [Zoom details are at the end of this release](#).

The Commercial 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.

Interested parties can join Botanix COO, Dr Howie McKibbin and representatives of *Triangle Insights Group* for a webinar to review the output from the Market Research Study at 9.00am Perth time today (Thursday 9 March) as follows:

### Zoom Call Details:

- Date:** Thursday 9<sup>th</sup> March 2023
- Time:** 12:00pm AEDT (Sydney/Melbourne), 9:00am AWST (Perth)
- To register:** [https://us02web.zoom.us/webinar/register/WN\\_HcbwrcHpRS2DJFXToTVrhA](https://us02web.zoom.us/webinar/register/WN_HcbwrcHpRS2DJFXToTVrhA)
- Dial in details:** Will be sent to you directly upon registration

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 progressing its lead product Sofpironium Bromide for the treatment of primary axillary hyperhidrosis, through FDA approval. A mid-cycle review for the product is expected in 1Q 2023 with approval on track for Q3 2023. Sofpironium Bromide is positioned to be a leading first line and second line therapy and represents a safe and effective new option for patients.

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. 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](mailto:investors@botanixpharma.com)

#### Investor enquiries

Hannah Howlett

WE Communications

P: +61 450 648 064

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

#### Media enquiries

Haley Chartres

H<sup>^</sup>CK

P: +61 423 139 163

[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.


# Investor Update

March 2023

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







# Botanix: emerging commercial dermatology leader

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



## World class team

US based team that have been responsible for more than 30 successful dermatology launches and two multi billion dollar exits



## Sofpironium Bromide (“SB”)

First and only new drug for “primary axillary hyperhidrosis” (medical condition which results in excessive underarm sweating) already approved in Japan<sup>1</sup>



## Opportunity for consolidation

Multiple stranded products in late-stage development or pending approval that could be consolidated and scaled



## Upcoming mid-cycle review catalyst

*FDA mid-cycle review of SB scheduled for 1Q 2023*



# Hyperhidrosis Market Opportunity

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Commercial Update



**TRIANGLE**  
INSIGHTS GROUP  
INSIGHTS THAT INSTILL CONFIDENCE  
a **trialcard** 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*

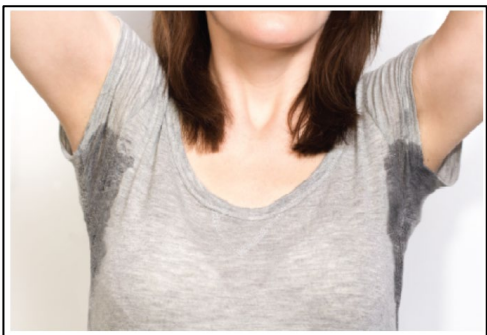
Previous experience with dermatology & immunology companies and portfolios.



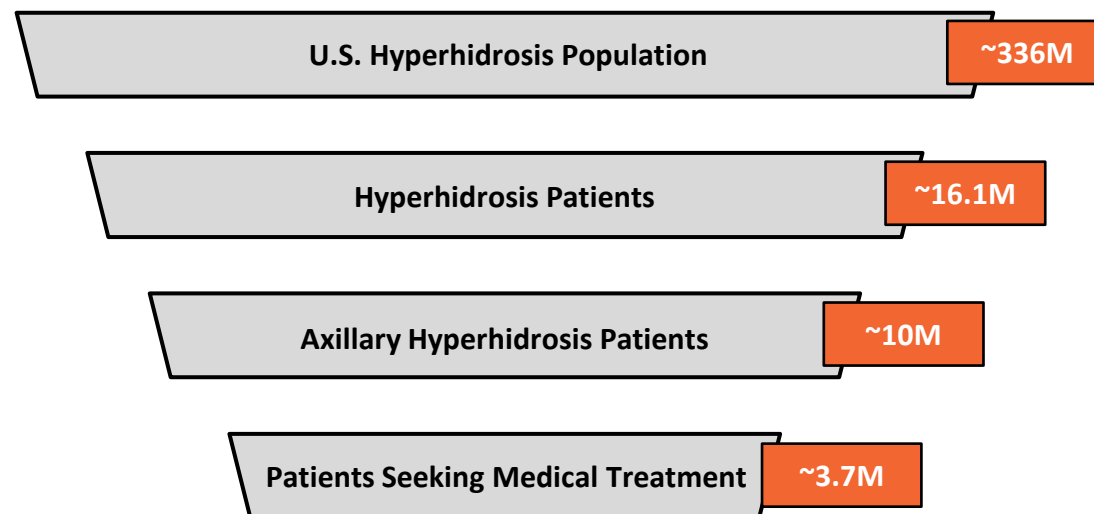
**Axillary hyperhidrosis is a chronic condition characterized by excessive underarm sweating with an estimated US treated prevalence of ~10M patients.**

## Axillary Hyperhidrosis: Overview & Epidemiology<sup>2</sup>

- **Hyperhidrosis (HH)** is a condition **characterized by chronic secretion of sweat** in amounts greater than physiologically needed to regulate body temperature<sup>1</sup>
  - Primary hyperhidrosis usually affects the *underarms (also known as “axillary” hyperhidrosis)*, palms, and soles but can also affect the face, scalp and other areas<sup>1</sup>



- **Impact on Patient Quality of Life:** Beyond the physical discomfort caused by hyperhidrosis, the condition often has psychological symptoms as well, causing anxiety and embarrassment which may disrupt careers, relationships, and general well-being



With a significant share of the prevalent population undiagnosed and untreated, opportunity exists to activate large segments of the overall patient population through patient & physician educational initiatives, and targeted marketing & sales efforts



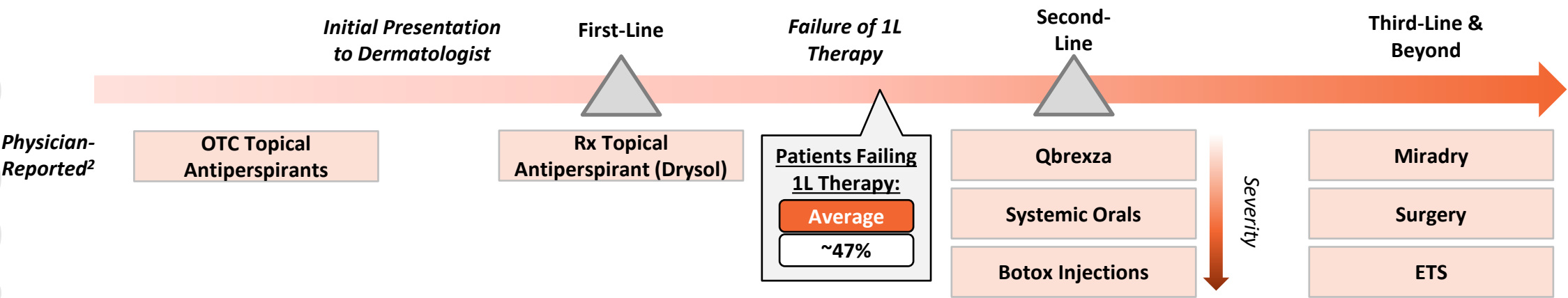
# Product X TPP: Topical Treatment of Axillary Hyperhidrosis

Product X Target Product Profile: Axillary Hyperhidrosis																			
Product Overview	Novel product designed as a topical gel to treat the excessive sweating associated with hyperhidrosis																		
Mechanism of Action	Selective M3 muscarinic receptor antagonist (anticholinergic)																		
Indication	Treatment of axillary (underarm) hyperhidrosis																		
Population	Axillary hyperhidrosis patients age ≥9 years with HH symptoms present for at least 6 months Entry HH Diagnostic Criteria: HDSM-Ax of 3 - 4 and minimum GSP of 50mg																		
Study Design	Two multicenter, randomized, double-blinded, vehicle-controlled phase III clinical trials with N = 350 and N = 351 subjects (Cumulative N = 701)																		
Efficacy	<div><div><p><b>Co-Primary Endpoints (pooled data across trials, n=644 total):</b></p><p><u>Share with ≥2-point Improvement in HDSM-Ax-7 from Baseline to End of Treatment</u></p><table border="1"><thead><tr><th>Group</th><th>% Responders</th></tr></thead><tbody><tr><td>Product X</td><td>60.02%</td></tr><tr><td>Vehicle</td><td>39.7%</td></tr></tbody></table><p><u>GSP Change from Baseline to End of Treatment</u></p><table border="1"><thead><tr><th>Group</th><th>GSP Change (mg)</th></tr></thead><tbody><tr><td>Product X</td><td>-138.1</td></tr><tr><td>Vehicle</td><td>-114.5</td></tr></tbody></table></div><div><p><b>Secondary Endpoint (pooled data across trials)</b></p><p><u>Share with ≥1-point Improvement on HDSM-Ax-7 from Baseline to End of Treatment</u></p><table border="1"><thead><tr><th>Group</th><th>% Responders</th></tr></thead><tbody><tr><td>Product X</td><td>84.6%</td></tr><tr><td>Vehicle</td><td>72.3%</td></tr></tbody></table></div></div>	Group	% Responders	Product X	60.02%	Vehicle	39.7%	Group	GSP Change (mg)	Product X	-138.1	Vehicle	-114.5	Group	% Responders	Product X	84.6%	Vehicle	72.3%
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Safety	<ul style="list-style-type: none"><li>Product X was well tolerated. Only 2.9% and 5.0% of patients discontinued treatment in each trial, respectively.</li><li>Treatment-Emergent AEs were mild or moderate in severity, no SAEs reported.</li><li>Common AEs were seen at similar rates in treatment and vehicle treatment groups, and included the following:<ul style="list-style-type: none"><li>Dry mouth (11.6%, 17.2% placebo), Application site pain (6.4%, 10.0% placebo), and Mydriasis (7.5%, 5.0% placebo)</li></ul></li></ul>																		
Formulation & Dosing	Product X 15% topical gel in a once daily application over a 6-week treatment period																		

**Note:** (HDSM) Hyperhidrosis Disease Severity Measurement – measured 1 – 4, (GSP) Gravimetrically-Measured Sweat Production – Measures the individual’s 5-minute production of sweat (mg)

Diagnosis is often delayed, with treatment typically starting with OTC APs, followed by prescription APs in the 1L setting, and variations in 2L therapies dependent on disease severity.

Hyperhidrosis Patient Journey and Treatment Paradigm



Presentation and Diagnosis

- 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 patients will go directly to dermatologists
  - Diagnosis involves qualitative symptom & history evaluation

Dermatologist-Reported Favorability of Current Treatments

- Physicians held positive views of both Qbrexza and Botox, but noted that access & patient OOP costs can prevent them from prescribing these treatments

(AP) Antiperspirants

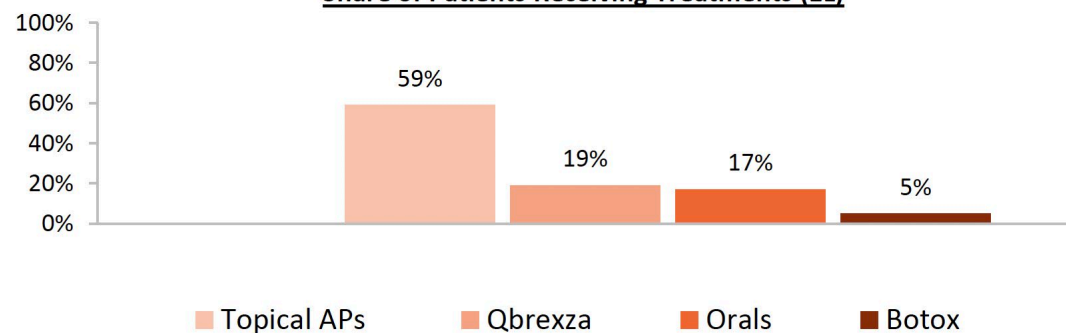
Sources: 1) International Hyperhidrosis Society Guidelines, 2) TIG Interviews with N=20 dermatologists, conducted September & October 2022

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

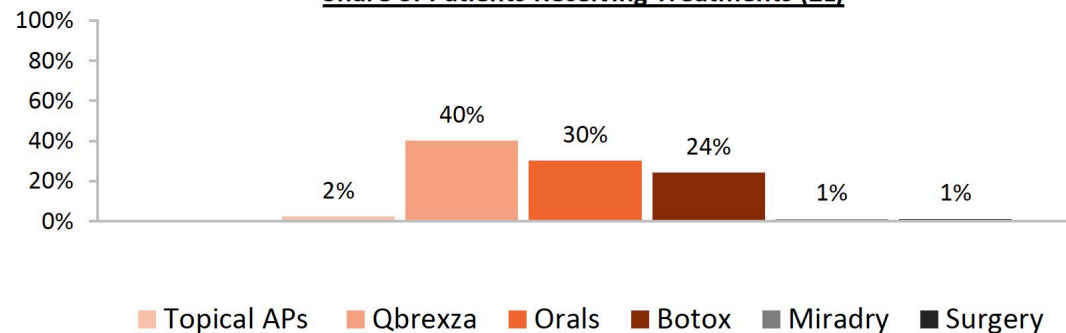
## Dermatologist Treatment Preferences and Anticipated Future SBG Prescribing

### Current Prescription Preferences

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

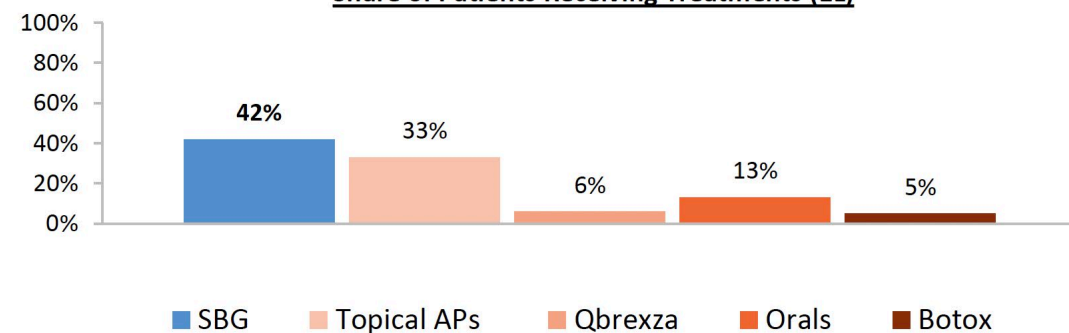


#### Share of Patients Receiving Treatments (2L)

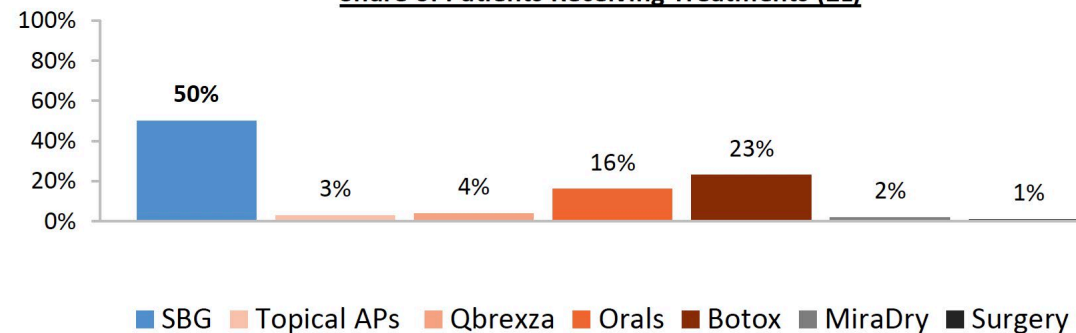


### Prospective Prescription Preferences

#### 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)



# Results from SBG's US phase III trials support favorable efficacy, tolerability, and safety.

## SBG Value Proposition: US Clinical Trial Results

### Clinical Efficacy<sup>1</sup>

Primary & Secondary Efficacy Endpoints (*pooled data across Phase III trials, n=644 total*) show statistically significant improvement in qualitative & quantitative measures related to HH sweating

60%

Patients reporting at least 2-point improvement on qualitative scoring system

85%

Patients reporting at least 1-point improvement on qualitative scoring system



Significant average reduction in measured sweat production

### Safety, Tolerability, and Route of Administration

#### Safety & Tolerability



SBG is well tolerated, with only ~3% & 5% of patients discontinuing in each Phase III trial



Only mild-to-moderate AEs (*dry mouth, application site discomfort*) were reported at similar rates to placebo groups

#### Ease of Administration



Applicator mimics a standard daily habit and conveniently fits within a patient's life

<sup>1</sup>Source: 11 Safirizonium Bromide Phase III Clinical Trial Results, 2022; 1) TIG Intensive with n=20 dermatologists, conducted September-October 2022

# Favorable receptivity among key US stakeholders well-positions SBG to achieve commercial success.

## SBG Value Proposition: US Stakeholder Receptivity (called “Product X” in blinded surveys)



### Physicians

5.9 / 7

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



SBG’s **applicator** seen as an improvement to current Rx topicals (wipe, spray)



Anticipated use in ~35% of 2L patients, with willingness to use 1L without PA/ST need

#### Why will Physicians use SBG?

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 for coverage** if priced appropriately

#### Why will Payers cover SBG?

Payers recognize a need for more treatment options, and expect coverage for SBG at reasonable 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, headaches, dry eyes)

#### Why will Patients use SBG?

Patients are motivated to try new treatments, particularly those with promise of being effective without impacting their daily routines & lives

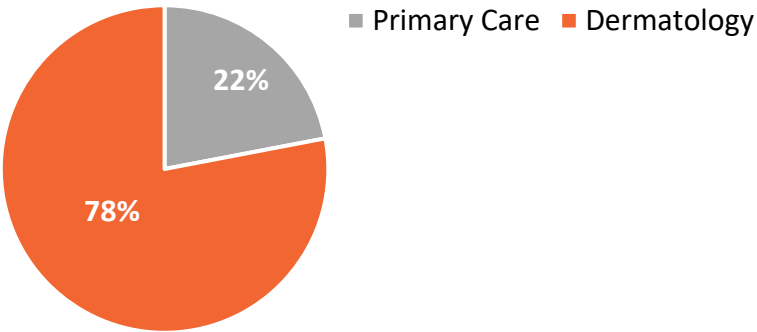
**Note:** Favorability scores fall within the expected range for favorable response from respective stakeholders

Source: TIG Interviews with n=20 dermatologists, n=10 payers, n=20 hyperhidrosis patients, conducted September-October 2022

The majority of patients seeking care for hyperhidrosis present directly to dermatologists, who are widely recognized as the primary providers for treatment of hyperhidrosis.

## Hyperhidrosis Presentation Overview

Share of Patients Presenting to Providers for Initial Diagnosis



*"Primary care usually doesn't know how to handle it. They'll point to OTC treatments, then push patients to go try seeing a dermatologist."*  
—Dermatologist



*"Patients will look online for their symptoms and find out about hyperhidrosis then go directly to a dermatologist. I think it's well understood that dermatology is at the forefront of treatment."*  
—Dermatologist

### Patient Presentation Commentary

#### Drivers of Presenting for Care

- Dermatologists suggest that patients will typically have dealt with their symptoms for at least several months before presentation, with 55% (n=11) suggesting longer than a year
  - Physicians suggest there is rarely an inciting event, but rather patients are driven to seek care by the **culmination of symptom fatigue and embarrassment**
  - **Broader online availability of reliable information around the validity of hyperhidrosis** as a condition was also noted to help promote patients to seek care

#### Treatment Prior to Presentation

- Ahead of clinical presentation, patients will most commonly have tried using OTC topical antiperspirants, such as CertainDri

#### Diagnosis

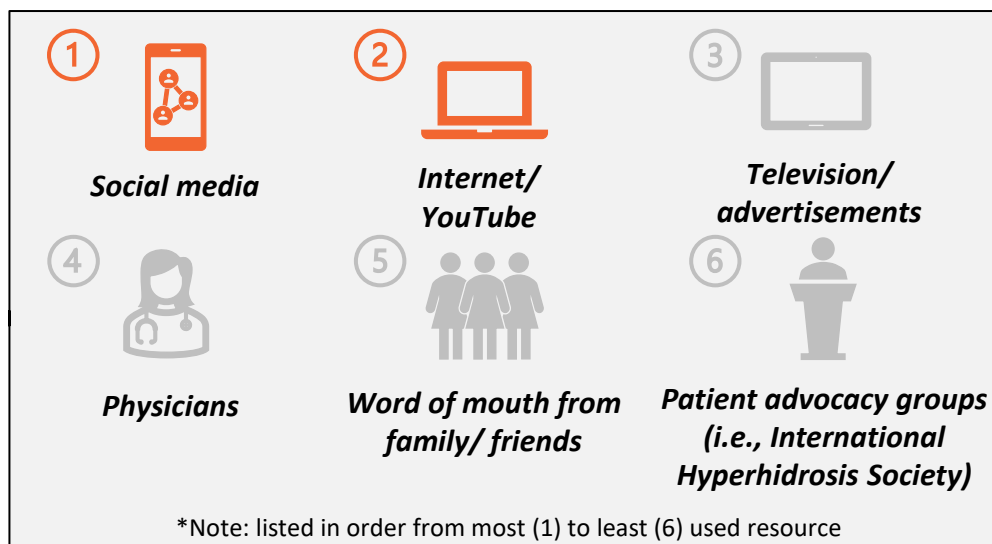
- Diagnosis uses qualitative conversation around symptoms, quality of life and any treatment history, rather than using formal measurements.



To activate unmotivated patients, it will be important to reach patients via a digital DTC campaign with messaging on efficacy over SoC, safety, and convenience/ease of use.

## Patient Activation

### New Products: Primary Channels for Reaching Patients



### Key Motivators for Treatment

Over 50% of patients reported a willingness to try a new treatment due to lack of efficacy from current options. Primary drivers for trying a new treatment include:



Reducing sweat enough to decrease visible sweat was deemed effective enough to warrant trying in 50% of patients



Convenience of use was noted as another key driver to try a new product; a trait which patients recognized in SBG



A minimal side effect profile was the other commonly reported reason patients would try a new treatment

**Motivating factors highlight a desire for effective treatment which does not interfere with patient's daily lives or routines**



*"If you went hard, all-in on social media, targeting those 18-35 y/o population, and spent on digital rather than broadcast DTC I would've seen more impact I think"*

— Ex-Dermira Commercial Leader



*"Success would be reducing my underarm sweat by about 50% so that I don't need to worry about visibly ruining my shirt."*

— Hyperhidrosis Patient

# Targeted digital approaches are more readily available and are resulting in higher margin approaches towards profit (especially for diseases with a high consumer focus)

## Direct to Patient Focus Resulting in Increased ROI and Revenue

- Leading pharma companies continue to invest in high ROI and targeted direct to patient approaches
- Dermatology and hyperhidrosis especially relevant for these business models (undertreated and high emotional connection for patients)

Leading Telemedicine Providers	<div><div>PULUS</div><div>REVOLUTIONIZING HEALTHCARE ENGAGEMENT</div><div>PRESCRIBERY</div><div>UpScriptHealth</div></div>
Products / Companies Supported <i>Illustrative, Not Exhaustive</i>	<div><div>Linzess</div><div>abbvie</div><div>Otezla</div><div>AMGEN</div><div>Contrave</div><div>CurraX</div><div>phexxi</div><div>EVOFEM</div><div>ROIVANT</div><div>ORGANON</div><div>Aytu</div><div>BIOPHARMA</div></div>

## Case Study

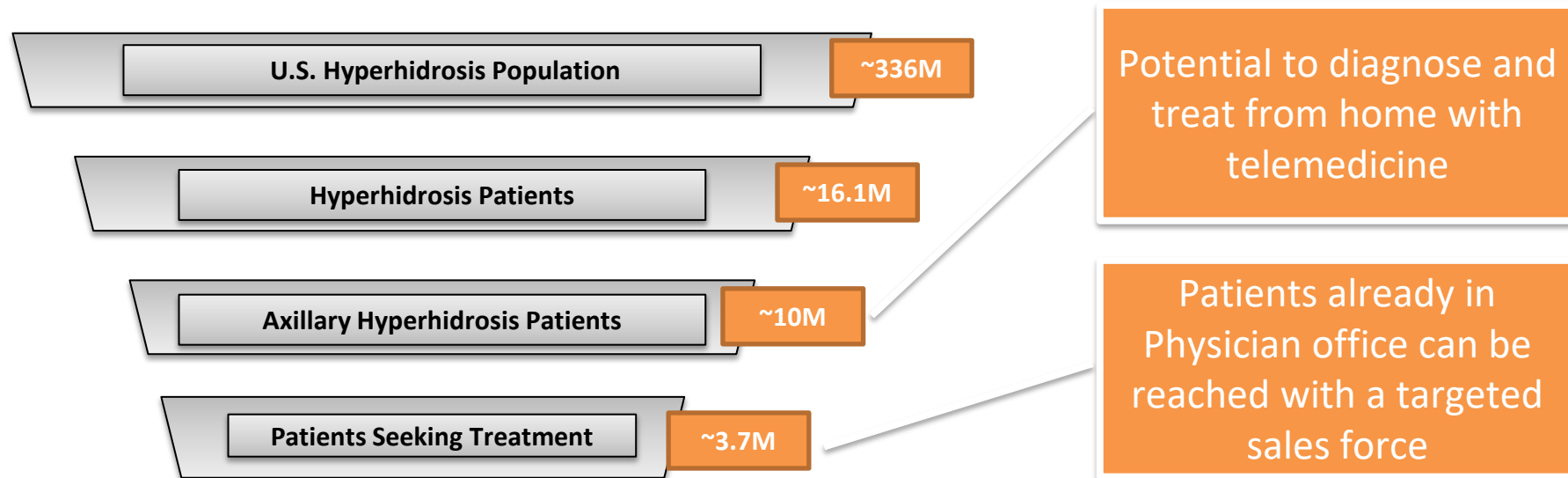
- Evofem launched Phexxi a hormone-free contraceptive gel in 2020



- Telemedicine is Phexxi’s primary customer acquisition tool
- Evofem also has ~70 in-person sales reps targeting ~12K OB/GYNs and 14 virtual sales reps
- Conversion rate progressing to script at 60%<sup>1</sup> (compared to ~6% benchmark conversion rate in pharma marketing)
- Decreased SG&A costs by focusing on digital marketing instead of broadcast DTC, which also shortens the buying cycle & reduces the time to see ROI

Sources: 1) Medical Marketing & Media, “The COVID-proof drug launch?”, October 29, 2020

# ~16M Patients in the U.S. suffer from Hyperhidrosis





# Value inflection points accrue as FDA review progresses

Critical mid-cycle review scheduled for 1Q 2023

