

12 July 2022

Updated Investor Presentation

Key highlights

- Release of updated corporate presentation to be used in a number of non-deal investor meetings scheduled this week
- The presentation includes:
 - an update on the accelerated FDA submission timetable of the New Drug Approval (NDA) for Sofpironium Bromide which is now planned for this quarter;
 - further insights into the market opportunity for Sofpironium Bromide; and
 - updated timetable for completion of rosacea (BTX 1702) Phase 1/2 clinical study and the canine dermatitis pilot study (BTX 1204A), which are now both fully enrolled and on target for completion in Q3 CY2022

Philadelphia PA and Phoenix USA, 12 July 2022: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or “the Company”), is pleased to release an updated corporate presentation being used for a number of investor meetings scheduled this week.

The presentation includes an update on the FDA filing timetable for Sofpironium Bromide which has been accelerated and is now planned for this quarter, further insights into the market opportunity for Sofpironium Bromide, as well as an update on the Company’s BTX 1702 Phase 1b/2 rosacea study and the BTX 1204A Phase 1b canine dermatitis study, which are on target for completion in Q3 CY2022.

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 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, planned to be filed for FDA in Q3 CY2022. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea, 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.

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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

July 2022

Preparing to file first dermatology product for FDA approval in Q3 2022



Botanix: a leader in topical drug development

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



Pharmaceutical 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 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

First and only new drug for “primary axillary hyperhidrosis” (medical condition which results in excessive underarm sweating) already approved in Japan with partner¹



Near-term catalysts

Upcoming filing for FDA approval for Sofpironium Bromide and data readouts from other pipeline products in 3Q CY2022

World class board and management team

Developed, secured approval for and commercialised over 30 dermatology products

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VINCE IPPOLITO

President and Executive Chairman

- COO of Anacor and Medicis; former President Dermavant; more than 17 years at Novartis.
- More than 35 years experience in pharma with 20+ years within dermatology



HOWIE MCKIBBON

Chief Commercial Officer

- Former SVP Commercial of Dermavant, Anacor 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



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



ANTHONY ROBINSON

VP of Development

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



DR JACK HOBLITZELL

SVP Pharmaceutical Development

- 30+ years leading world-class technical operations
- 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 Veliccept 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

Corporate Overview

Positioned to transition to commercial dermatology company

ASX: BOT TRADING INFORMATION

Share price	A\$0.07
6-month low / high	A\$0.052/0.095
Shares outstanding	979,233,384
Market Capitalisation	A\$68.5m
Cash (31 Mar 2022)	A\$ 16.4m
Debt (31 Mar 2022)	Nil
Enterprise value	A\$54.1m

SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Board and Management	8.29%
Caperi Pty Ltd, Co-Founder	5.4%

SHARE PRICE PERFORMANCE



Sofpironium Bromide leads late-stage pipeline

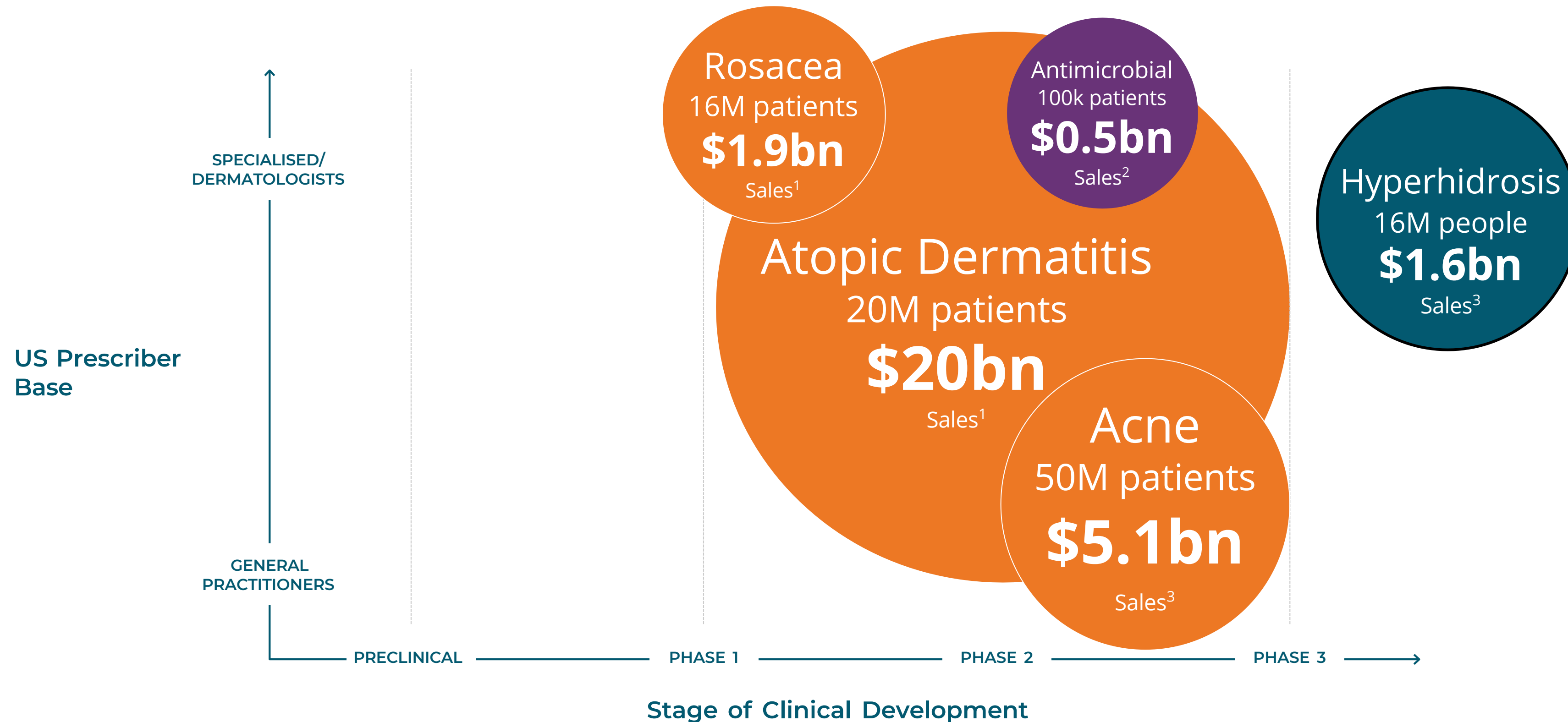
Planned for FDA filing in 3Q 2022 with 12-month review period

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED	STATUS (CY)	
Axillary Hyperhidrosis (excessive underarm sweating)	Sofprionium Bromide							FDA approval filing planned for 3Q 2022
Moderate to severe acne	BTX 1503							Phase 3 study commencement pending
Rosacea	BTX 1702							Phase 2 study planned for completion 3Q 2022
Atopic Dermatitis	BTX 1204A							Canine study planned for completion 3Q 2022
Antimicrobial	BTX 1801							Phase 2 study preparing for launch in 2H 2022

Sofpironium Bromide is a significant opportunity in its own right, but also fits well alongside acne, rosacea and dermatitis

Target markets with significant US patient numbers and high unmet needs

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1. Grandview Research. www.Grandview-research.com
 2. Using GSK Bactroban Nasal Pricing/BTX 1801 pricing to be developed following analyses of potential impact on healthcare system; assumes 5% YOY pricing following product approval/launch
 3. Symphony Health Solutions, METYS, data ending December 2019 – weighted

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Sofpironium Bromide



Accelerating Botanix towards revenue generation

Newly acquired asset Sofpironium Bromide being prepared for FDA approval filing in 3Q 2022



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 and side effects were mild to moderate with 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 16 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^{1,2}



De-risked Asset

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

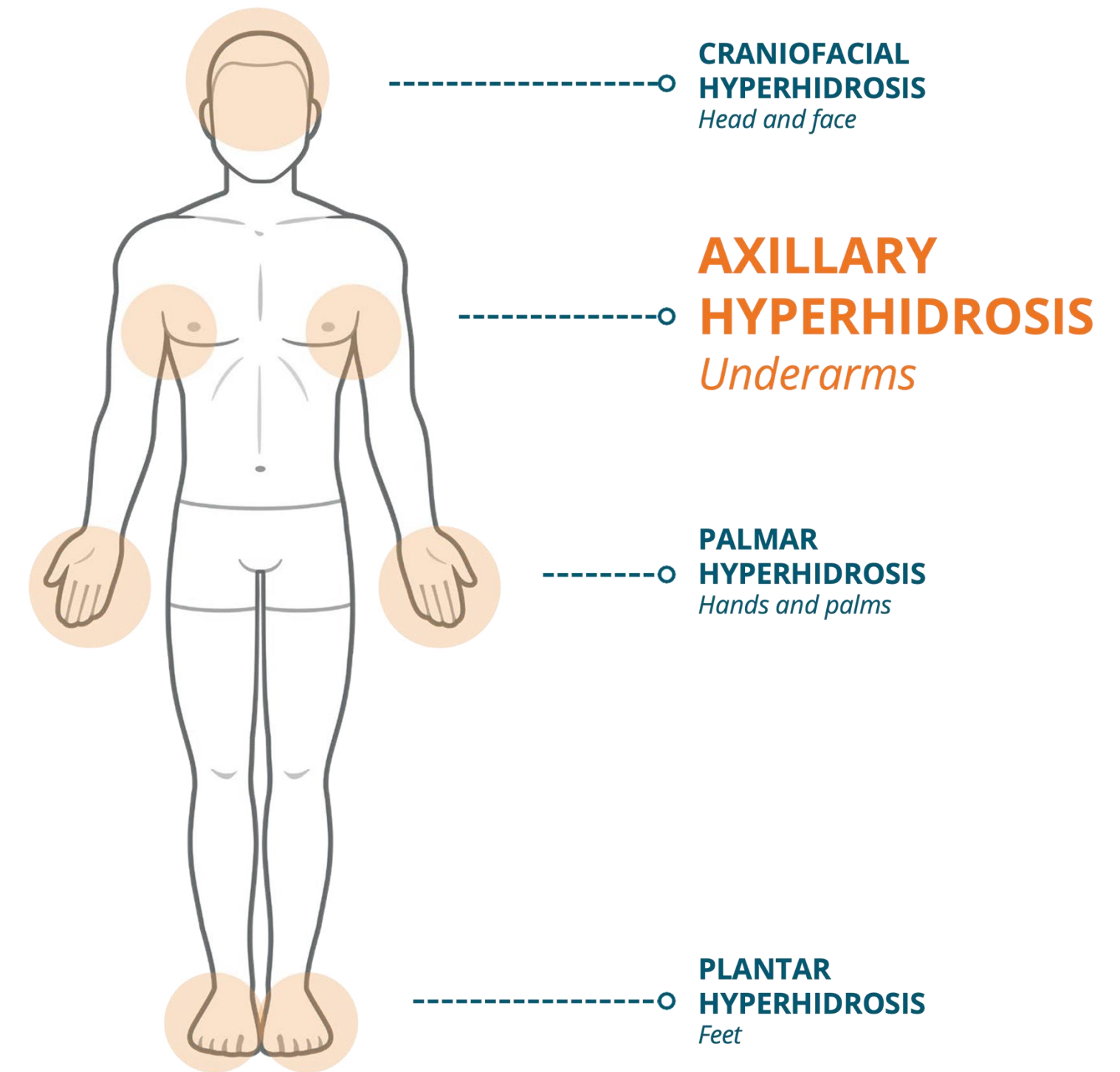
Hyperhidrosis

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

Hyperhidrosis affects ~16M people in the US¹:

- Results from overstimulation of the nervous system (a physiological not psychological condition)¹
- 90% of axillary (underarm) patients also have it in a second region¹
- The most common age of onset for axillary hyperhidrosis patients is 12-17²

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



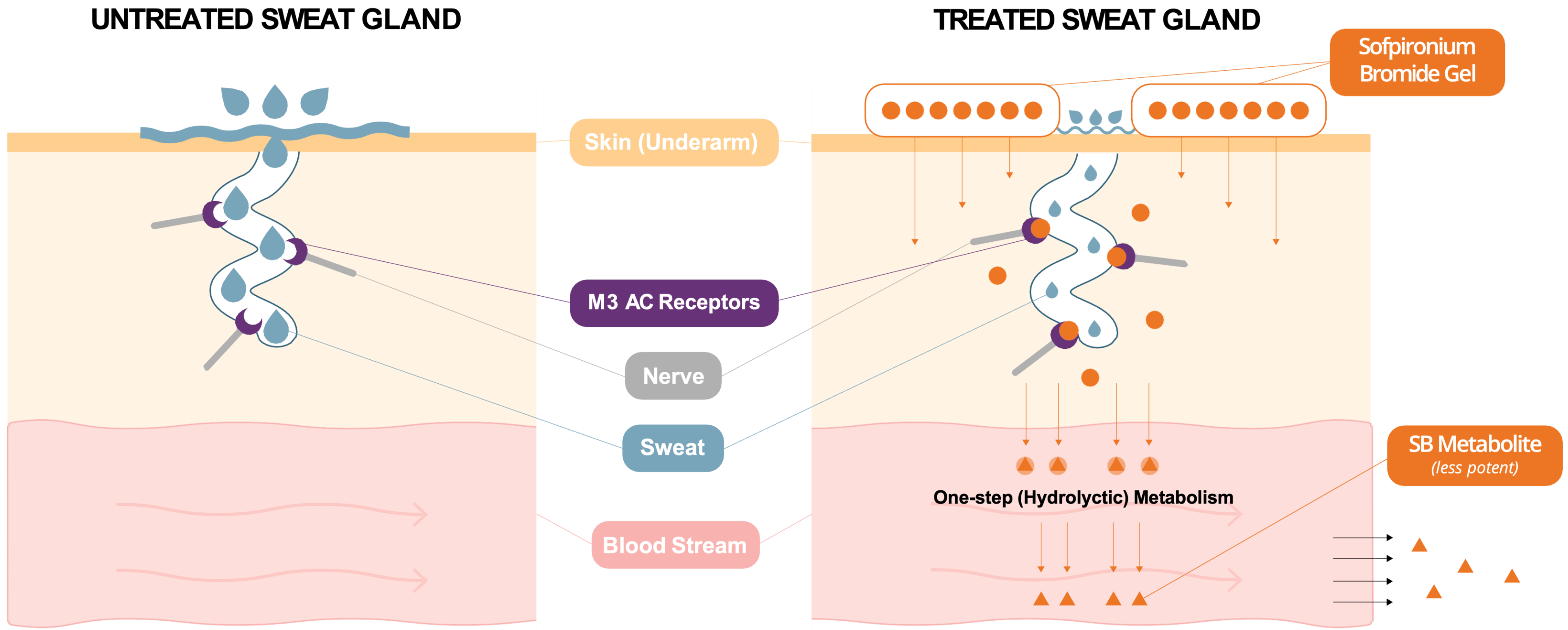
PLACE NAPKINS OR
PADS UNDER THEIR
ARMS OR THEIR
POCKETS



HIDE UNDER
DARK-COLOURED,
BULKY CLOTHES

Sofpironium Bromide mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion

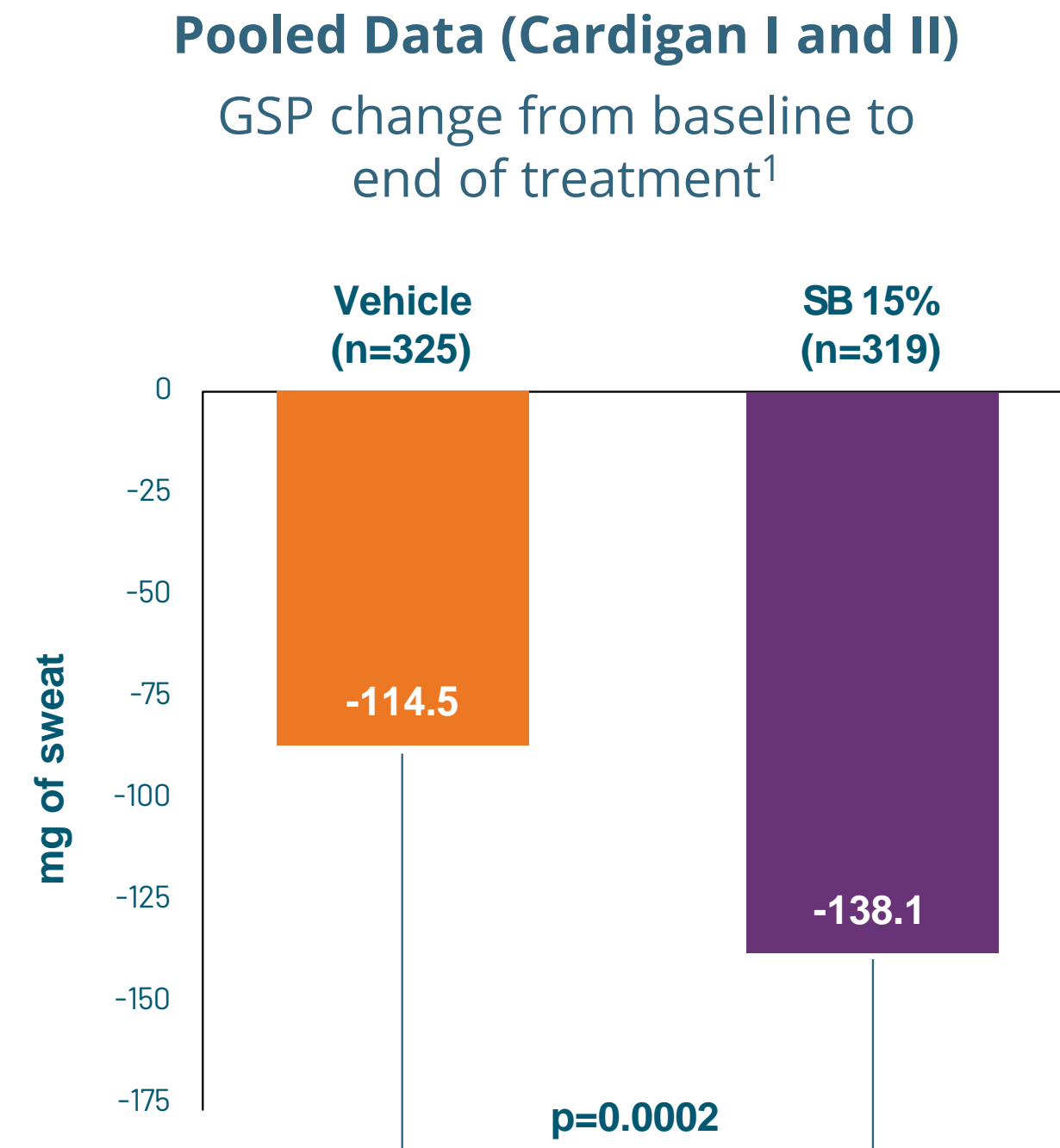
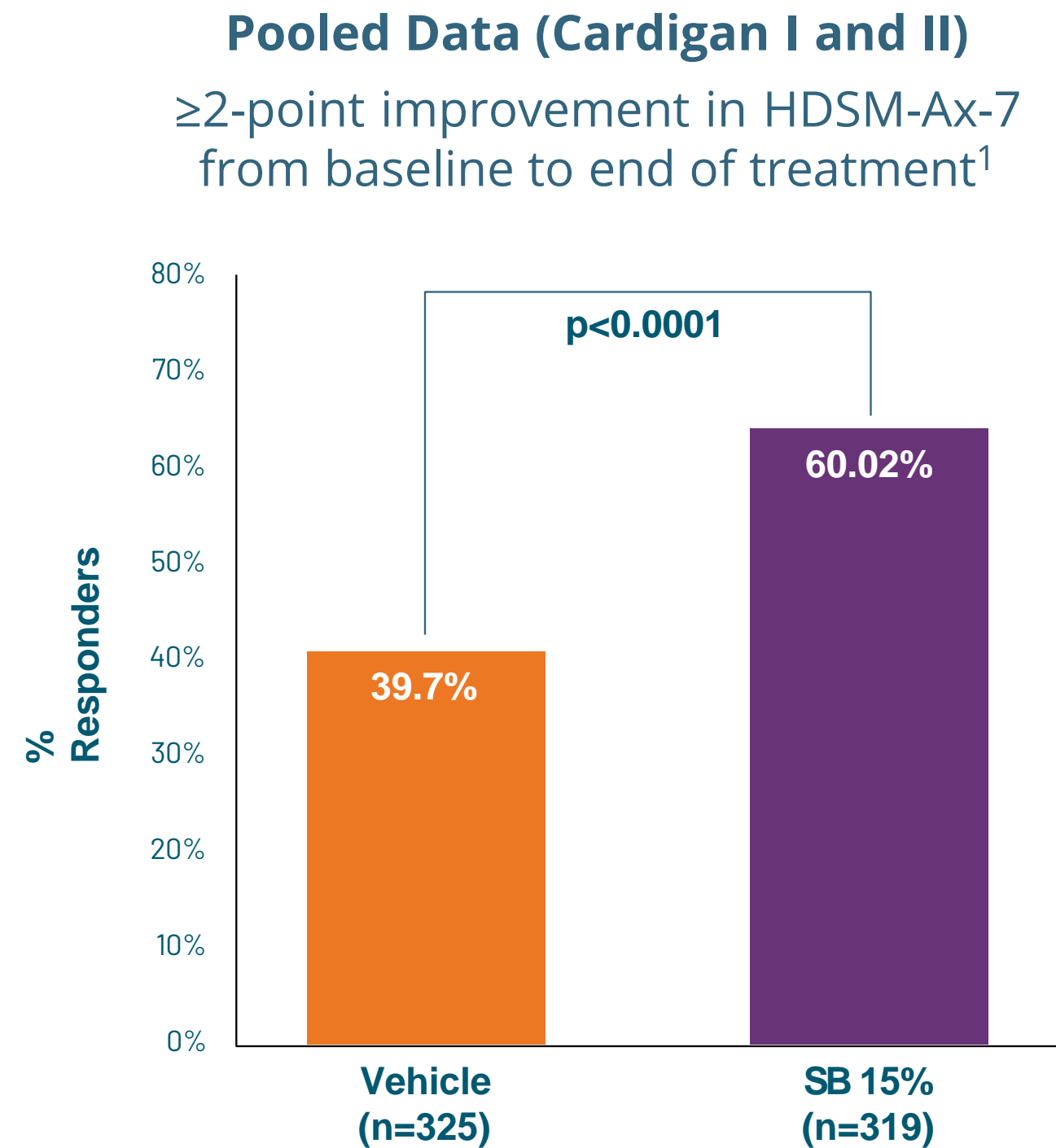


M3 AC Receptors = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

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

Phase 3 co-primary endpoints - highly statistically significant

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



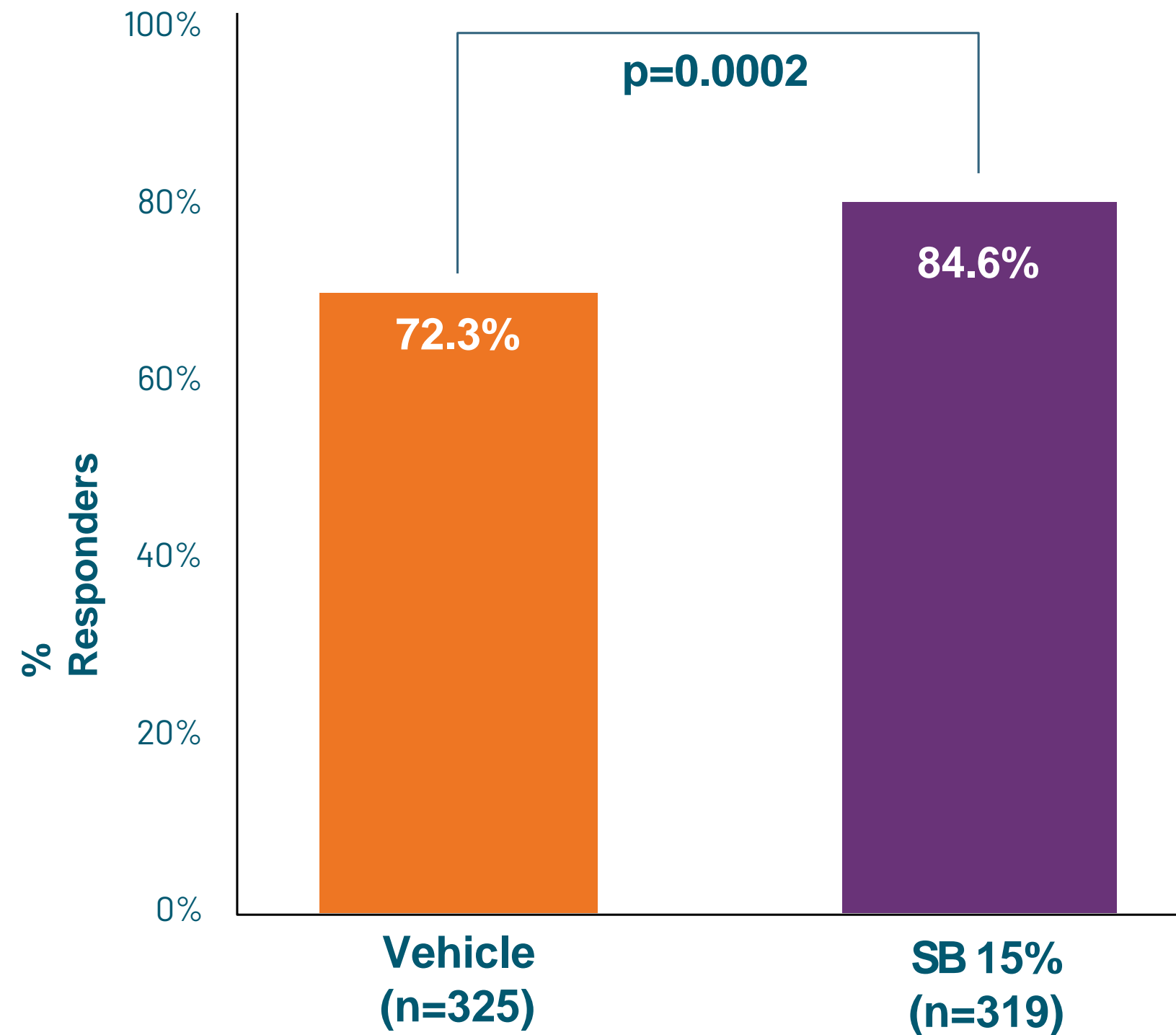
SB = Sofpironium Bromide

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 (≥ 1 -point improvement) from baseline to end of treatment¹



SB = Sofpironium Bromide

Hyperhidrosis treatment continuum

No new chemical entities have been approved for hyperhidrosis

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OTC [ ]

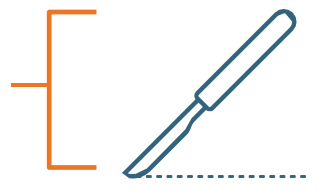
Aluminum Chloride

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Botox injection

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Cutting Nerves



Clinical Strength [ ]

Reformulated oral drug into a solution

[]

Heat energy device

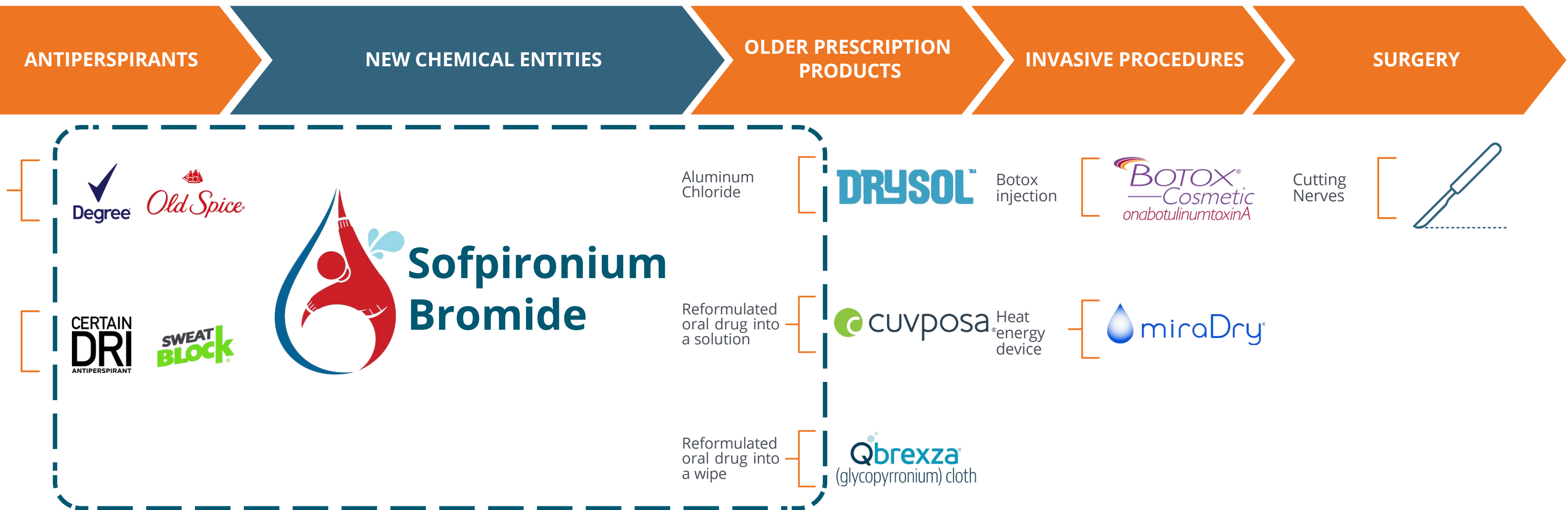
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Reformulated oral drug into a wipe

[]

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

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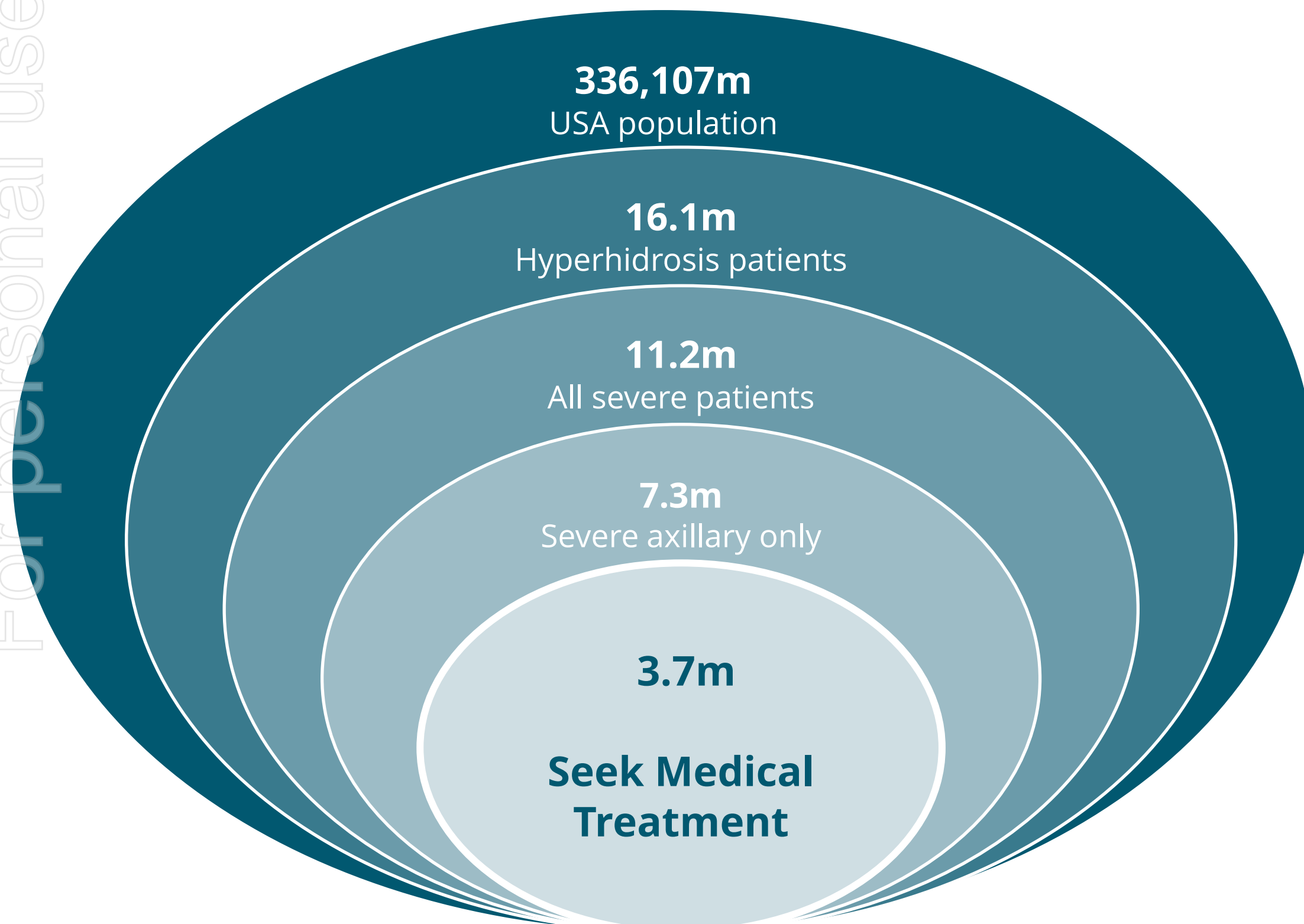


Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would pay anything for a treatment to stop their excessive sweating¹

Market opportunity for hyperhidrosis¹

Even a modest market share provides a significant financial opportunity

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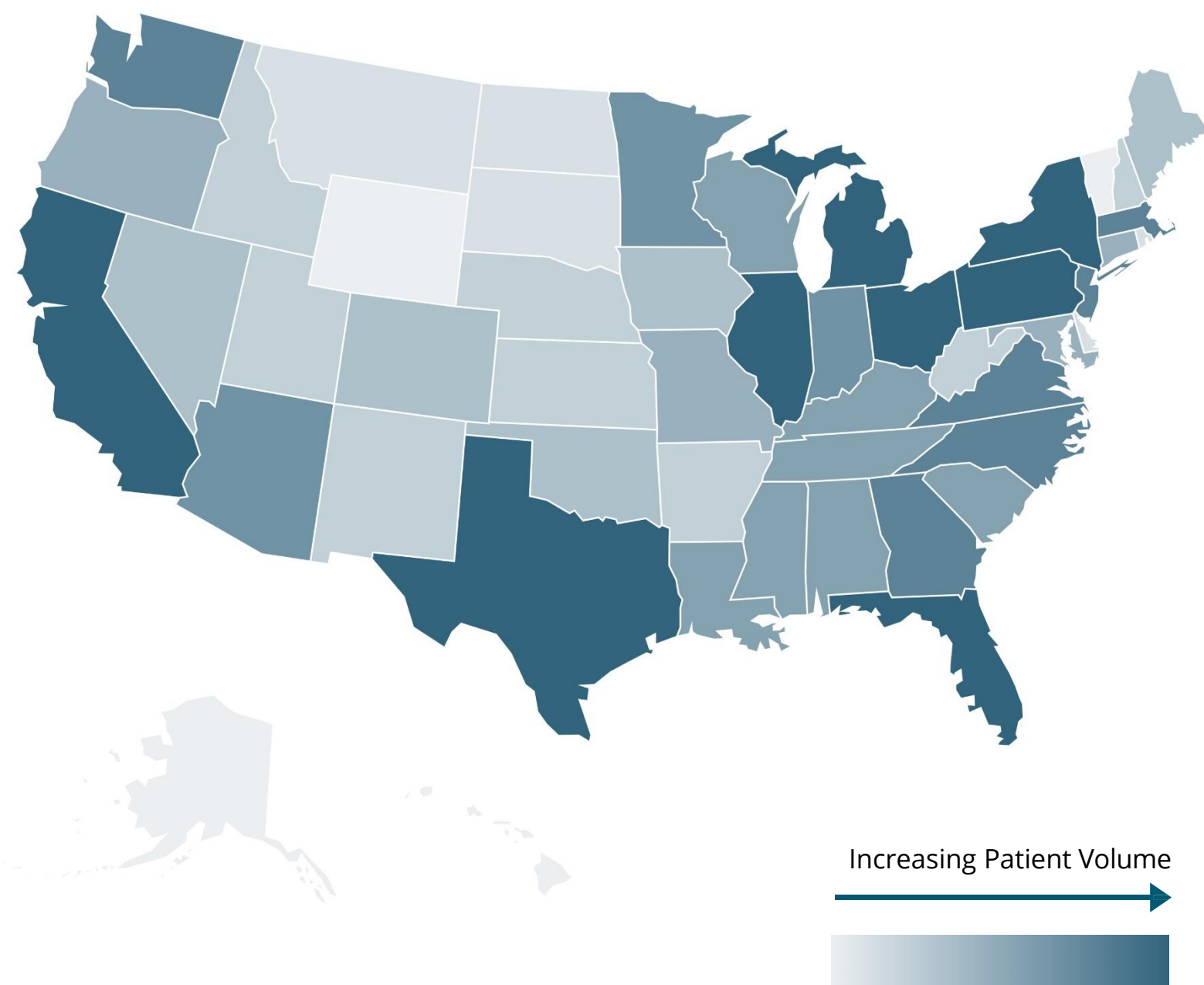


Share of patients already seeking treatment	Patients	Potential gross sales*
0.5%	18,500	\$144,300,000
1.0%	36,700	\$288,600,000
1.5%	55,500	\$432,900,000
2.0%	74,000	\$577,200,000
2.5%	92,500	\$721,500,000
3.0%	111,000	\$865,800,000

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

Focused prescriber base and active patients enables a cost-effective launch

Geographic Spread of Patient Claims
Data for Hyperhidrosis



Efficiently target and extend reach

- The majority of dermatologists can be covered with a very small sales force
- A regionally targeted digital campaign can reach the vast majority of patients
- Patients can be diagnosed online and referred directly to a pharmacy partner for fulfillment
- A closed loop process will maintain continuity of care

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

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Key Upcoming Milestones

Rapid pathway to approval and revenue



1H 2022

3Q 2022

1H 2023

3Q 2023

**Expected
Timing**
(calendar
year)

- NDA submission for approval

- Commercial manufacturing for launch
- Targeted FDA approval

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

- Sale force and market prep
- FDA mid-cycle review

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Pipeline dermatology programs



BTX 1702: Rosacea Phase 1b/2 study fully recruited

Study completion targeted for 3Q 2022



- Papulopustular rosacea is a highly visible chronic skin disease characterised by redness (inflammation) and acne-like-break-outs¹
- Patients diagnosed with Rosacea tend to have higher incidences² of:

- Depression
- Social Anxiety
- Embarrassment
- Decreased quality of life

Study Details

Three dose groups, ~120 patients:

- BTX 1702 high dose - twice daily: 40 patients
- BTX 1702 low dose - twice daily: 40 patients
- Vehicle - twice daily: 40 patients

Sites

~15 dermatology sites across Australia and NZ

Patients

Adults (18+ years) with moderate to severe papulopustular rosacea

Treatment Period

8 weeks

Endpoints

- Safety and tolerability
- Change in inflammatory lesion counts from baseline at days 15, 29 and 57
- Proportion of patients with Investigator's Global Assessment (IGA) treatment success
- Change in Clinician's Erythema Assessment (CEA) scale

BTX 1801: Phase 2 study preparing to launch in 2H 2022

Targeting nasal decolonisation of *Staph aureus* in patients undergoing haemodialysis to reduce incidence of life threatening blood stream infections

Phase 2 study 9-week study preparing to initiate in 2Q 2022

Three dose groups, ~75 subjects:


- BTX 1801 high dose: 25 subjects
- BTX 1801 low dose: 25 subjects
- Vehicle: 25 subjects

Sites: 3-4 Australian sites

Treatment period: 5-day daily treatment followed by every other day for 8 weeks

Endpoints: eradication of *Staph aureus* in the nares of subjects

FDA incentives provide accelerated development and increased market exclusivity

-  **QIDP¹ status** > Extra 5 years (total of 8 years) exclusivity from generic competition
- Fast track status** > Following IND submission, allows increased consultation with FDA and de-risks clinical trials and accelerates development pathway
- LPAD² status** > Allows smaller, fewer and / or shorter clinical trials for FDA approval

Botanix plans to apply for remaining 2 programs to accelerate development, reduce clinical costs and increase exclusivity

1. QIDP: Qualified Infections Disease Product
2. LPAD: Limited Population Pathway for Antimicrobial and Antifungal Drugs

Executing on key commercial and clinical milestones

Calendar year

**Sofpironium
Bromide**

FDA filing for approval in 3Q 2022

**Rosacea
BTX 1702**

Enrolment complete, data 3Q 2022

**Dermatitis
BTX 1204A**

Enrolment complete, data 3Q 2022

**Antimicrobial
BTX 1801**

Phase 2 study preparing to launch 2H 2022

**Acne
BTX 1503**

Study start pending completion of BTX 1702 study

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North Perth W. Australia 6006



Authorised for release by Vince Ippolito, Executive Chairman

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

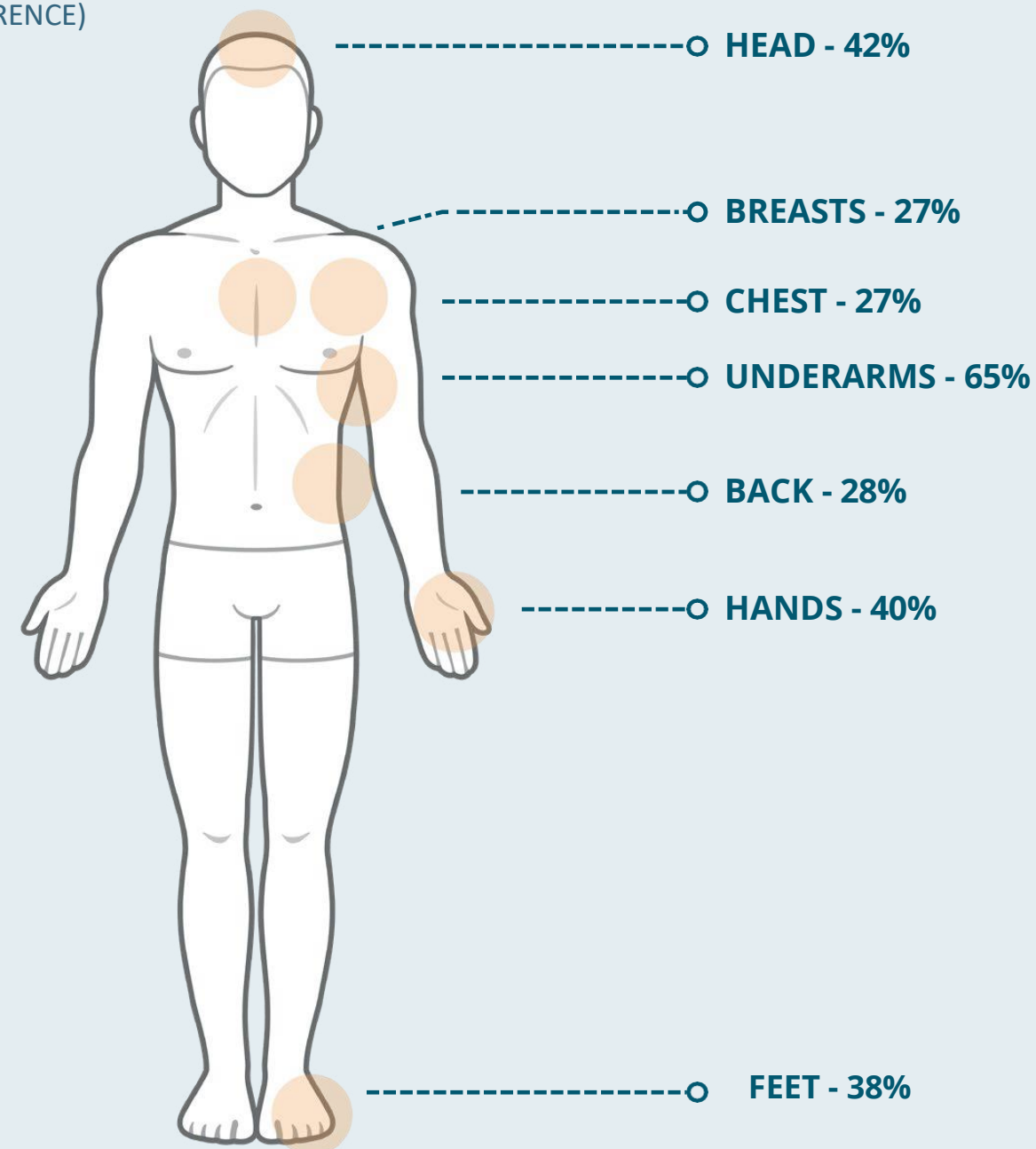
- US provisional utility application filed for the novel applicator system (expires 2039)
- Design application filed in US (and other key jurisdictions) covering the applicator and container system (expiry not before 2034)

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 AREA¹

(% 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