

4 May 2022

## Botanix acquires dermatology asset to accelerate path to revenue

### Key highlights

- Botanix has acquired Sofpironium Bromide gel 15%, the first and only new chemical entity developed to treat “primary axillary hyperhidrosis” – a medical condition which results in excessive underarm sweating
- Sofpironium Bromide achieved statistical significance in all primary and secondary endpoints and was found to have a favourable safety profile in Phase 3 pivotal studies and in the 48-week safety study
- Plan to submit a New Drug Approval (NDA) for Sofpironium Bromide in the 2H 2022 with an FDA anticipated approval in 2H 2023 (assuming a 12-month review process)
- Deal structured with minimal upfront payments, with most of the consideration payable in Net Sales milestones and royalties
- Significant market for hyperhidrosis with 15 million patients in US with the market expected to grow to US\$2.8 billion per annum by 2030<sup>1</sup>
- De-risked asset with drug already approved by Japanese equivalent of FDA (PMDA) and recently launched by the existing partner, Kaken Pharmaceuticals
- Sofpironium Bromide complements our existing dermatology pipeline, leverages our world class management team with a track record in successfully launching products and accelerates the path to revenue generation

**Philadelphia PA and Phoenix AZ, 4 May 2022:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or “the Company”), is pleased to announce the acquisition of a novel dermatology asset known as Sofpironium Bromide gel, 15% (“Sofpironium Bromide”), which has been developed to treat primary axillary hyperhidrosis (a medical condition which results in excessive underarm sweating). The acquisition has been agreed with US NASDAQ listed company Brickell Biotech Inc. (“Brickell”) which developed the asset through successful pivotal studies in late 2021. The closing of the acquisition occurred on 3 May 2022 (US time).

A comprehensive overview of Sofpironium Bromide, the market for hyperhidrosis, the data successfully generated for the drug and information about the acquisition and opportunity is outlined in the attached presentation.

**Botanix President and Executive Chair Vince Ippolito said:** *“We are very excited to complete the acquisition of Sofpironium Bromide, which represents the first and only new chemical entity developed for primary axillary hyperhidrosis”*

*“Having demonstrated statistically significant efficacy and favourable safety in pivotal studies, we are well advanced in preparing Sofpironium Bromide for FDA approval in the second half of this year and*

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<sup>1</sup> Reports and Data, Hyperhidrosis Treatment Market by Treatment Type, By Disease Type, By End User, By Regional Outlook and Segment Forecasts 2022

*look forward to accelerating Botanix into a commercial dermatology company much sooner than we originally expected.”*

### About Sofpironium Bromide

Sofpironium Bromide is a new chemical entity developed to be a best-in-class, once daily, topically administered therapy for the treatment of primary axillary hyperhidrosis. Sofpironium Bromide is an anticholinergic/antimuscarinic drug that blocks sweating at the gland, by binding to the receptor and thereby blocking the sweat signal. Sofpironium Bromide is delivered to the underarms as a gel formulation, using a patent-pending applicator that allows the patient to avoid direct contact with the drug on their hands. Approximately 85% of patients using Sofpironium Bromide gel 15% experienced a clinically meaningful improvement in their condition over the course of the Phase 3 studies.

Positive results from Phase 3 clinical studies were reported in late 2021 for Sofpironium Bromide, with all primary and secondary endpoints achieving statistical significance. More than 700 patients were enrolled in the two Phase 3 studies and approximately 300 patients participated in a 48-week safety study of Sofpironium Bromide. There were no treatment related serious adverse events in any of the studies and adverse events were transient and mild to moderate in nature.

**Botanix Chief Medical Adviser, Dr Patricia Walker said:** *“The data demonstrates that once-daily topical Sofpironium Bromide achieved early, sustained, and significant improvements in primary axillary hyperhidrosis signs and symptoms consistent across all efficacy measures and was generally well-tolerated over six weeks of treatment,”*

*“There is a real need for new and improved hyperhidrosis treatment options, and the results from these pivotal Phase 3 studies further support the potential for Sofpironium Bromide to become a first-line therapy of choice for patients with primary axillary hyperhidrosis.”*

Botanix is currently working with Brickell to complete the filing of Sofpironium Bromide for FDA approval, which it expects to occur in 2H 2022, expecting a 12-month review cycle. Preparation for this New Drug Application (NDA) filing is well advanced.

### The Sofpironium Bromide Acquisition Transaction

Botanix’s US wholly owned subsidiary (Botanix SB Inc.) has executed an acquisition agreement and a transition services agreement with Brickell, to purchase all of Brickell’s interests in Sofpironium Bromide, and receive services from Brickell to assist in the NDA filing and approval of the asset respectively.

The financial terms of the acquisition agreement are summarised as follows:

- Botanix has acquired all assets owned or controlled by Brickell primarily related to Sofpironium Bromide, including its interest in a license for Sofpironium Bromide (from the patentee, Bodor Laboratories Inc.);

- Botanix has agreed to pay Brickell US\$3M as an upfront payment and US\$2M if a positive “Day-74 letter” is received from FDA after NDA filing (which letter notifies the applicant if any deficiencies in the NDA filing are identified by FDA during the initial review phase);
- If FDA approval is received before 30 September 2023 Botanix will pay Brickell US\$4M, which is reduced down to zero, if the NDA is approved after 17 February 2024;
- Botanix will pay a milestone payment of US\$4M if marketing approval is received from an international regulatory authority in the European Union/United Kingdom;
- Botanix will pay a milestone payment of US\$4M for marketing approval is received for a new indication, from an international regulatory authority in the USA or European Union/United Kingdom;
- Botanix will reimburse Brickell for some development expenses related to Sofpironium Bromide incurred in recent months;
- Botanix will pay Brickell one-time sales milestone payments once Net Sales exceed US\$75 million for the first time in a year. Such milestones are payable on incremental annual Net Sales amounts and are capped at US\$160 million. Botanix would only pay this aggregate of milestones, if Net Sales to Botanix amounted to more than US\$1.8 billion, which is contingent upon sales performance of the product and is not guaranteed;<sup>2</sup> and
- Botanix will also pay royalties to Brickell and Bodor that in the aggregate start at 12% and rise to 20%, above \$500M of annual Net Sales.

Botanix will assume responsibility for the future development of Sofpironium Bromide including filing for approval with FDA and any other international regulatory authority outside of Kaken’s Far East Asia licensed territory. The asset has been licensed to leading pharmaceutical company Kaken Pharmaceuticals (“Kaken”) in Japan, who has already secured approval of sofipironium bromide 5% for the treatment of primary axillary hyperhidrosis from the Japanese equivalent of the FDA, the Pharmaceuticals and Medical Devices Agency (“PMDA”). Kaken launched sofipironium bromide 5% in late 2020 and is expected to work closely with Botanix to support the approval of the product in the USA and will take the lead in filing for approvals in other Far East Asian countries. As part of the purchase price, Botanix is entitled to retain 25% of the royalties and milestone payments that Botanix receives from Kaken.

### **Sofpironium Bromide advances Botanix towards being a leading commercial dermatology company**

The successful acquisition of Sofpironium Bromide advances Botanix towards its goal of becoming a leading commercial dermatology company. Sofpironium Bromide is an exciting opportunity, with more than 15 million patients that suffer from hyperhidrosis in the US alone.<sup>3</sup> Existing therapies are not ideal, either because of the lack of efficacy, unfavourable side effect profile, risk of drug exposure to the skin, or pain from invasive procedures or surgery.

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<sup>2</sup> Brickell’s Form-8K SEC filing refers to US\$168M in regulatory and other sales milestones. This comprises EU/UK approval for primary axillary hyperhidrosis, new indication approval and sales milestones together, all which are contingent and subject to achievement of each of these milestones individually.

<sup>3</sup> *ibid*

This Sofpironium Bromide asset fits very well at the front of our growing pipeline and complements our existing development stage assets.

Botanix remains committed to its exciting dermatology and antimicrobial pipeline with its Phase 2 BTX 1702 (rosacea) clinical study on track to complete recruitment shortly and its BTX 1204A canine study in atopic dermatitis, also completing recruitment in the near term. The Company is also well advanced with commencing our BTX 1801 antimicrobial study, with ethics approvals being prepared to be submitted this quarter.

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 (USA) which is committed to the development of pharmaceutical products that are underpinned by science and supported by well-controlled randomised clinical trials. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide for the treatment of primary axillary hyperhidrosis planned to be filed for FDA in 2H 2022, and a series of other products in late-stage clinical studies for the treatment of rosacea, dermatitis and acne. Botanix is also developing a topical antimicrobial product for the eradication of bacteria, initially in patients 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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### 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, 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 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 or its partners’ ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company’s or its partners’ ability to obtain marketing approvals for its product candidates. 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.

# Sofpironium Bromide

May 2022



# Accelerating Botanix towards revenue generation

Newly acquired asset Sofpironium Bromide being prepared for FDA approval filing in 2H 2022



## Sofpironium Bromide

First and only new chemical entity for “primary axillary hyperhidrosis” (a medical condition which results in excessive underarm sweating)



## Positive Phase 3 Data

All co-primary and secondary endpoints statistically significant. Side effects were mild to moderate and no treatment-related serious adverse events



## Attractive Terms

Minimal upfront payment and back-ended deal decreases risk and allows Botanix to share success when it's achieved (based on commercial success)



## Significant Market

More than 15 million people suffer from hyperhidrosis in the US alone and market for treatments is ~\$US1.6B per annum which is projected to grow to \$US2.8B by 2030<sup>1,2</sup>



## De-risked Asset

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

# Sofpironium Bromide Deal Summary

Accelerates Botanix's first product to US market in late 2023

- US\$3M upfront payment with US\$2M on receipt of FDA 'day 74 letter' (indicating NDA filing is acceptable for review)
- US\$4M payment on FDA approval if before 30 September 2023, down to zero if approved after 17 February 2024
- US\$4M milestones are payable if approval is received from a EU/UK regulator, or for another indication
- Sales milestones only payable once Net Sales exceed US\$75M per annum and are capped at US\$160 million (implying Net Sales to Botanix of more than US\$1.8B)
- Royalties on Net Sales start in the low double digits and rise to 20%, above US\$500M of Net Sales
- Botanix retains 25% of all sales milestones and royalties payable by partner Kaken in Japan

# World class board and management team

Developed, secured approval for and commercialised over 30 dermatology products



**VINCE IPPOLITO**

*President and Executive Chairman*

- COO of Anacor and Medicis; former President Dermavant; more than 17 years at Novartis.
- More than 30 years experience in pharma with 20+ years within dermatology interactions and mental health



**MATT CALLAHAN**

*Board Executive Director*

- Serial founder and ex-investment director of two venture capital firms in life sciences
- Developed four products through FDA approval and launch



**DR BILL BOSCH**

*Board Executive Director*

- 30+ years experience in pharma industry
- Co-inventor of SoluMatrix™ drug delivery technology and NanoCrystal® Technology



**HOWIE MCKIBBON**

*Chief Commercial Officer*

- Former SVP Commercial of DermavantAnacor and Medicis
- 20+ years working in dermatology - launched more than 15 brands and managed over 35 dermatology products



**DR PATRICIA WALKER**

*Chief Medical Adviser*

- Former President and head R&D Brickell Biotech
- Former CMO/CSO at Kythera, Inamed and Allergan Medical responsible for multiple products including Botox and Tazorac



**ANTHONY ROBINSON**

*VP of Development*

- Recently Vice President R&D at Advicenne
- Senior leadership roles at Aquestive Therapeutics, Intrommune and Shire Pharmaceuticals



**DR JACK HOBLITZELL**

*SVP Pharmaceutical Development*

- 30+ years leading world-class technical operations to manufacture and deliver pharmaceuticals
- Senior leadership roles at Assertio Therapeutics, Pfizer, King, Ivax and Teva



**DR IRA LAWRENCE**

*Clinical and Regulatory Adviser*

- 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries
- Former SVP R&D Medicis, Astellas and Fujisawa



**DR CLARENCE YOUNG**

*Chief Medical Adviser, Antimicrobials*

- Recently Chief Medical Officer at Velicept Therapeutics
- Senior leadership roles at Iroko Pharmaceuticals, Novartis, Protez and GlaxoSmithKline



**LYNDA BYRNE**

*Commercial Adviser, Antimicrobials*

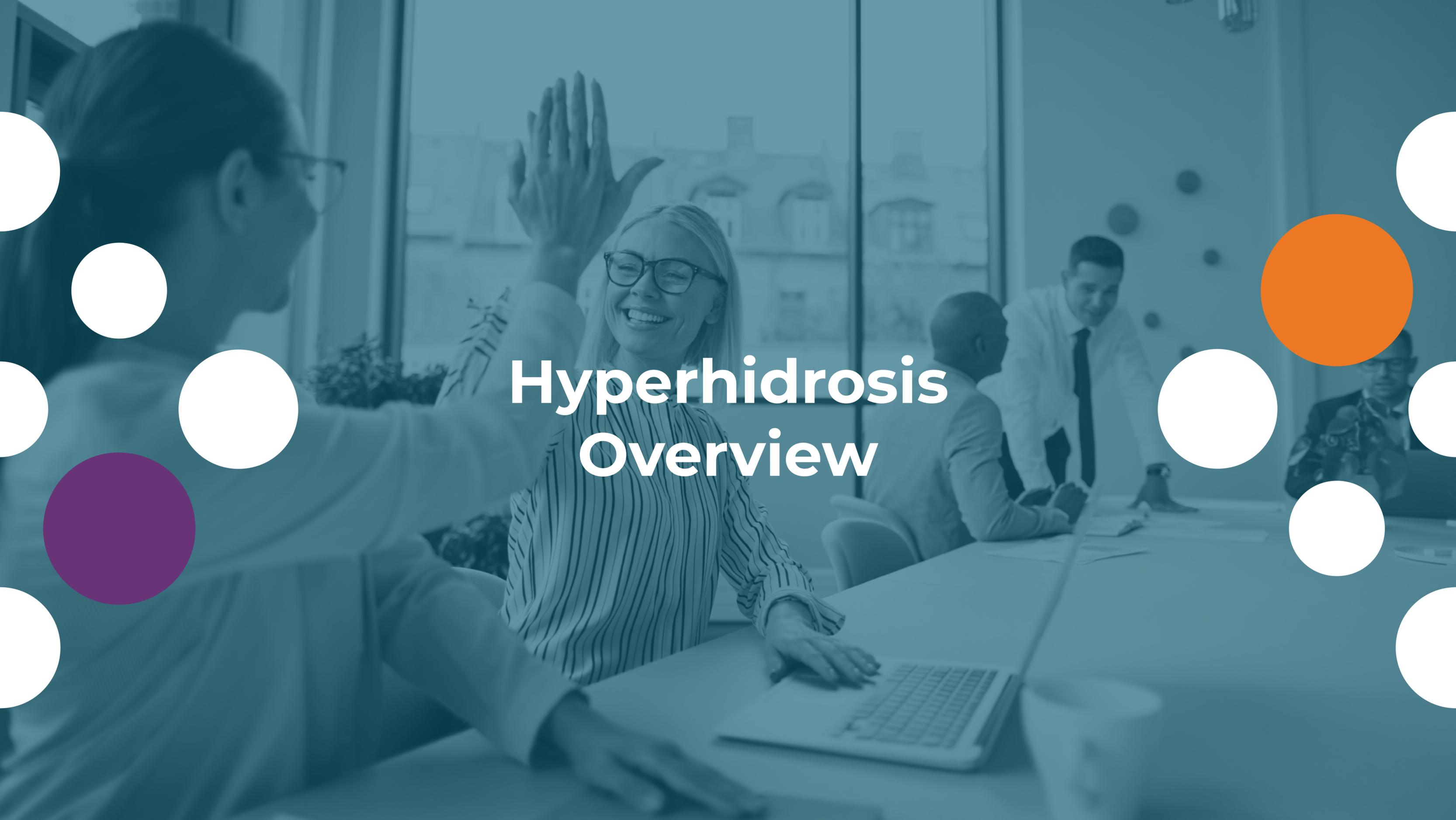
- Managing Partner BAL Pharma Consulting
- Senior leadership roles at Motif Biosciences, Nabriva Therapeutics, Shire Abbot and BMS

# Sofpironium Bromide complements existing pipeline

Accelerates revenue generation, M&A opportunities and adds dermatology indication

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED	STATUS	
Axillary Hyperhidrosis (excessive underarm sweating)	Sofpironium Bromide							FDA approval filing planned 2H 2022
Moderate to severe acne	BTX 1503							Phase 3 commencement pending
Rosacea	BTX 1702							Phase 2 study underway – enrollment complete mid 2022
Atopic Dermatitis	BTX 1204A							Canine study complete 2Q 2022
Antimicrobial	BTX 1801							Phase 2 study commencing 2Q 2022

**Sofpironium Bromide is a significant opportunity in its own right, but also fits well alongside acne, rosacea and dermatitis as a new dermatology indication which accelerates Botanix towards revenue generation**



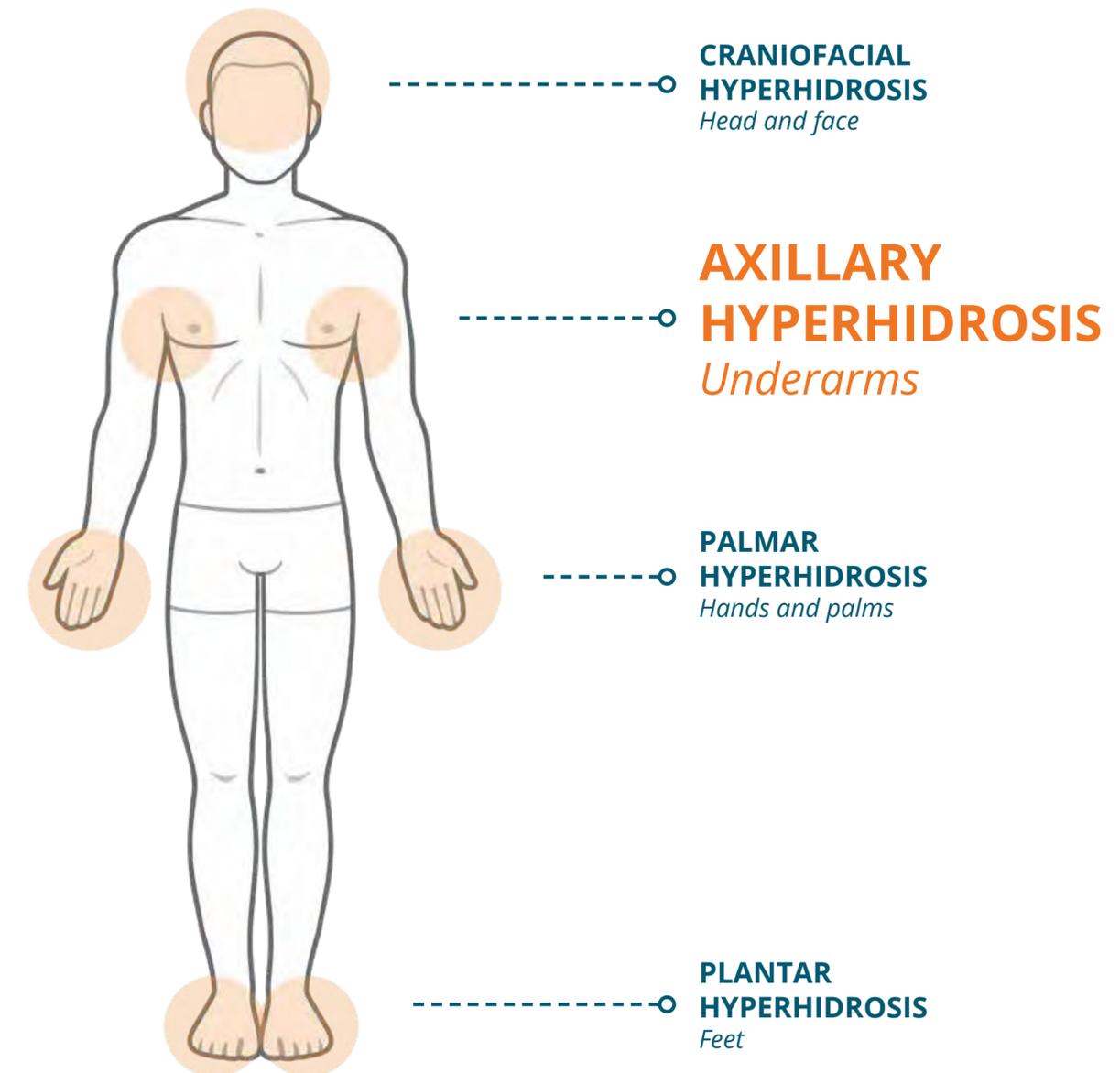
# Hyperhidrosis Overview

# Hyperhidrosis

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

Hyperhidrosis affects ~15M people in the US<sup>1</sup>:

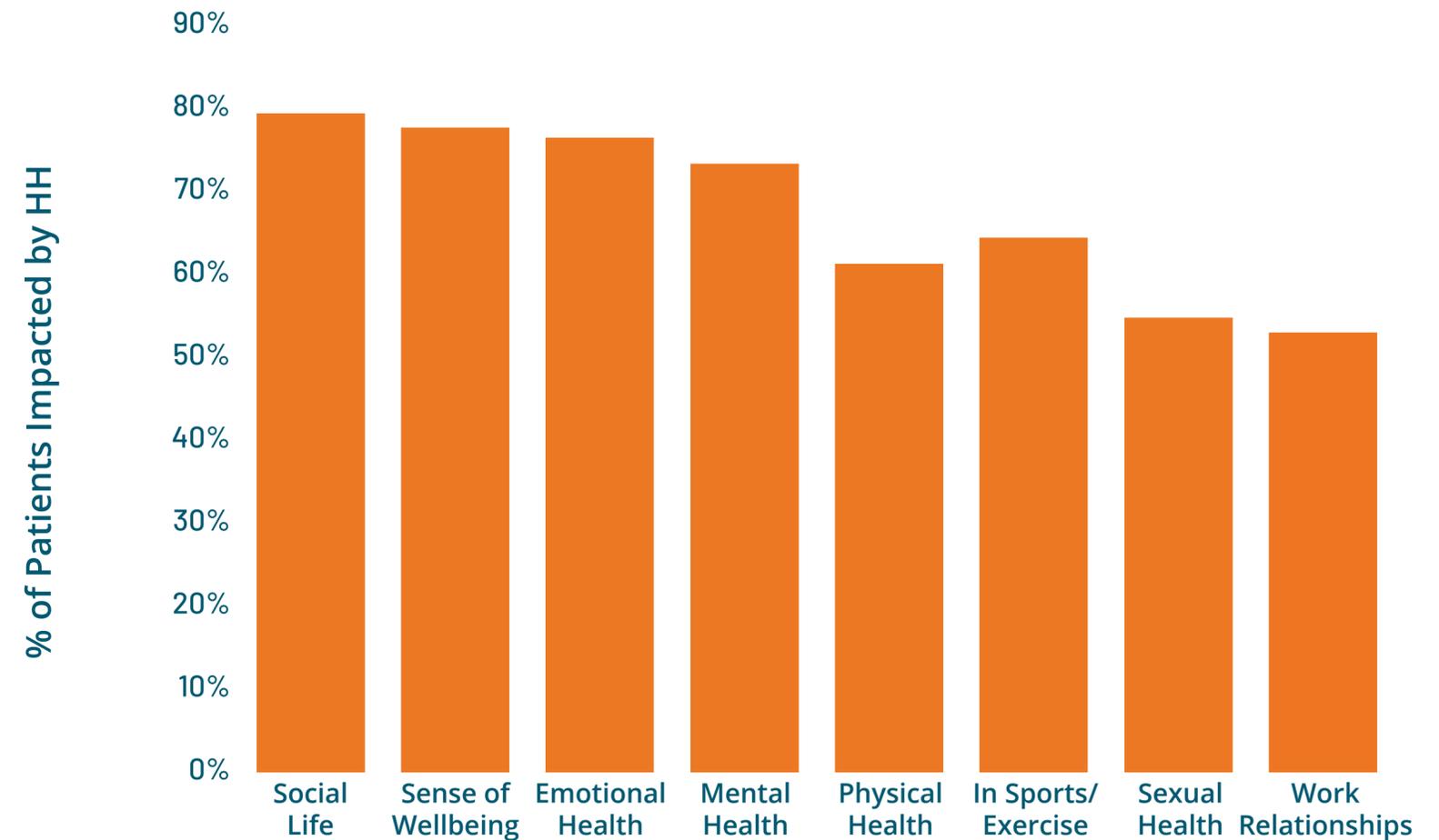
- Results from overstimulation of the nervous system (a physiological not psychological condition)<sup>1</sup>
- 80% of patients have hyperhidrosis in more than one region<sup>1</sup>
- 90% of axillary (underarm) patients also have it in second region<sup>1</sup>
- The most common age of onset for axillary hyperhidrosis patients is 12-17<sup>2</sup>



# Underarm (axillary) hyperhidrosis has significant impact on daily living

Patients develop multiple coping strategies in the absence of effective, tolerable treatment<sup>2</sup>

**~77% of patients with hyperhidrosis report negative impact on their lives<sup>1</sup>**



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING



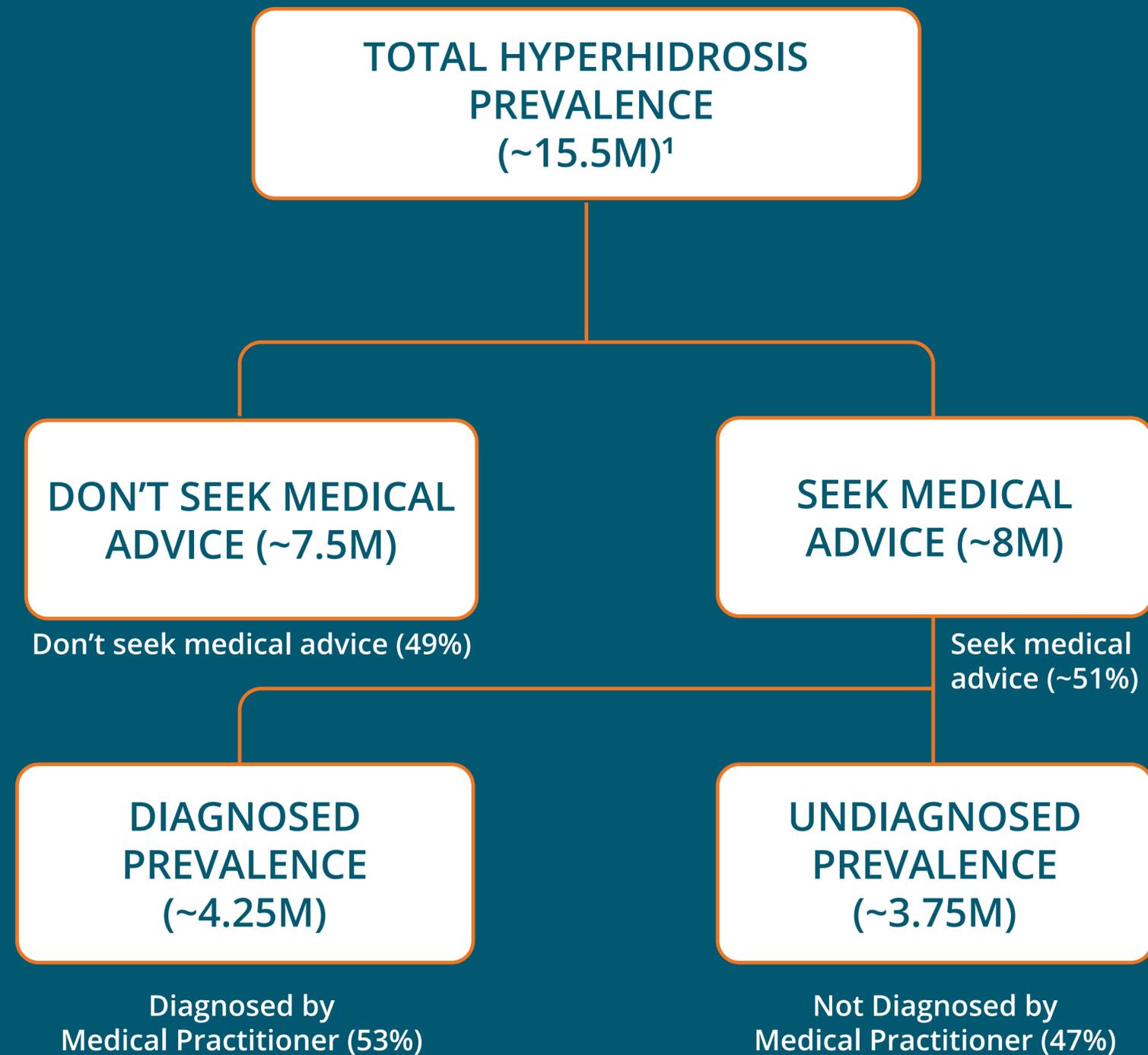
PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS



HIDE UNDER  
DARK-COLORED,  
BULKY CLOTHES

# Hyperhidrosis is a significant problem

More than 15 million patients in US - vast majority go undiagnosed or untreated



# Hyperhidrosis Treatment Continuum

No new chemical entities ever approved for hyperhidrosis

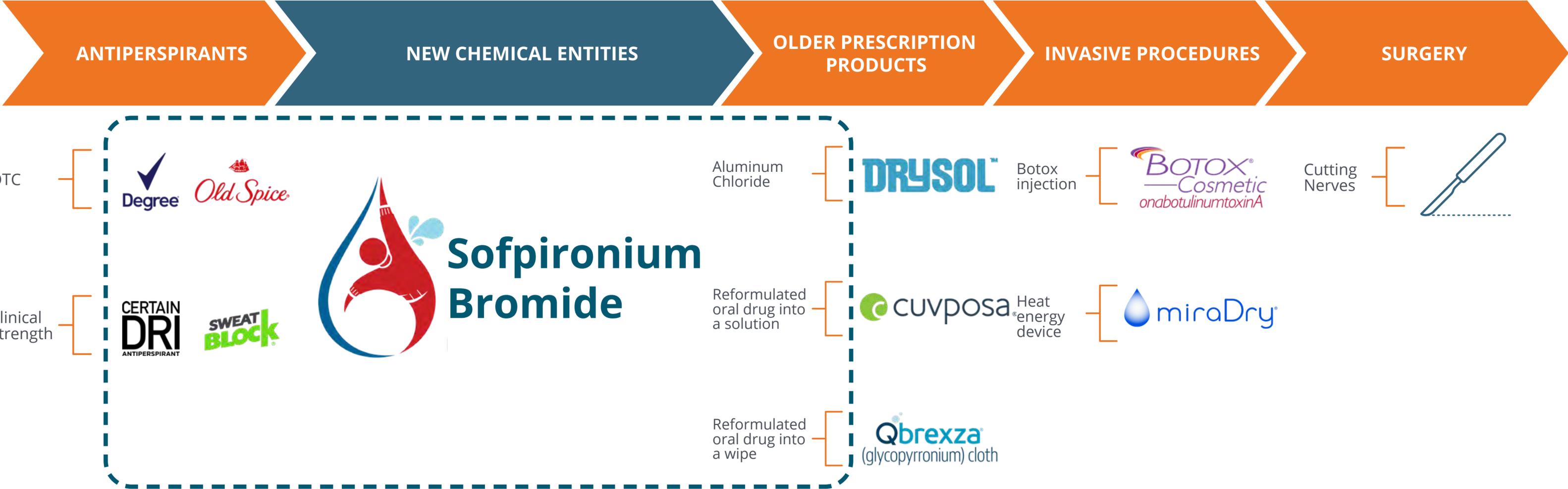


# Existing treatment options are not ideal

Lack of efficacy, poor side effect profiles and lack of insurance coverage are key concerns

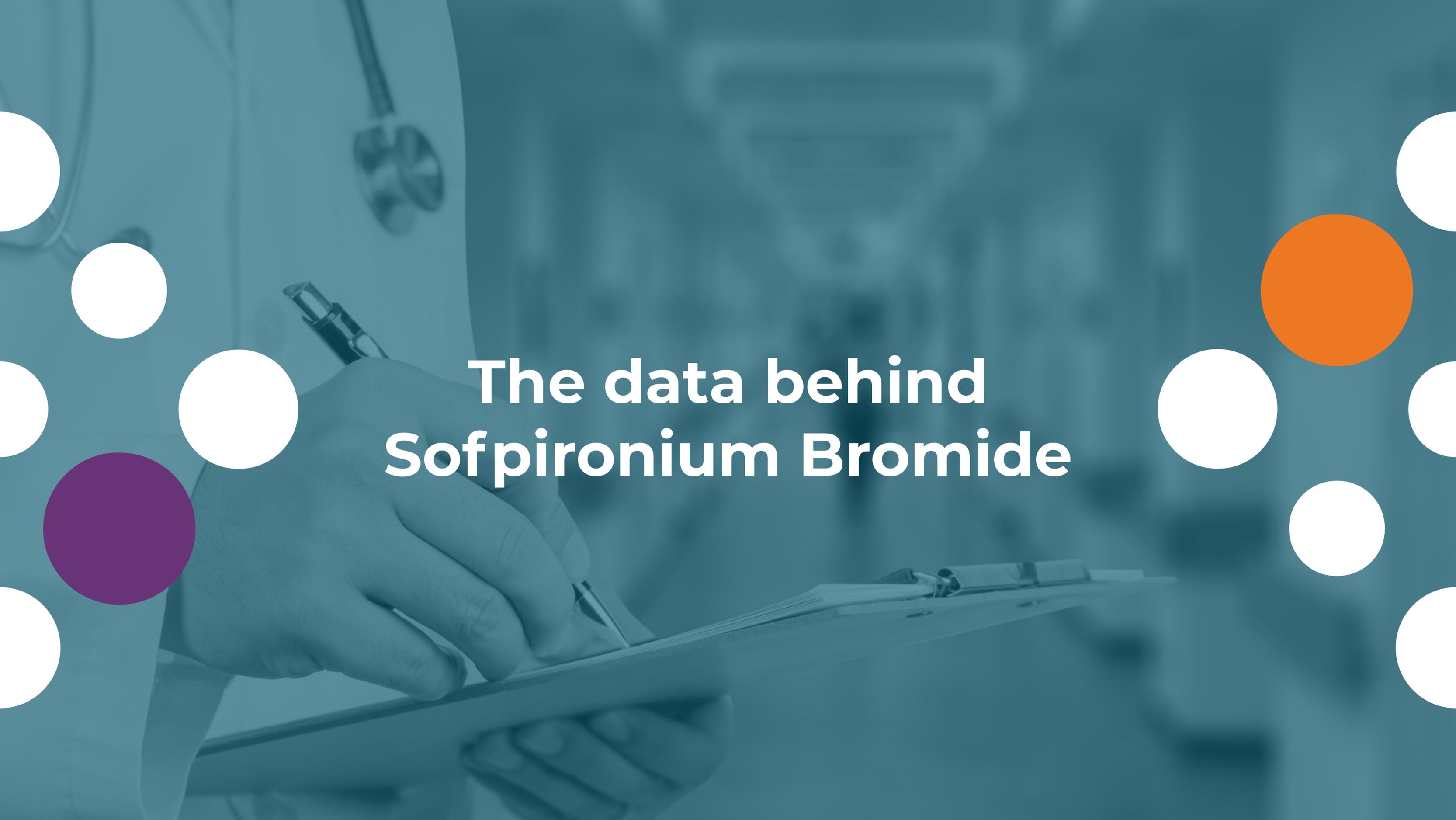
	Mechanism of Action <sup>1,2</sup>	Example Products/ Procedures	Potential Concerns <sup>1,2</sup>
Topical Anti-perspirants	Mechanically obstructs the sweat gland	<ul style="list-style-type: none"> <li>Aluminum chloride</li> <li>Drysol®/Certain-Dri®/SweatBlock®</li> </ul>	<ul style="list-style-type: none"> <li>Can lack efficacy</li> <li>Can cause burning and stinging</li> </ul>
Older systemic oral drugs	Interferes with nerve signals to the sweat gland	<ul style="list-style-type: none"> <li>Anticholinergics (Glycopyrronium etc)</li> <li>Beta blockers</li> </ul>	<ul style="list-style-type: none"> <li>Intolerable side effects for some such as dry mouth, constipation etc.</li> </ul>
Reformulations of older systemic drugs	Competitively bind the relevant sweat gland receptors	<ul style="list-style-type: none"> <li>Qbrexza®</li> </ul>	<ul style="list-style-type: none"> <li>Dry mouth, inflammation, burning and stinging</li> </ul>
Botox injections	Inhibits the release of the messenger chemical that triggers sweating	<ul style="list-style-type: none"> <li>Botox®</li> <li>Dysport®</li> </ul>	<ul style="list-style-type: none"> <li>Pain during injections</li> <li>Limited insurance coverage – high out of pocket costs</li> </ul>
Thermal energy	Delivers heat energy to the sweat glands	<ul style="list-style-type: none"> <li>miraDry®</li> </ul>	<ul style="list-style-type: none"> <li>High out of pocket costs</li> <li>Common side effects include swelling, redness and pain</li> </ul>
Surgery	Interrupts transmission of nerve signals - removes /injures sweat glands	<ul style="list-style-type: none"> <li>Endoscopic thoracic sympathectomy (ETS)</li> <li>Excision, curettage, liposuction, and laser</li> </ul>	<ul style="list-style-type: none"> <li>High cost</li> <li>Pain, infection, more sweating elsewhere</li> </ul>

# Significant opportunity for a new topical agent with class leading efficacy and safety



**Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would pay anything for a treatment to stop their excessive sweating<sup>1</sup>**

Sources: 1. Doolittle, J. et al. Arch Dermatol Res, 2016.



**The data behind  
Sofpironium Bromide**

# Sofpironium Bromide Overview

FDA submission well advanced - planned for 2H 2022



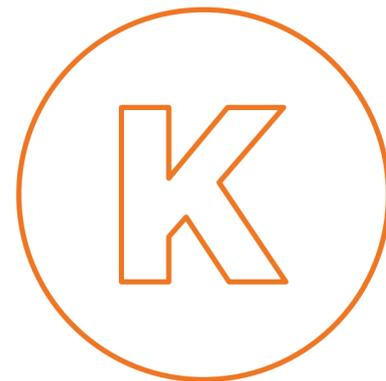
Efficacy hit statistical significance on all co-primary as well as all secondary endpoints<sup>1</sup>



Long term studies demonstrate safety profile consistent with Phase 3 studies<sup>1</sup>



Patient friendly device removes need to touch product during application



Molecule already approved by Japanese FDA (PMDA) with partner Kaken Pharmaceuticals



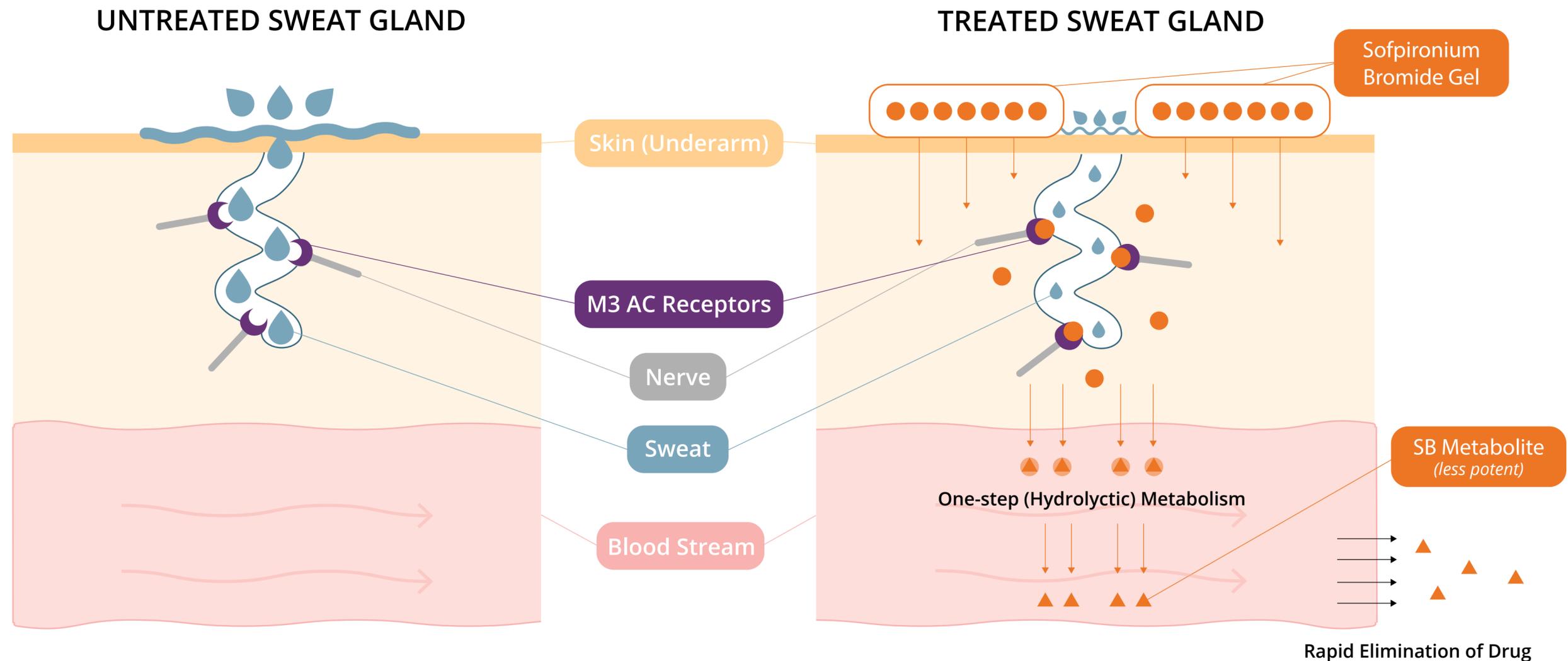
Opportunities for new indications and delivery options, including using Permetrex™



Significant market opportunity – hyperhidrosis market was US\$1.6B in 2021 and is expected to grow to US\$2.8B by 2030<sup>2</sup>

# 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

# Phase 3 pivotal study - highlights

All co-primary and secondary efficacy endpoints were statistically and clinically significant

85% of the subjects had a clinically meaningful  $\geq 1$ -point change in the patient reported outcome measure (HDSM-Ax)<sup>1</sup>

55% of patients met a more rigorous 2-point change (HDSM-Ax)<sup>1</sup>

Over 60% of those subjects had both a 50% or greater reduction in sweat production and the clinically meaningful 1-grade change (HDSM-Ax)<sup>1</sup>

Average reduction in sweat at week 6 was  $\sim 138\text{mg}^1$



<https://cardigan.sweat2much.com>

# Endpoints for hyperhidrosis include objective and subjective measures

New more detailed patient reporting scale developed for Sofpironium Bromide

Evaluation via a quantitative measurement as well as a patient reported outcome (PRO) measurement scale

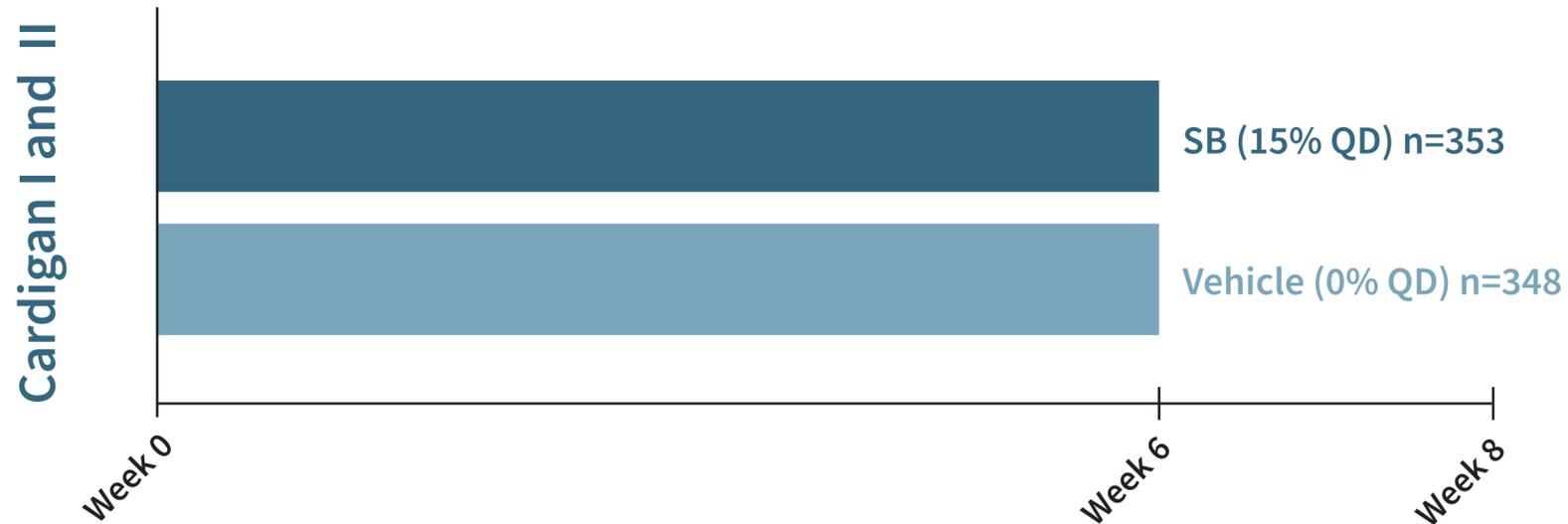
## QUANTITATIVE MEASUREMENT

- Gravimetric measurement of axillary (underarm) sweat production
- Filter paper applied to dried under arm for 5 minutes, then weighed
- Always used in clinical trials as end point to measure reduction in sweat production

## PATIENT REPORTED OUTCOME MEASUREMENTS

- Older treatments used Hyperhidrosis Disease Severity Scale (HDSS) which is not a validated outcome measure
- A new Hyperhidrosis Disease Severity Measure Axillary (HDSM-Ax) scale was developed for axillary hyperhidrosis
- HSDM-A is a more disease centric measurement where a 1-point change has been validated as being clinically meaningful

# Phase 3 Study Design



## Abbreviations:

HDSM-Ax: Hyperhidrosis Disease Severity Measure -Axillary  
GSP: Gravimetric Sweat Production  
SB = Sofpironium Bromide  
QD = once daily

## Study Details

- Two Phase 3 randomised, placebo-controlled studies
- Randomised 1:1
- 6 weeks treatment, 2-week follow-up

## Key Inclusion Criteria

- Ages 9+ with HDSM-Ax-7 of 3-4
- GSP >50 mg sweat production per underarm ('axilla'), with a 2-axilla combined total of  $\geq 150$ mg

## FDA Recommended Co-Primary Endpoints

- The proportion of subjects achieving  $\geq 2$ -point improvement in the HDSM-Ax-7 scale score from baseline to end
- The change in Gravimetric Sweat Production (GSP) from baseline to end

## Secondary Endpoints

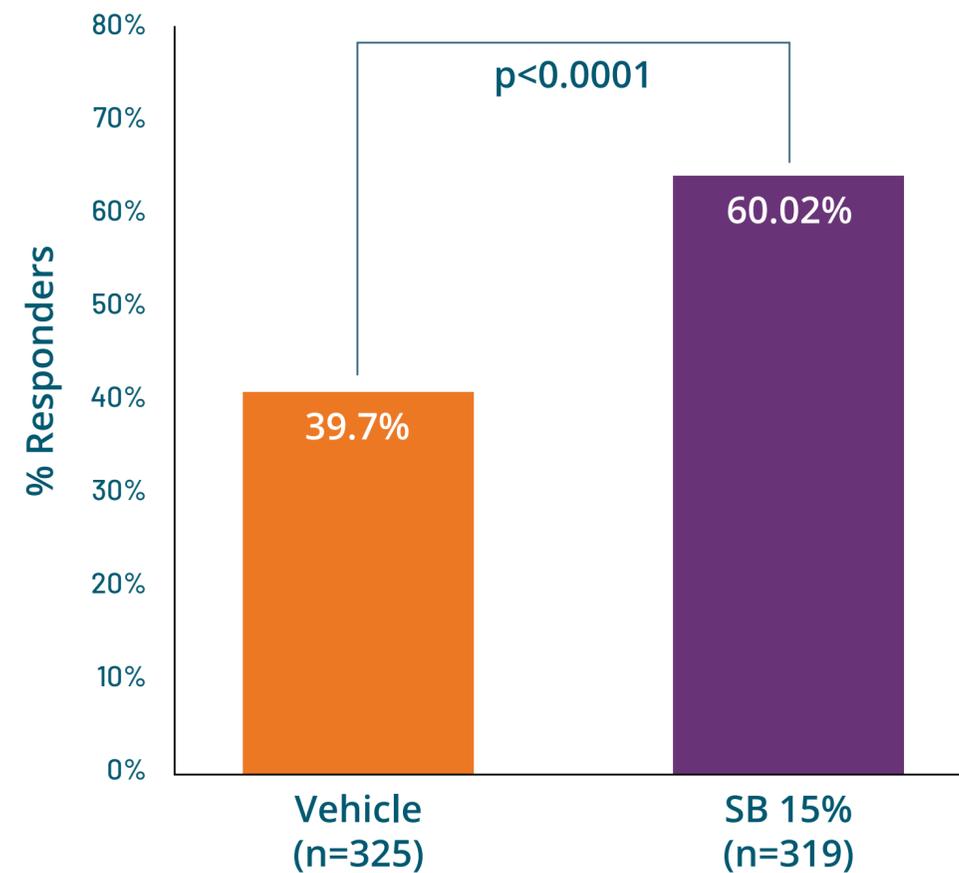
- The proportion of subjects achieving  $\geq 1$ -point improvement in HDSM-Ax-7 score
- The proportions of subjects achieving  $\geq 2$ -point improvement in HDSM-Ax-7 score from baseline to end and achieving  $\geq 70\%$  reduction of GSP
- The proportions of subjects achieving  $\geq 1$ -point improvement in HDSM-Ax-7 score from baseline to end and achieving at least 50% reduction of GSP

# Phase 3 co-primary endpoints - both were statistically significant

Measured reduction in Gravimetric Sweat Production (GSP) and HDSM-Ax-7 scale responses

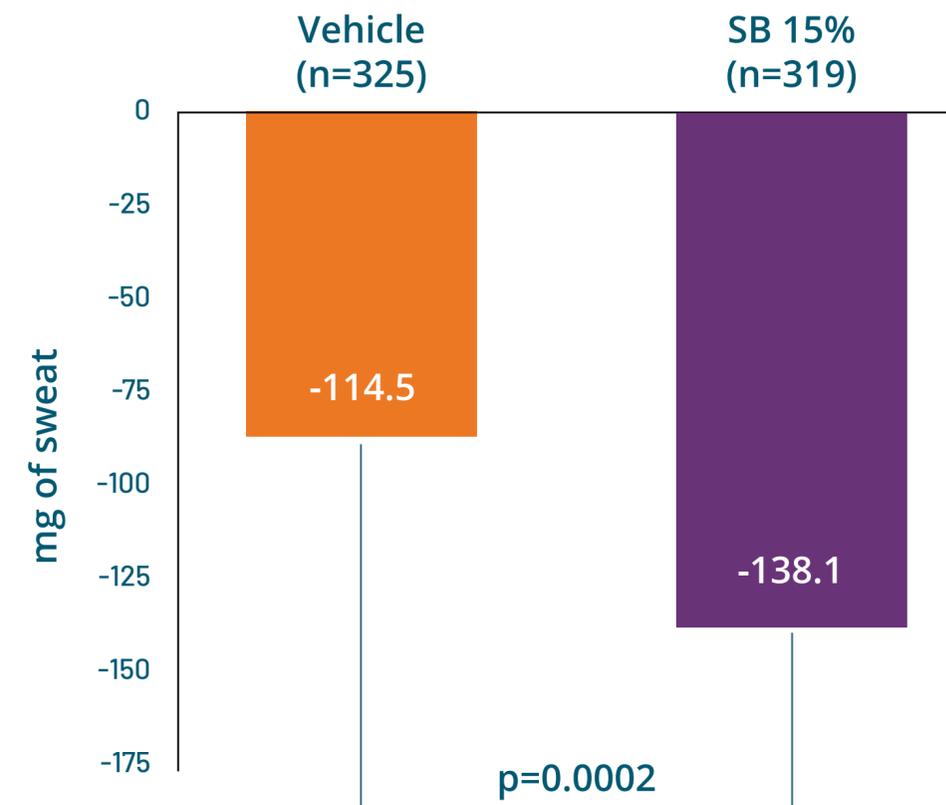
## Pooled Data (Cardigan I and II)

≥2-point improvement in HDSM-Ax-7 from baseline to end of treatment<sup>1</sup>



## Pooled Data (Cardigan I and II)

GSP change from baseline to end of treatment<sup>1</sup>



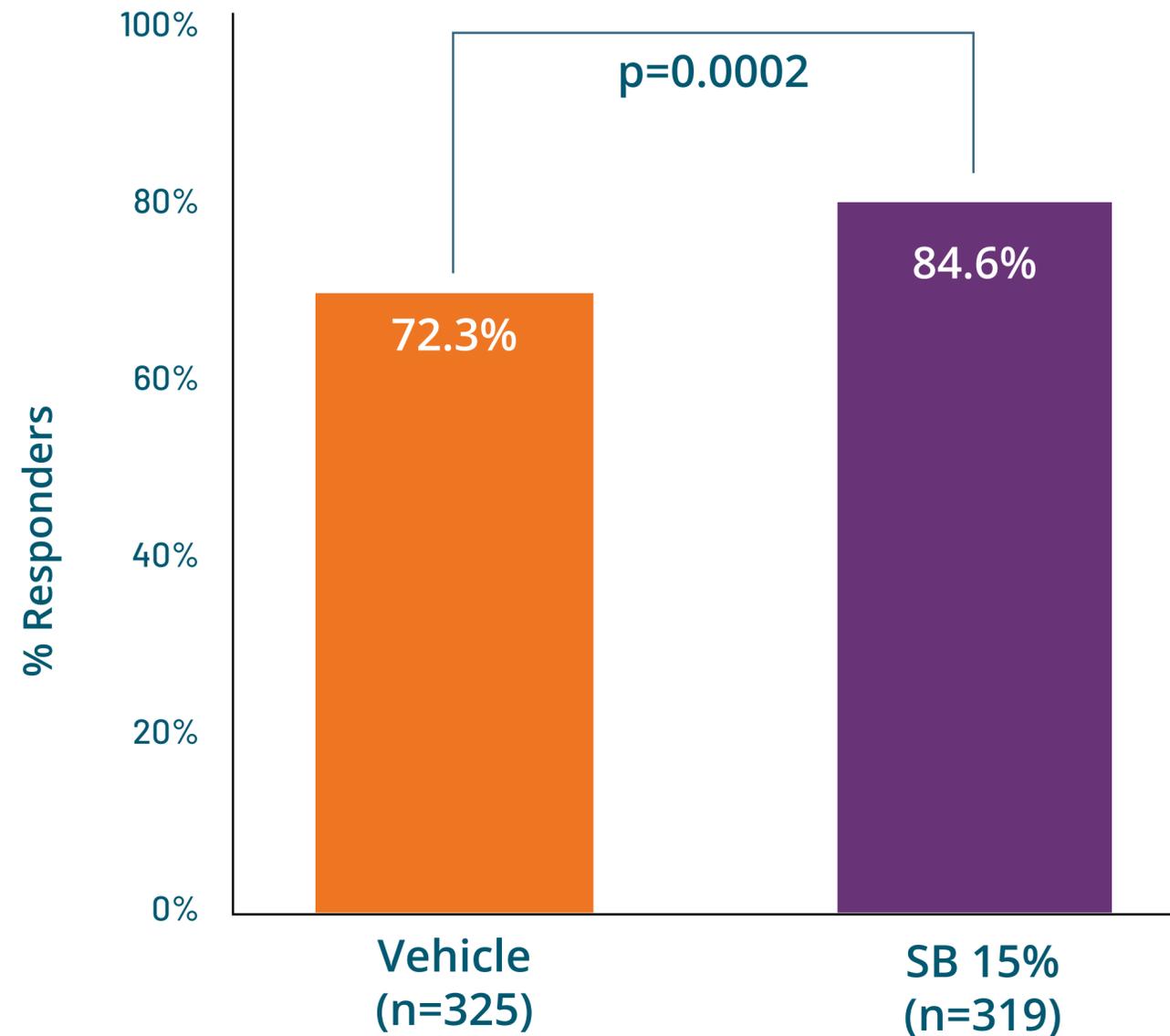
SB = Solfpironium Bromide

## 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 = Solfipronium Bromide



Sofpironium bromide gel was generally well tolerated in both Phase 3 and long term (48 week) studies<sup>1</sup>



The majority of treatment-emergent adverse events in sofpiroonium bromide gel treatment group were mild to moderate in severity, and were transient in nature<sup>1</sup>



The Phase 3 studies each had a very low drop-out rate (~4%)<sup>1</sup>



No treatment-related serious adverse events were reported<sup>1</sup>



Efficacy in the long-term safety study continued to improve on average from commencement to week 48<sup>1</sup>

# Favorable safety profile in Phase 3 and long-term safety studies

# Sofpironium Bromide - convenient, touch free delivery



Applicator allows for contact free application



Dose metered pump provides reliability and flexibility



Container size is convenient and portable

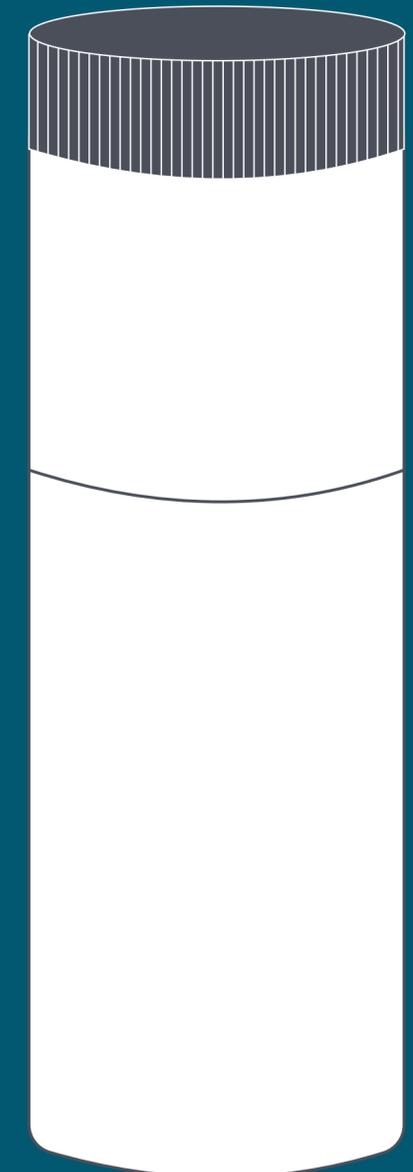
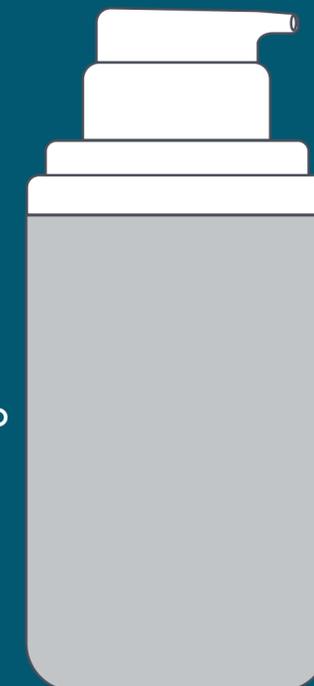
CAP



APPLICATOR



METERED-DOSE PUMP =  
LESS WASTE





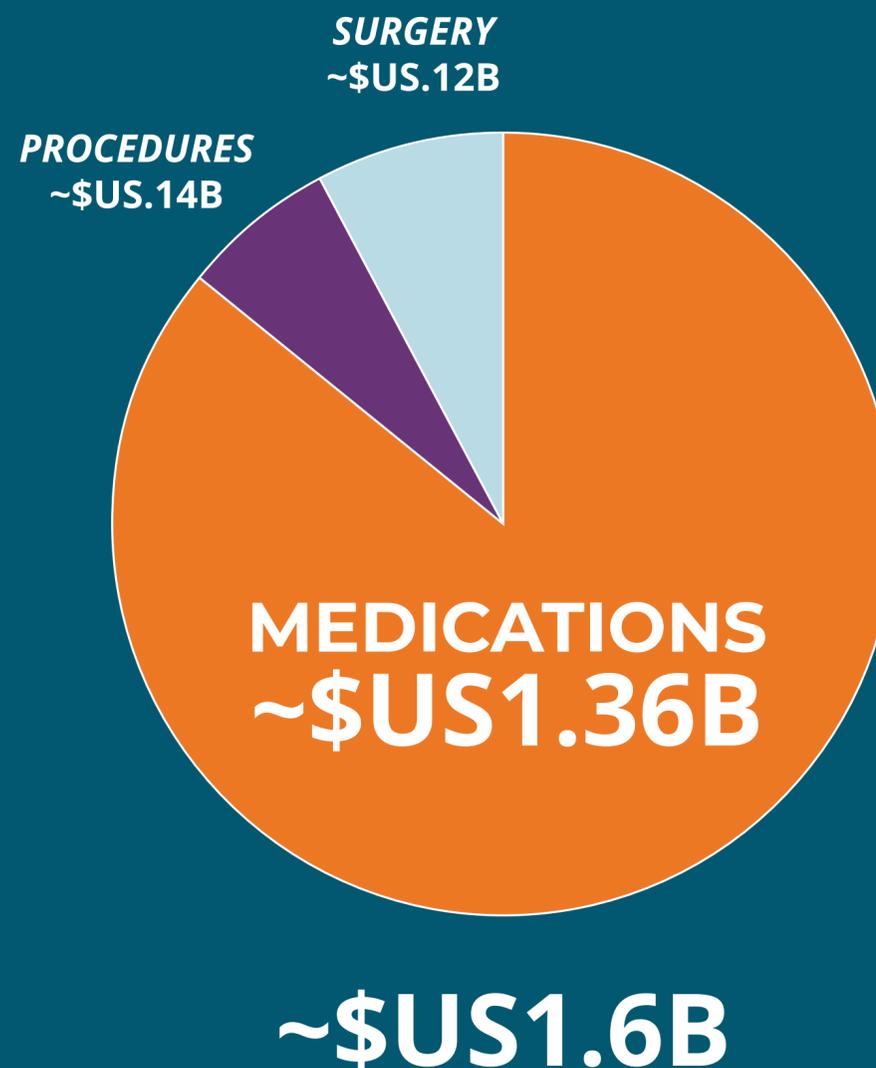
**Sofpironium Bromide  
commercial  
opportunity**

# Hyperhidrosis market projected to grow to \$US2.8B by 2030<sup>1</sup>

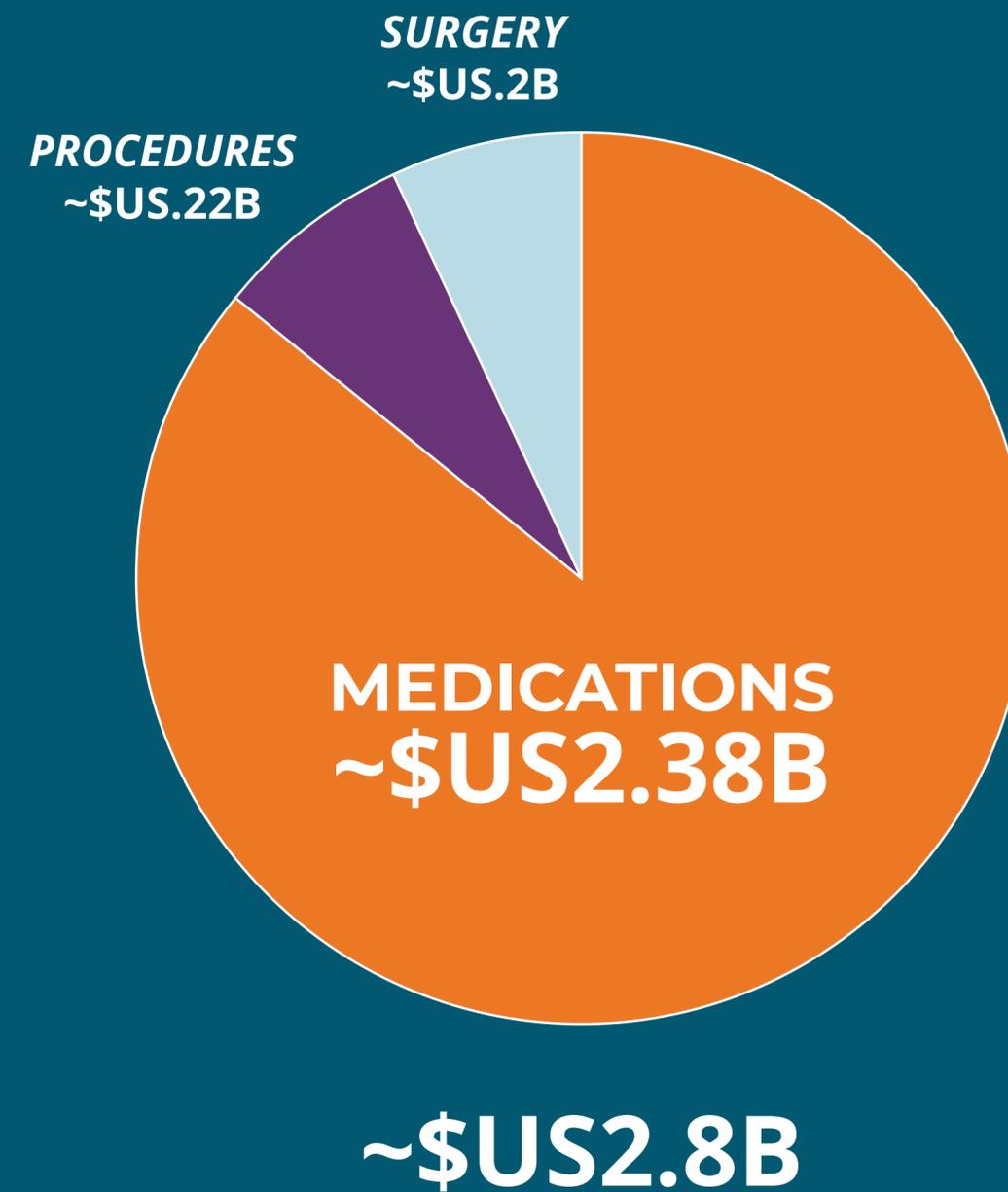
Largest growth segment is medications with a 6% compounded annual growth rate

Significant opportunity for a new topical agent with class leading efficacy and safety

2021



2030

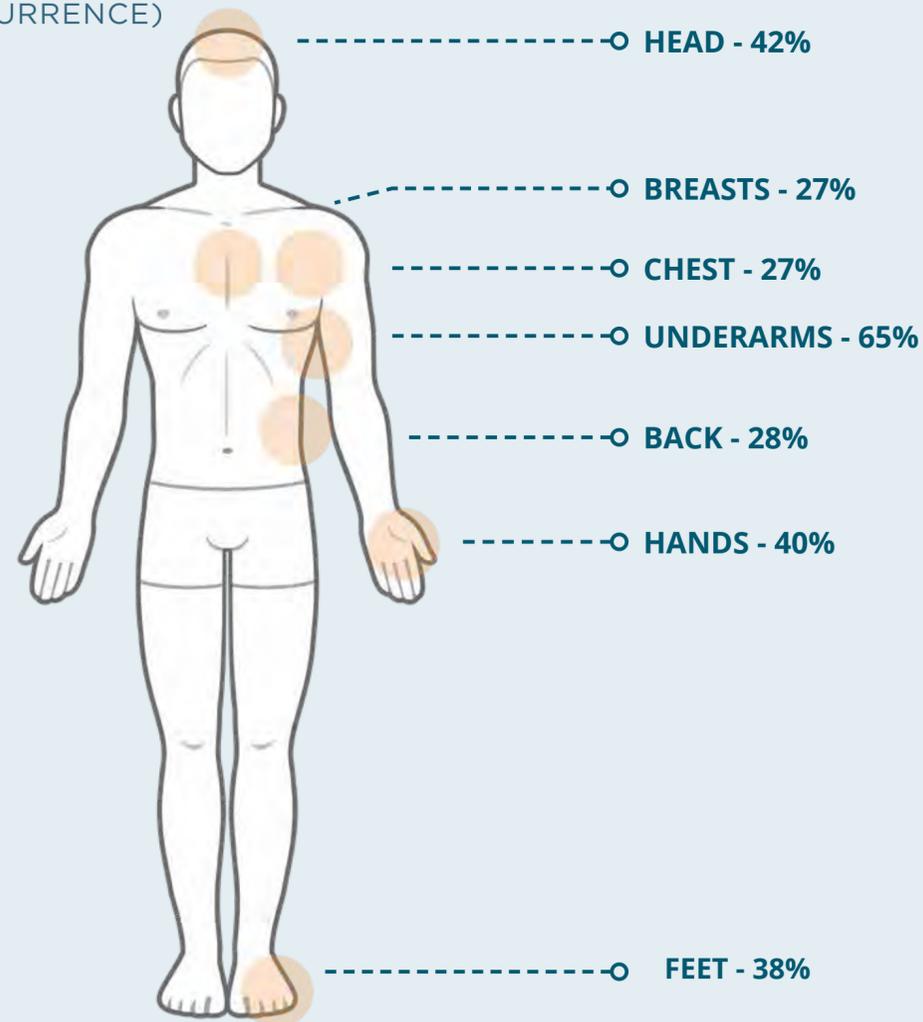


# Opportunities for expansion with Sofpironium Bromide

Can be approved for other distinct body areas, using Permetrex™ and new delivery devices

## US HH SUFFERERS BY BODY AREA<sup>1</sup>

(% OCCURRENCE)



## OTHER OPPORTUNITIES

### Indication expansion

- New indications for treatment of palms, feet breasts etc
- Fast clinical pathway leveraging FDA approval for axially (under arms)

### Formulation and packaging changes

- Utilise new Permetrex™ formulation for better penetration for hard to treat areas (hands/feet)
- Next generation roll on applicator to be filed for approval after FDA approval for first bottle design

# Kaken partnership – Japan and Asia

Sofpironium Bromide is already approved in Japan and has recently been launched



Kaken is a leading specialty pharmaceutical company ~US\$1.26B Market Cap Net Sales of \$660M (FY2021) >\$60M annual R&D spend

Kaken has rights to sofpiroonium bromide in Japan, Korea, China & certain other Asian countries



SOFPIRONIUM BROMIDE GEL, 5% (ECCLOCK®)

ECCLOCK® approved in Japan in late 2020

ECCLOCK® placed on Japan's National Health Insurance drug reimbursement price list

Commercialisation commenced in 2021

**Botanix is entitled to a share of milestone payments and royalties from Kaken sales of Sofpironium Bromide**

# Key Upcoming Milestones

Rapid pathway to approval and revenue

Expected Timing

1H 2022

2H 2022

1H 2023

2H 2023

- NDA submission for approval
- Day 74 review letter from FDA

- Commercial manufacturing for launch
- FDA approval

- ✓ Pre Submission meeting with FDA
- Post-transaction transition

- FDA feedback on proposed trade name
- FDA mid-cycle review

# Sofpironium Bromide IP and regulatory summary

Protected by strong IP in the US and other major global markets and expecting strong regulatory exclusivity

## COMPOSITION OF MATTER

- US patent issued with claims covering compounds, compositions, and methods of use (expires 2027, excluding PTE)
- US non-provisional and national stage applications filed covering crystalline forms and manufacturing process of Sofpironium Bromide; already issued in Japan (expiry not before 2040)

## METHOD OF DOSING

- US patent issued with claims covering uses of Sofpironium Bromide for treatment of hyperhidrosis (expires 2034)
- National stage filings pending or allowed (granted in EP, JP & CA)

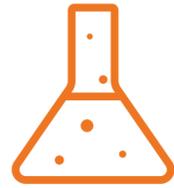
## FORMULATION

- US patents issued with claims covering novel topical compositions and uses for treatment of hyperhidrosis (expires 2034)
- PCT filed (national stages pending and available) covering Japan commercial formulation

## APPLICATOR SYSTEM

- US provisional utility application filed for the novel applicator system (expires 2039)
- Design application filed in US (and other key jurisdictions) covering the applicator and container system (expiry not before 2034)

# Summary



First and only new chemical entity to treat axillary (underarm) hyperhidrosis planned for FDA approval filing in 2H 2022



Positive Phase 3 data with statistical significance on all endpoints and favorable long term safety



Significant opportunity with more than 15 million patients - market for treatments currently exceeds US\$1.6B per annum, projected to grow to US\$2.8B by 2030



De-risked asset with Japanese FDA approval in place and partnership with Kaken Pharmaceuticals



Experienced team with more than 30 dermatology product launches, ready to execute

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