

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

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## 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/>

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# Investor Update

JP Morgan Healthcare Conference  
January 2023

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





# 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<sup>1</sup>



## 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*

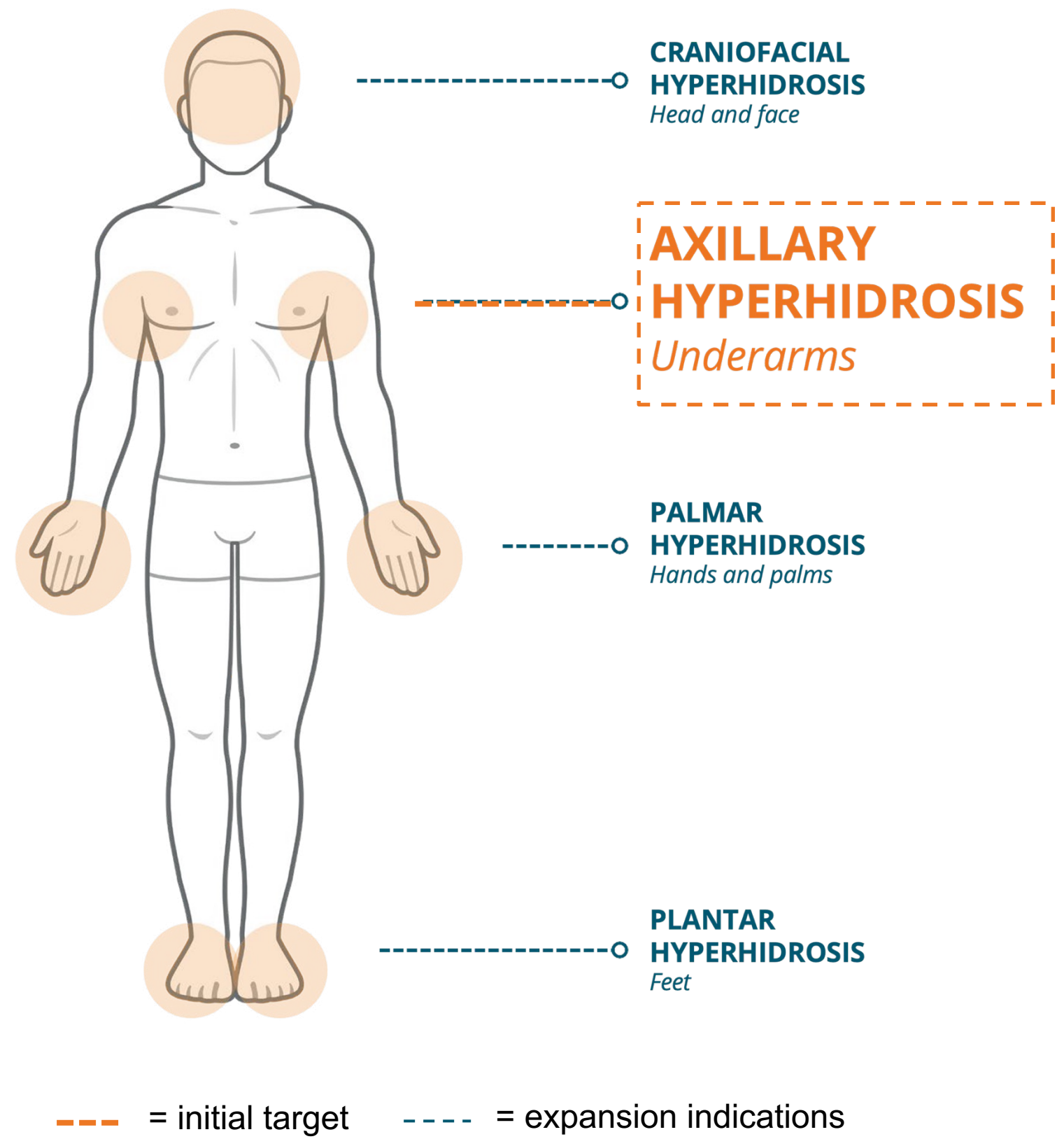
# Hyperhidrosis

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

Hyperhidrosis affects ~16M people in the US:<sup>1</sup>

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

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



FREQUENTLY CHANGE CLOTHES



FRESHEN UP BY WIPING OR BATHING



PLACE NAPKINS OR PADS UNDER THEIR ARMS OR THEIR POCKETS



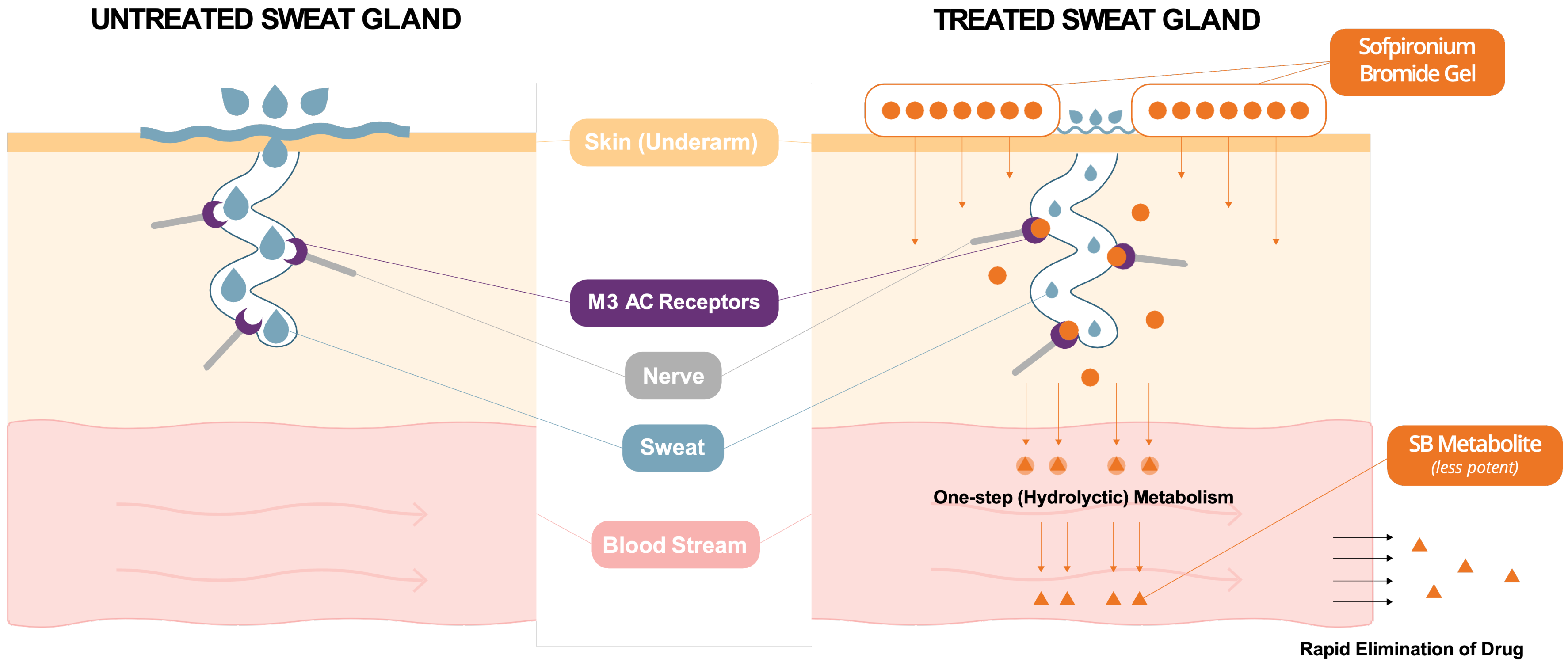
HIDE UNDER DARK-COLOURED, BULKY CLOTHES

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



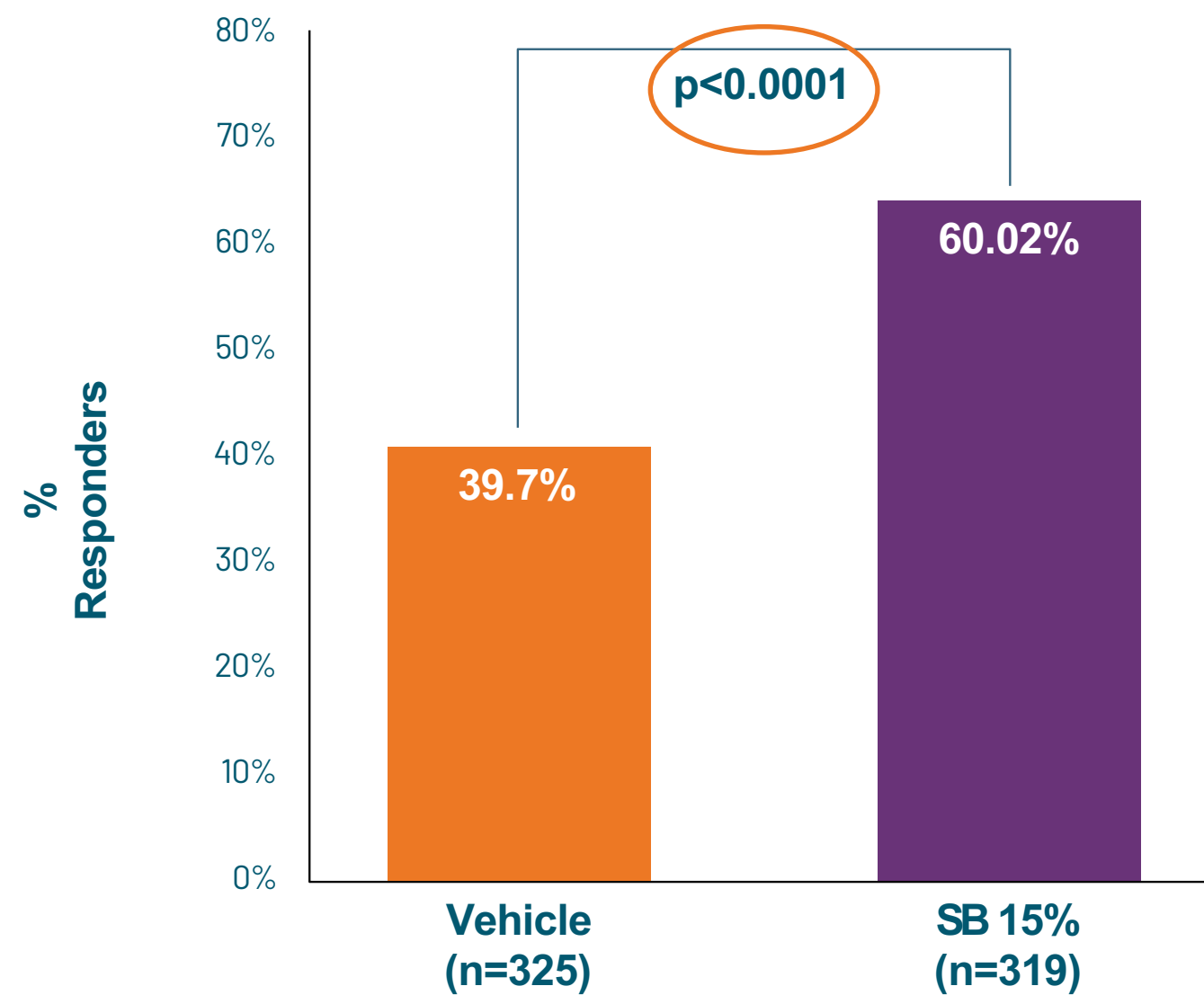
**M3 AC Receptors** = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

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

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

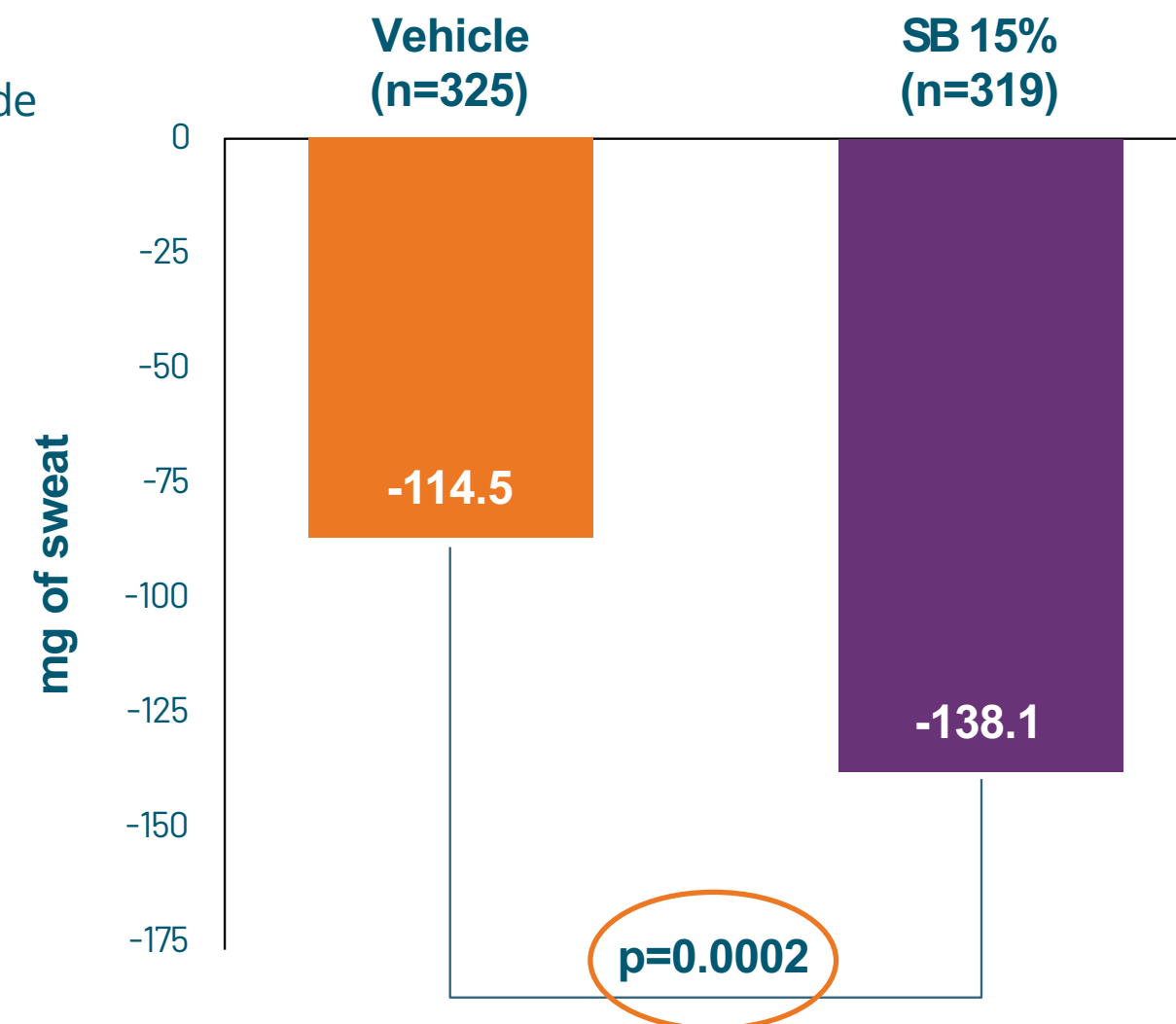
**Pooled Data (Cardigan I and II)**  
≥2-point improvement in HDSM-Ax-7  
from baseline to end of treatment<sup>1</sup>



SB = Solfipronium 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<sup>1</sup>



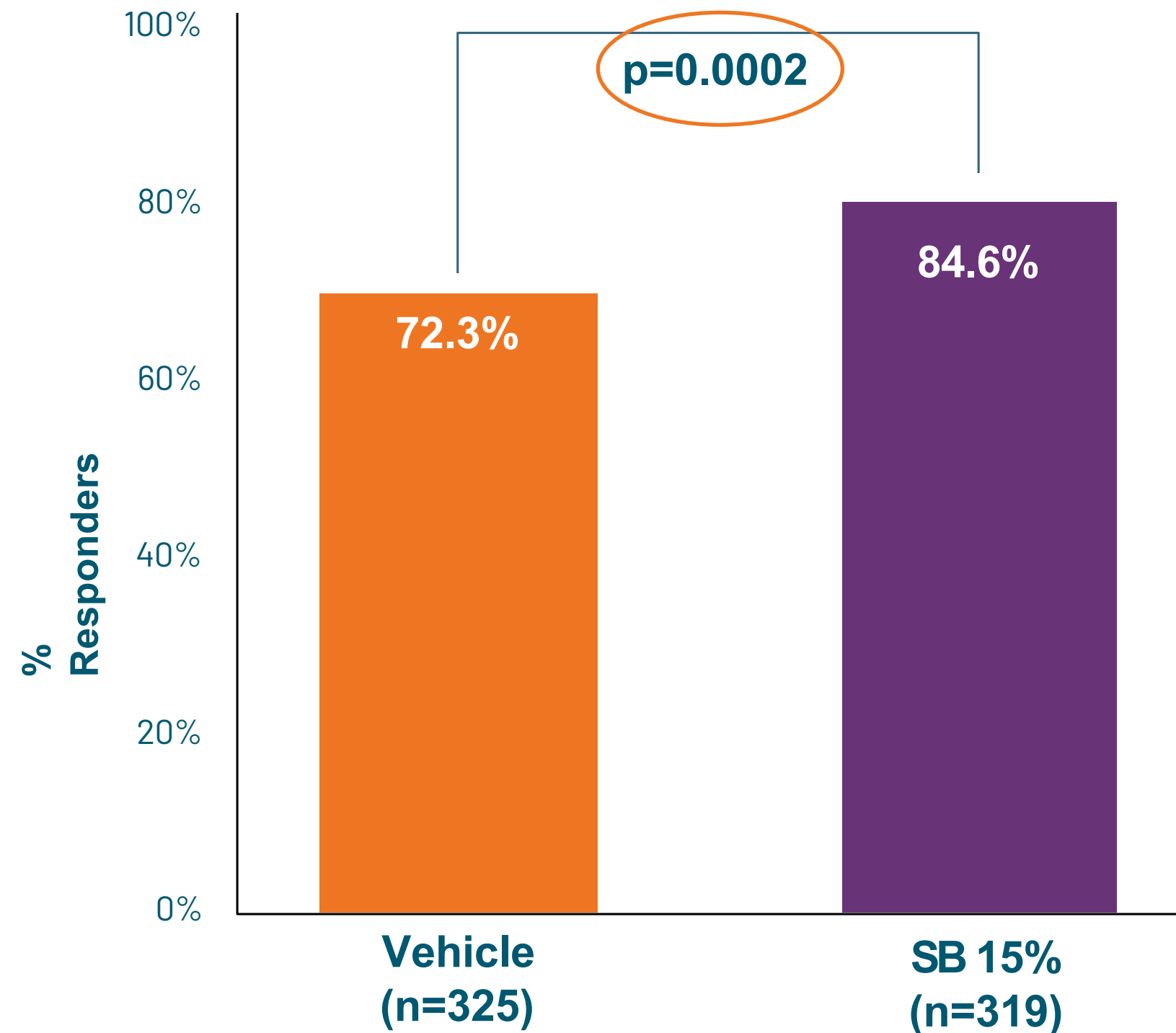
GSP (Gravimetric Sweat Production) is an objective measurement of underarm sweat production over 5 minutes

## 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 ( $\geq 1$ -point improvement) from baseline to end of treatment<sup>1</sup>



SB = Solfpironium Bromide



# Stakeholder research shows a significant market opportunity for Sofpironium Bromide



## 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

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

Stakeholders indicated the *top two unmet needs* are as follows:  
1) New treatment options (i.e., limited options) and 2) 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

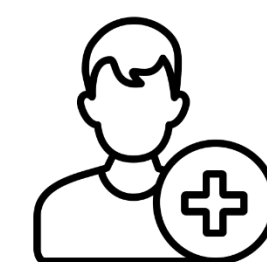
A rating of 4 out of 7 is high based on our experience with payers across therapeutic areas



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.**”

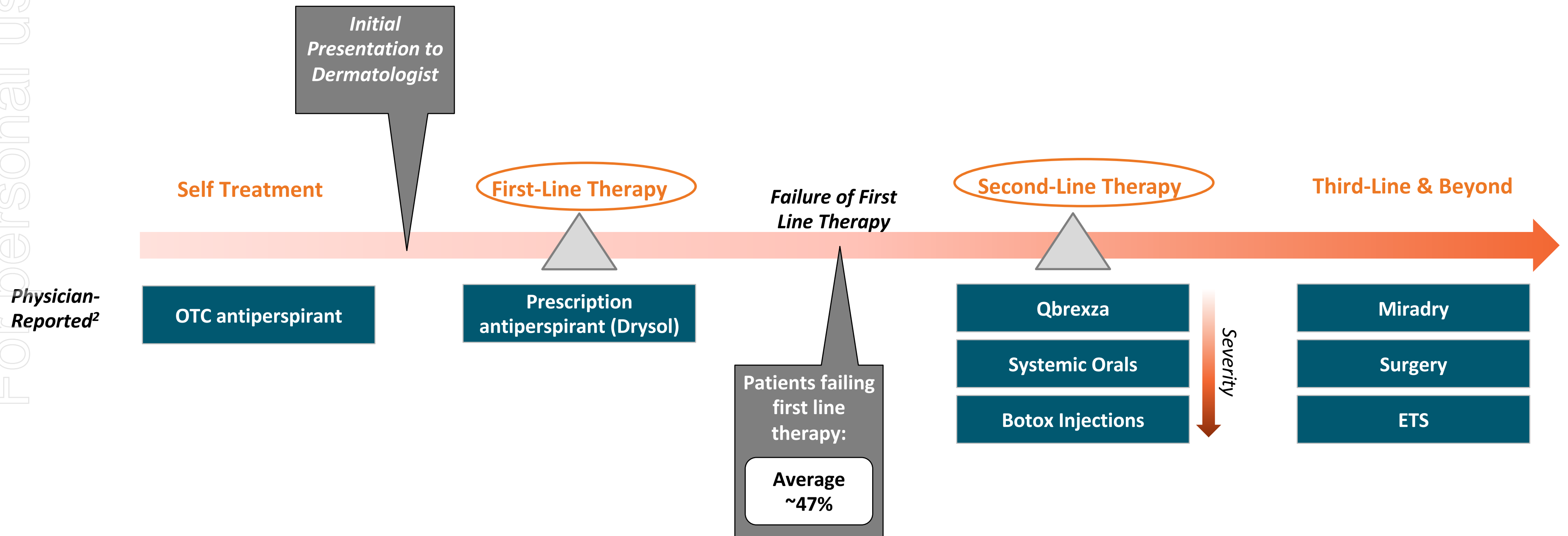
– Patient

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.

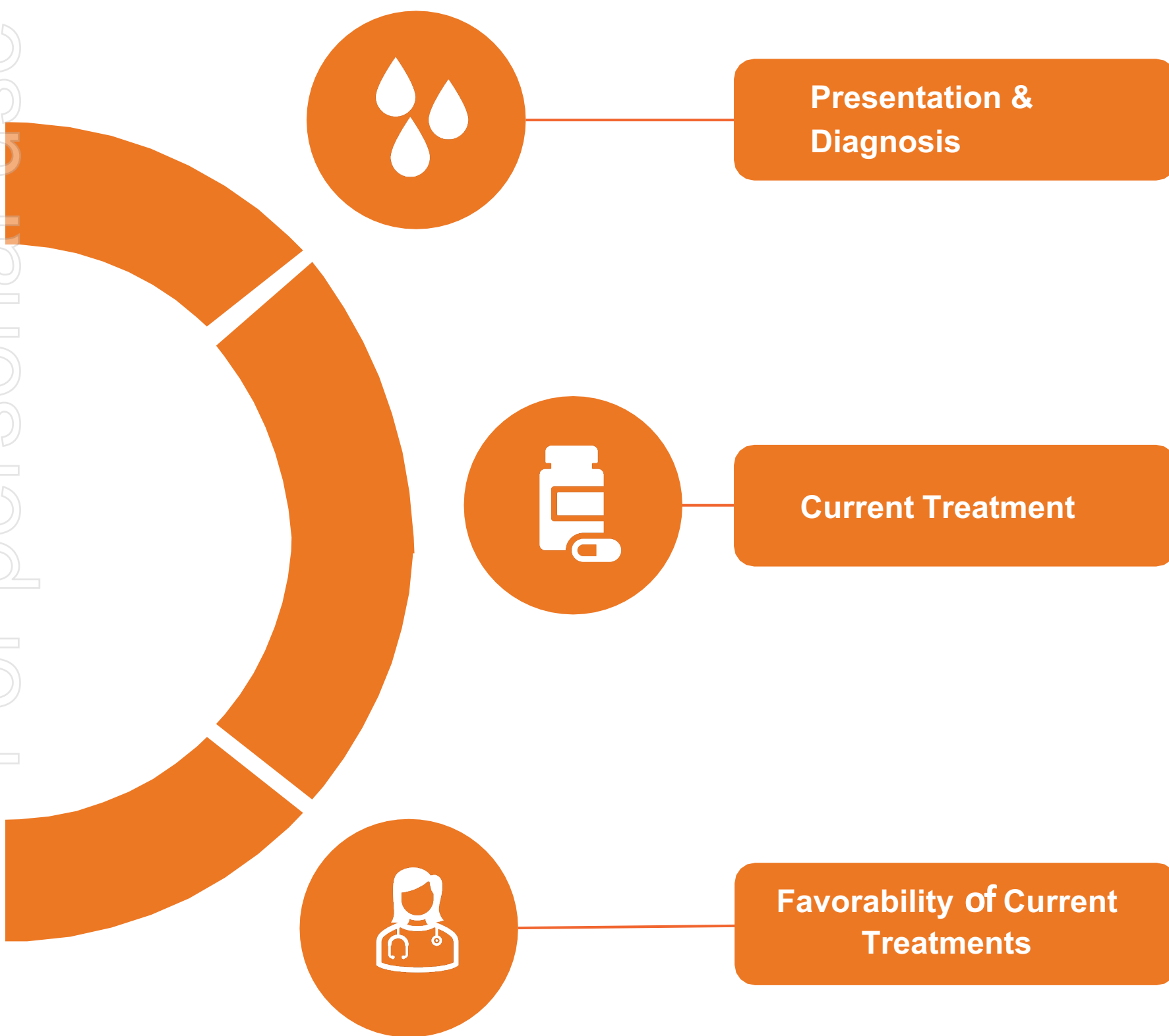


# Research shows almost half of all patients fail first line prescription antiperspirants and progress to second line therapies

## Hyperhidrosis Patient Journey and Treatment Paradigm



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



- 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

- 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

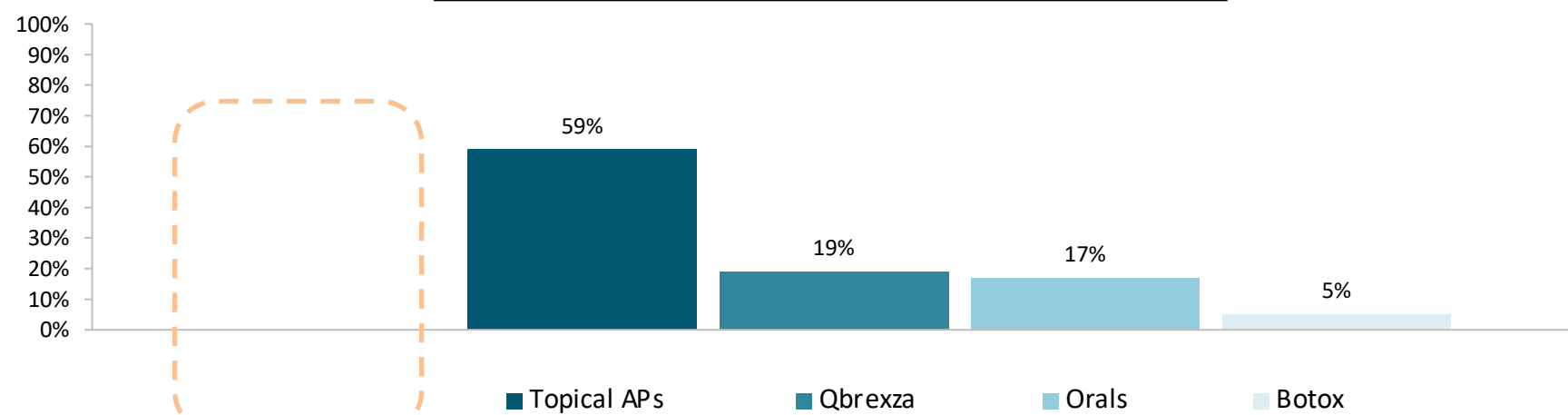
- Physicians were generally positive with the existing limited range of second line therapies, but noted that access and co-pay costs can be preventative in using these treatments (even when the treatments are covered)
- Dermatologists suggested a willingness to work through prior authorization requirements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



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

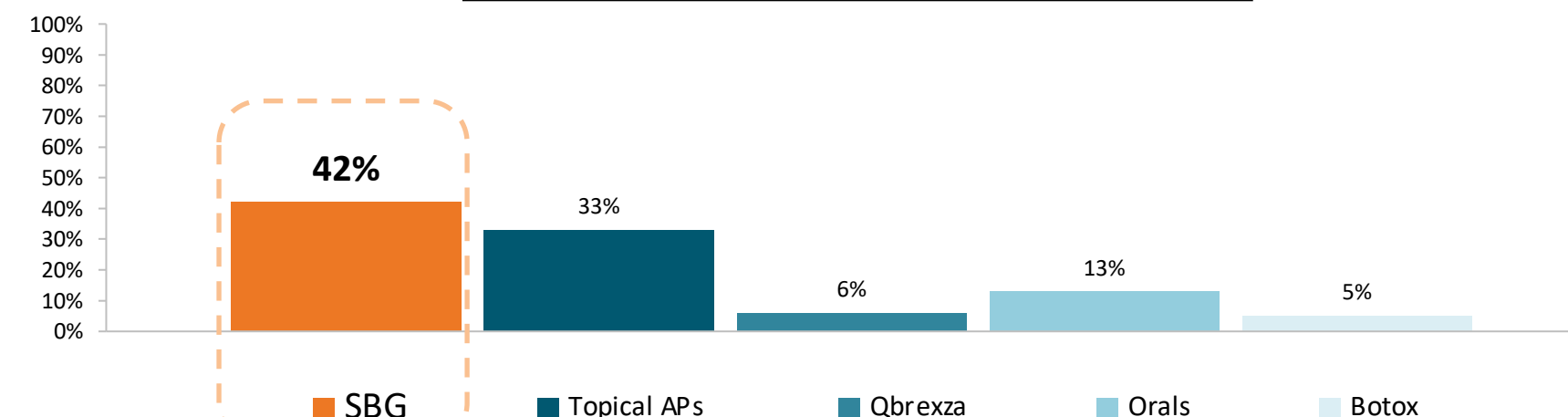
Current Prescription Preferences

Share of Patients Receiving Treatments (1L)

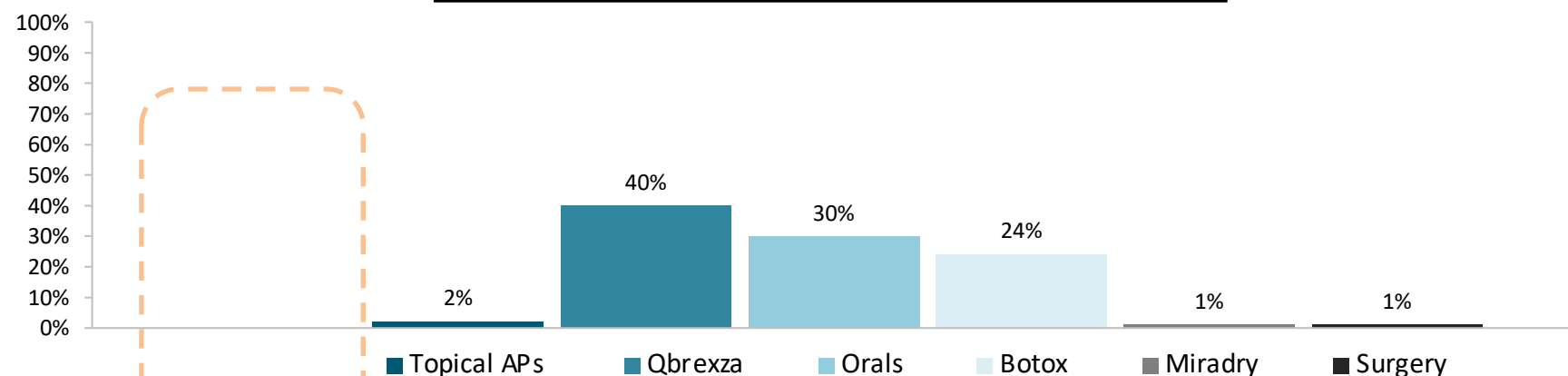


Prospective Prescription Preferences

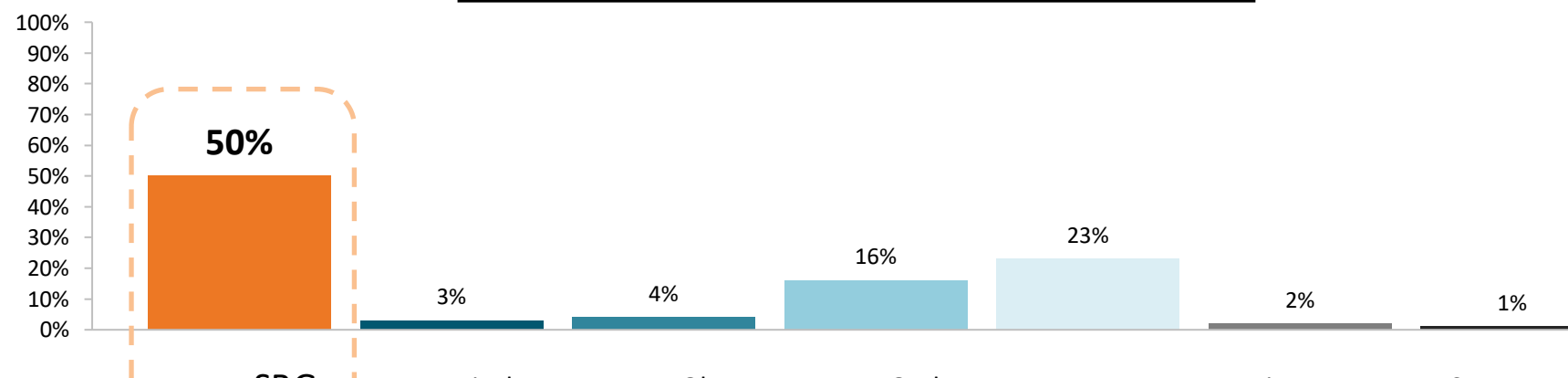
Share of Patients Receiving Treatments (1L)



Share of Patients Receiving Treatments (2L)



Share of Patients Receiving Treatments (2L)



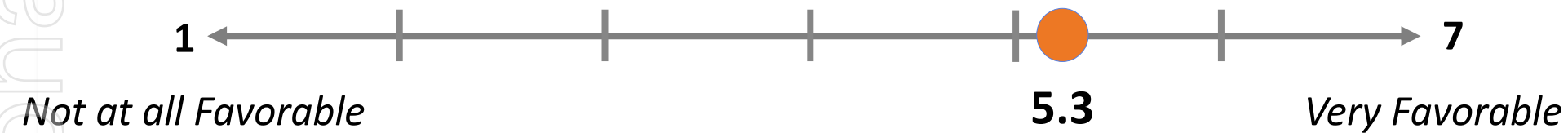
\*Share of patients by treatment type shows a weighted average across severities

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

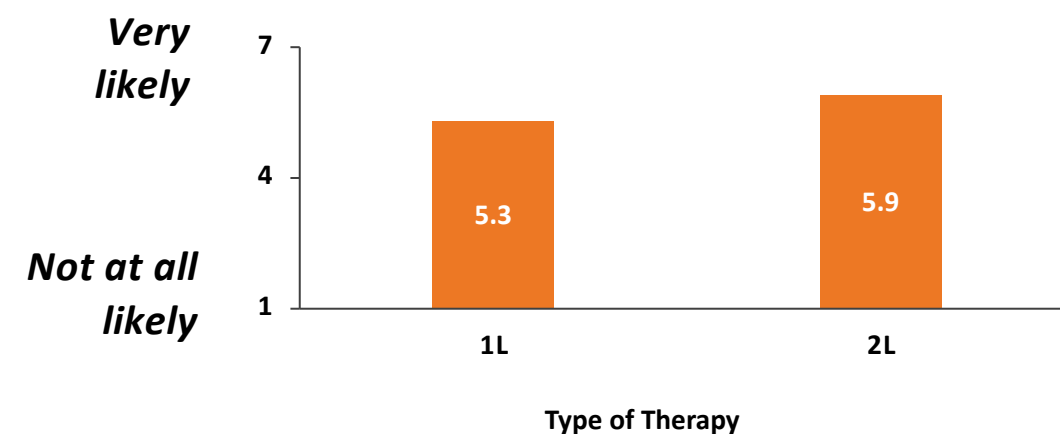
# Patients would also use Sofpironium Bromide as a *new first line* therapy as well as in preference to *existing* second line therapies

## 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?



### 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.”*

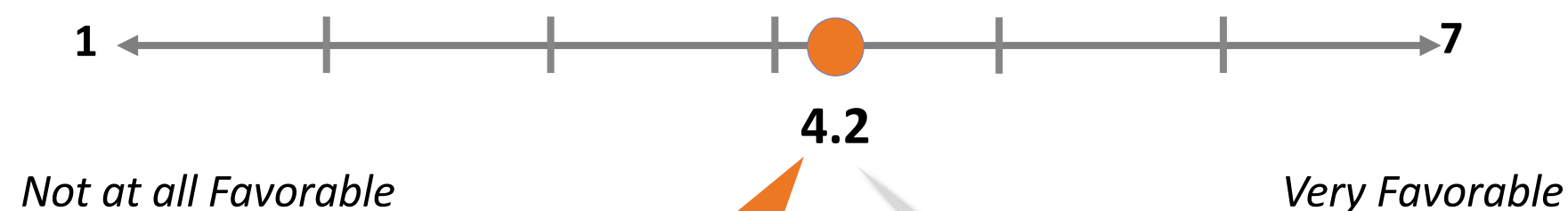
– Patient



# 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

### 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

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



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

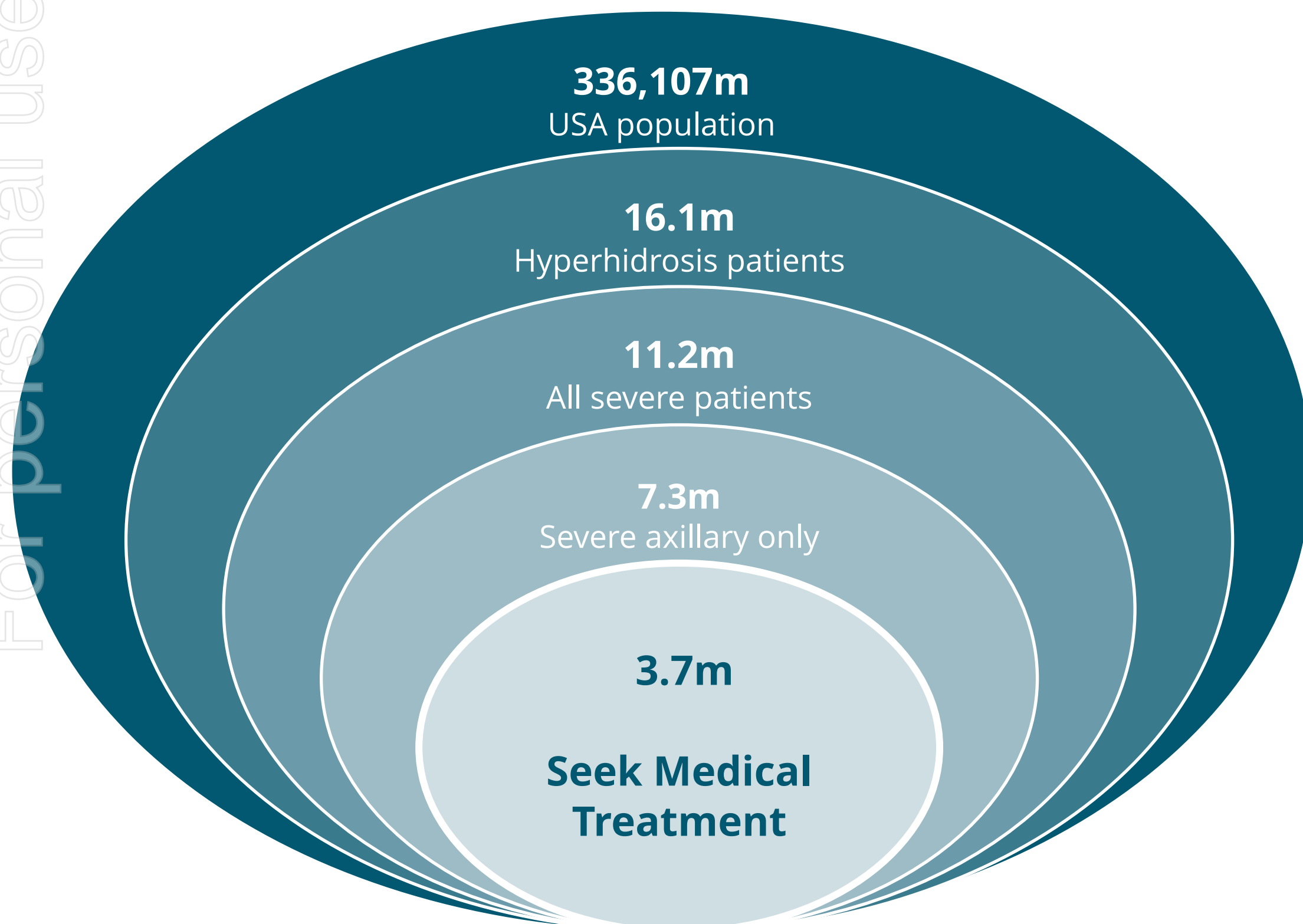
- Inclusion on the National Health Insurance drug reimbursement price list supports the perceived need for the product from payers and suggests receptivity to Ecclock's (SBG) value proposition
- Initial performance in the Japanese market is promising, with year 2 sales estimated to reach ~300K units



# US market opportunity for hyperhidrosis<sup>1</sup>

Even a modest market share provides a significant financial opportunity

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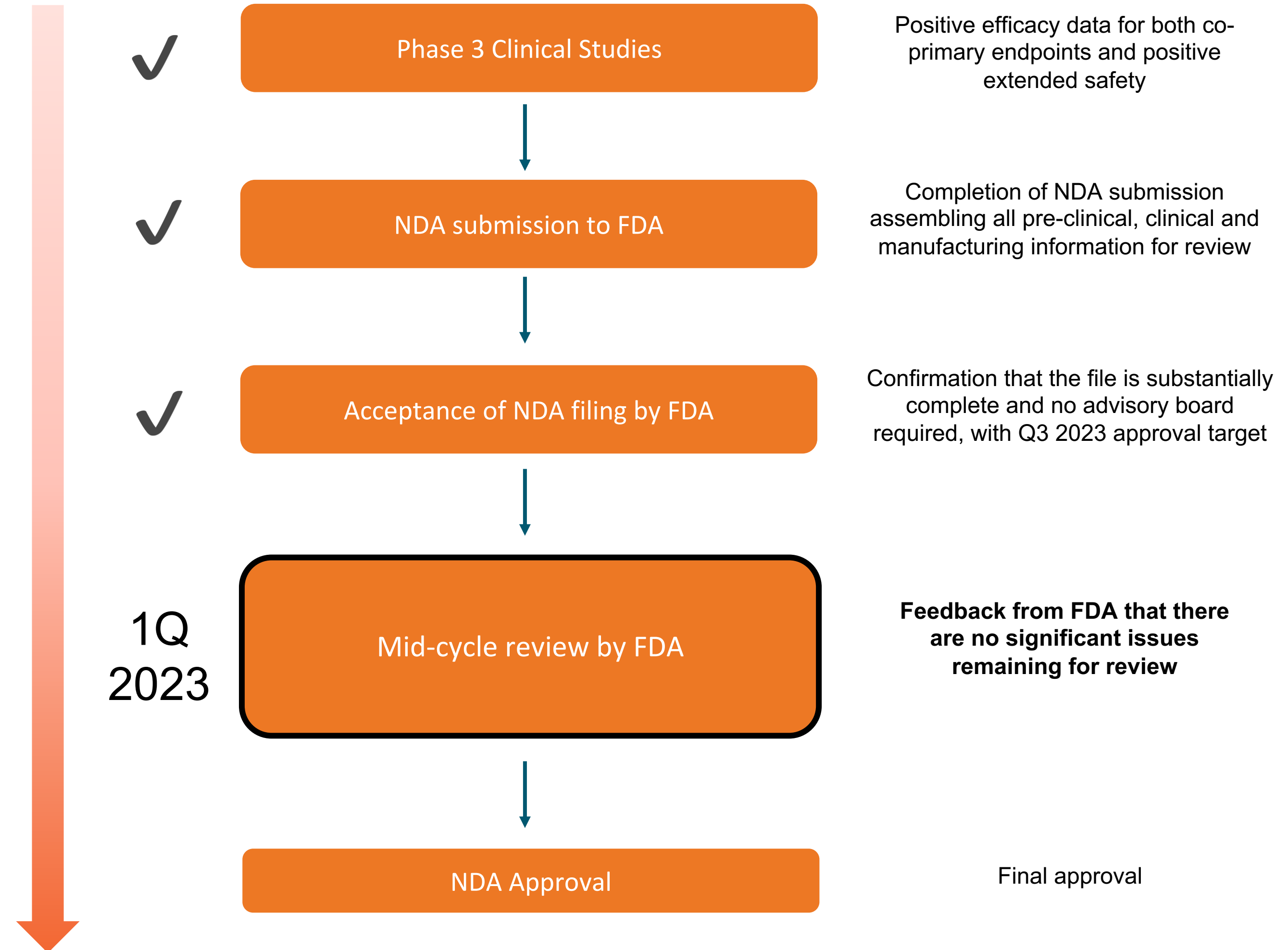


Share of patients <u>already seeking treatment</u>	Patients	Potential gross sales*
0.5%	18,500	\$144,300,000
1.0%	36,700	\$288,600,000
1.5%	55,500	\$432,900,000
2.0%	74,000	\$577,200,000
2.5%	92,500	\$721,500,000
3.0%	111,000	\$865,800,000

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

# Value inflection points accrue as FDA review progresses

Critical mid-cycle review scheduled for 1Q 2023





# 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**

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**Authorised for release by Vince Ippolito, Executive Chairman**