

16 May 2022

## Investor Presentation

### Key highlights

- Release of updated corporate presentation for Botanix's non-deal investor roadshow this week
- The presentation includes recap of the recent acquisition of Sofpironium Bromide, which has positive Phase 3 data and is being prepared for FDA approval filing, in 2H 2022
- Presentation also includes updates on the Company's clinical pipeline with near term catalysts with BTX 1702 rosacea study recruitment nearing completion and the BTX 1204A canine study also nearing completion
- Botanix retains a strong cash position of \$16.4 million at 31 March 2022

**Philadelphia PA and Phoenix USA, 16 May 2022:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to release an updated corporate presentation for its investor roadshow taking place this week with US based leadership.

The presentation includes a recap of the recent acquisition of Sofpironium Bromide, as well as an update on the Company's BTX 1702 Phase 1b/2 rosacea study which is nearing completion of recruitment and the BTX 1204A Phase 1b canine dermatitis study which is also completing enrollment.

The Company's cash position remains strong with \$16.4 million at 31 March 2022. No capital raising is planned as part of this roadshow.

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

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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.

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# Investor Update

May 2022

Transforming into a commercial stage dermatology company



# Botanix: a leader in topical drug development

Clinical stage dermatology company developing new treatments for common skin diseases and infection, leveraging its novel delivery technology Permetrex™



## Pharmaceutical focus

New treatments for common skin diseases - such as 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 by clinical efficacy



## Leaders in cannabinoid drug development

Most advanced pipeline globally for cannabinoids in skin diseases, with positive Phase 2 data and multiple late-stage programs underway



## Sofpironium Bromide

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



## Near-term catalysts

Upcoming NDA filing for Sofpironium Bromide, and data readouts for Phase 1b/2 rosacea study, canine dermatitis study and start of antimicrobial Phase 2 study

# 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

Well funded and positioned to transition to commercial dermatology company

## ASX: BOT TRADING INFORMATION

Share price	A\$0.077
6-month low / high	A\$0.061/0.115
Shares outstanding	973,142,074
<b>Market Capitalisation</b>	<b>A\$74.9m</b>
Cash (31 Mar 2022)	A\$ 16.4m
Debt (31 Mar 2022)	Nil
Enterprise value	A\$58.5m

## SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Matt Callahan, Founder and Executive Director	7.27%
Caperi Pty Ltd, Co-Founder	5.4%

## SHARE PRICE PERFORMANCE



# New acquisition (Sofpironium Bromide) complements existing pipeline

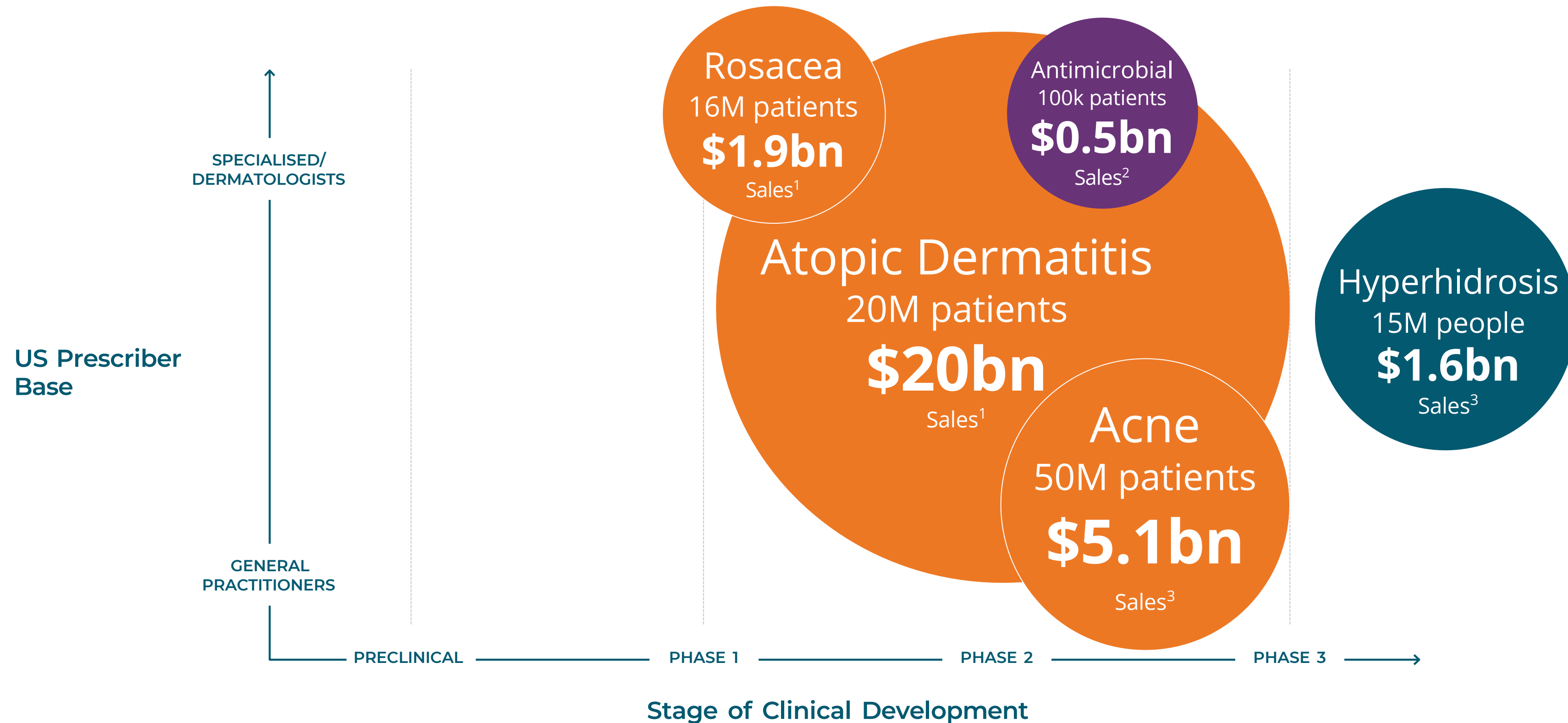
Accelerates revenue generation,  
M&A opportunities and adds  
dermatology indication

INDICATION	PRODUCT	PHASE 1	PHASE 1B	PHASE 2	PHASE 3	APPROVED	STATUS	
Axillary Hyperhidrosis (excessive underarm sweating)	Sofprionium 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**

# Target markets with significant annual revenues and high unmet needs

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1. Grandview Research. [www.Grandview-research.com](http://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 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

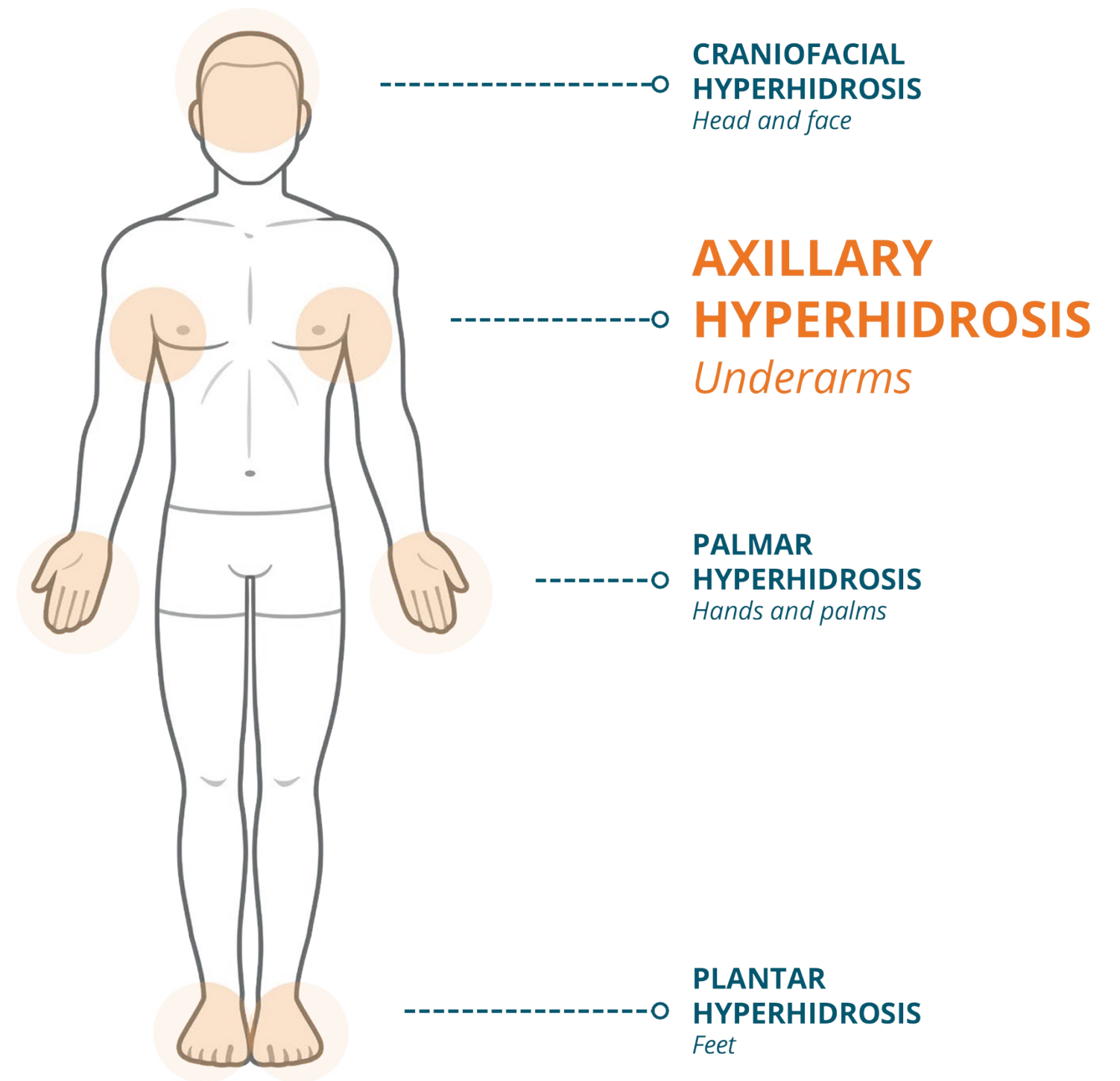
# Hyperhidrosis

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>

Source: 1. Doolittle, J. et al. Arch Dermatol Res, 2016. 2. Hamm H. et al. Dermatology, 2006.



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING



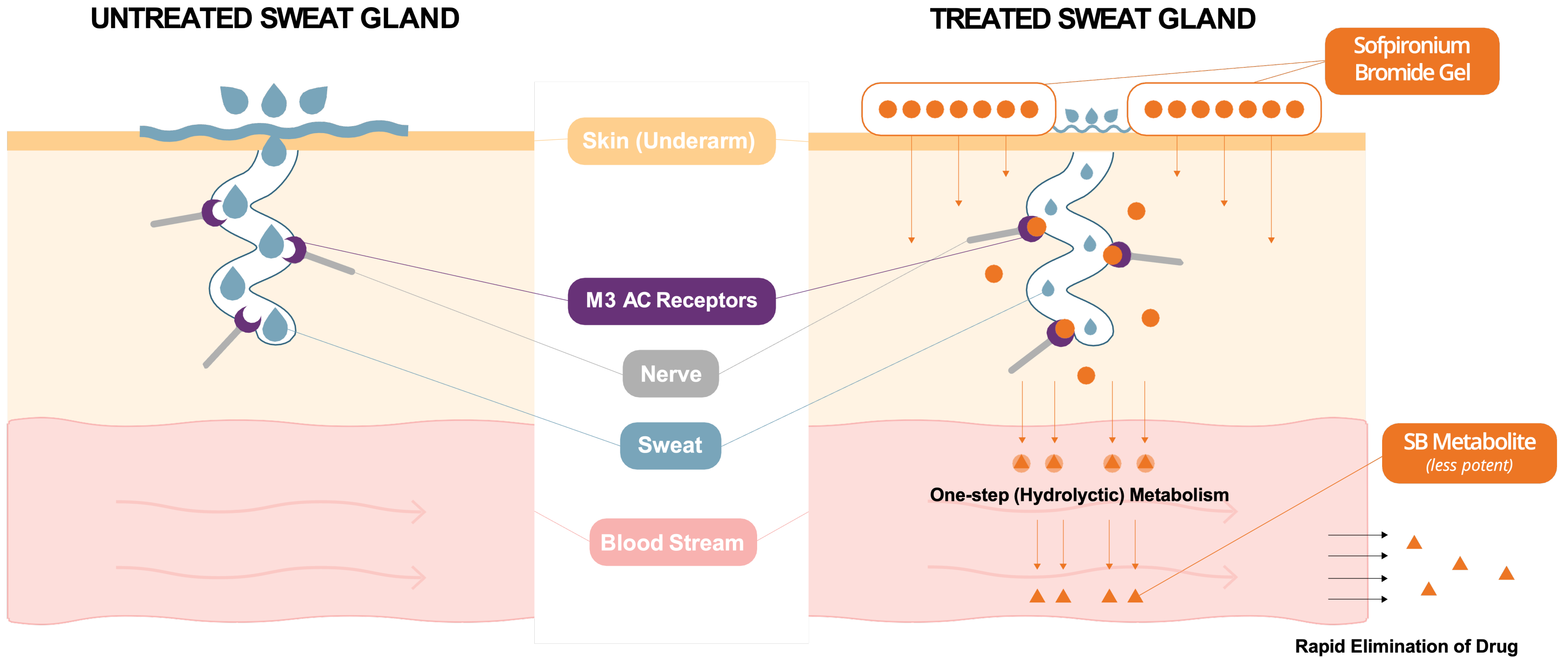
PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS



HIDE UNDER  
DARK-COLOURED,  
BULKY CLOTHES

# Sofpironium Bromide mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion

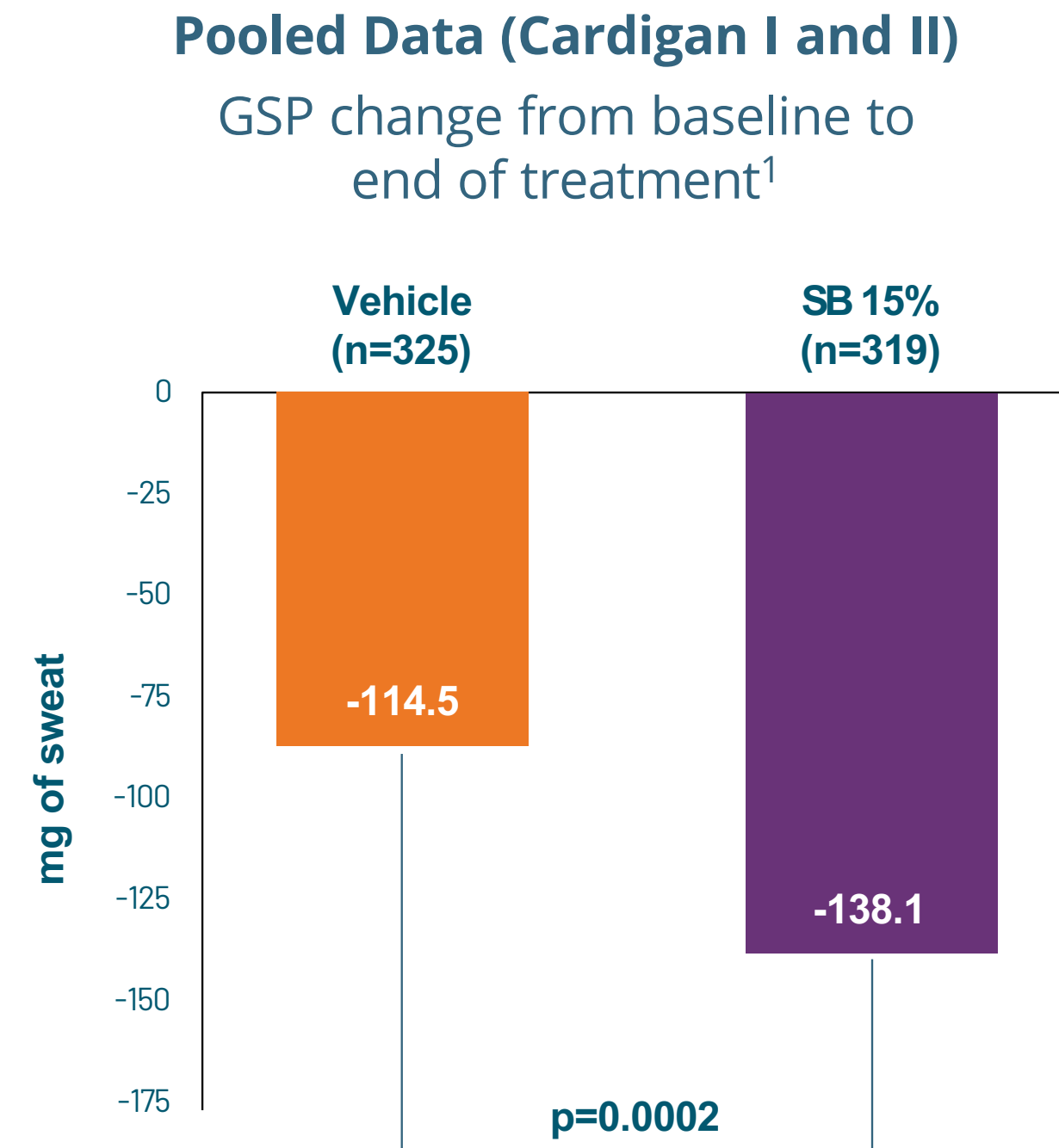
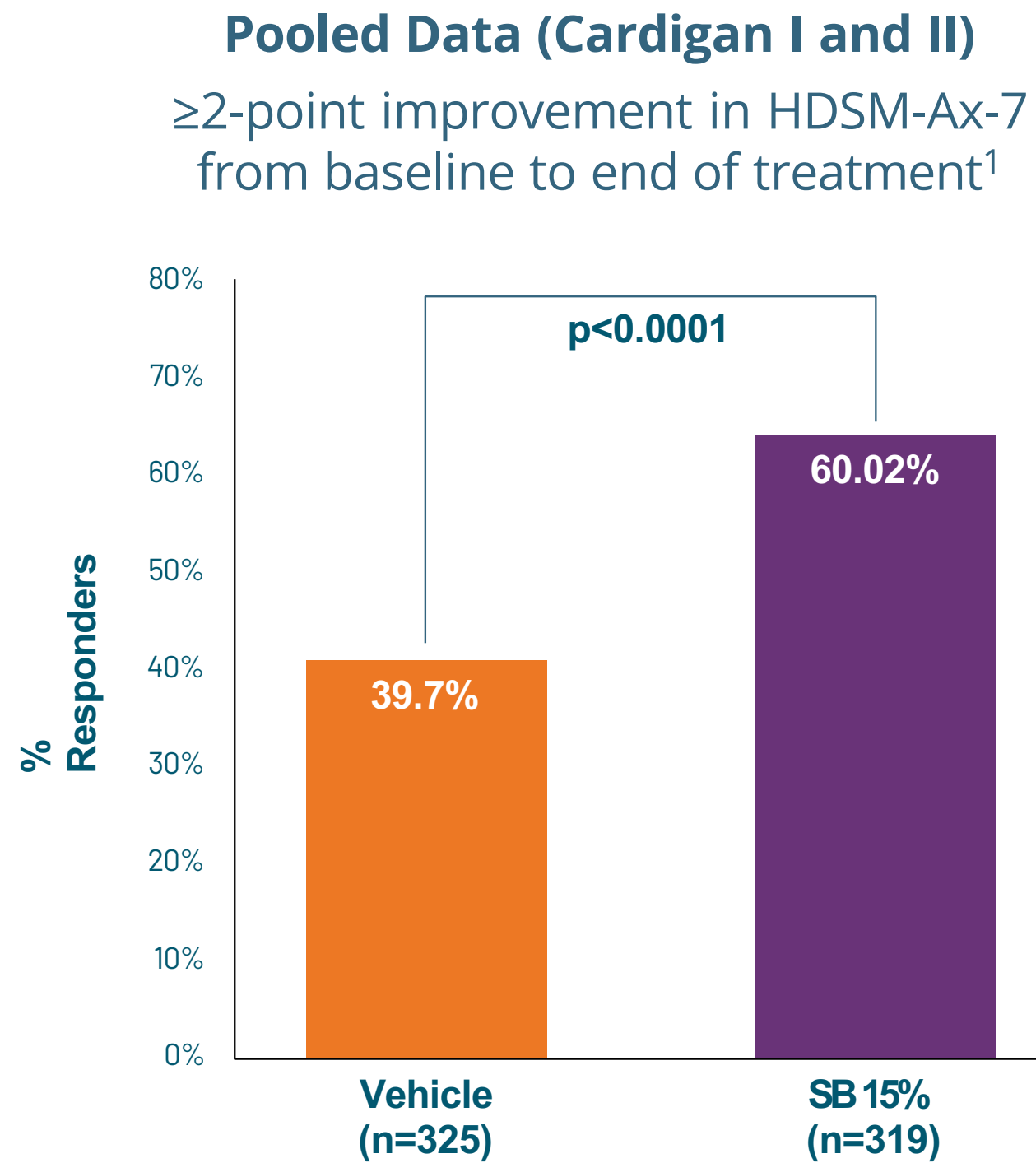


**M3 AC Receptors** = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

**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



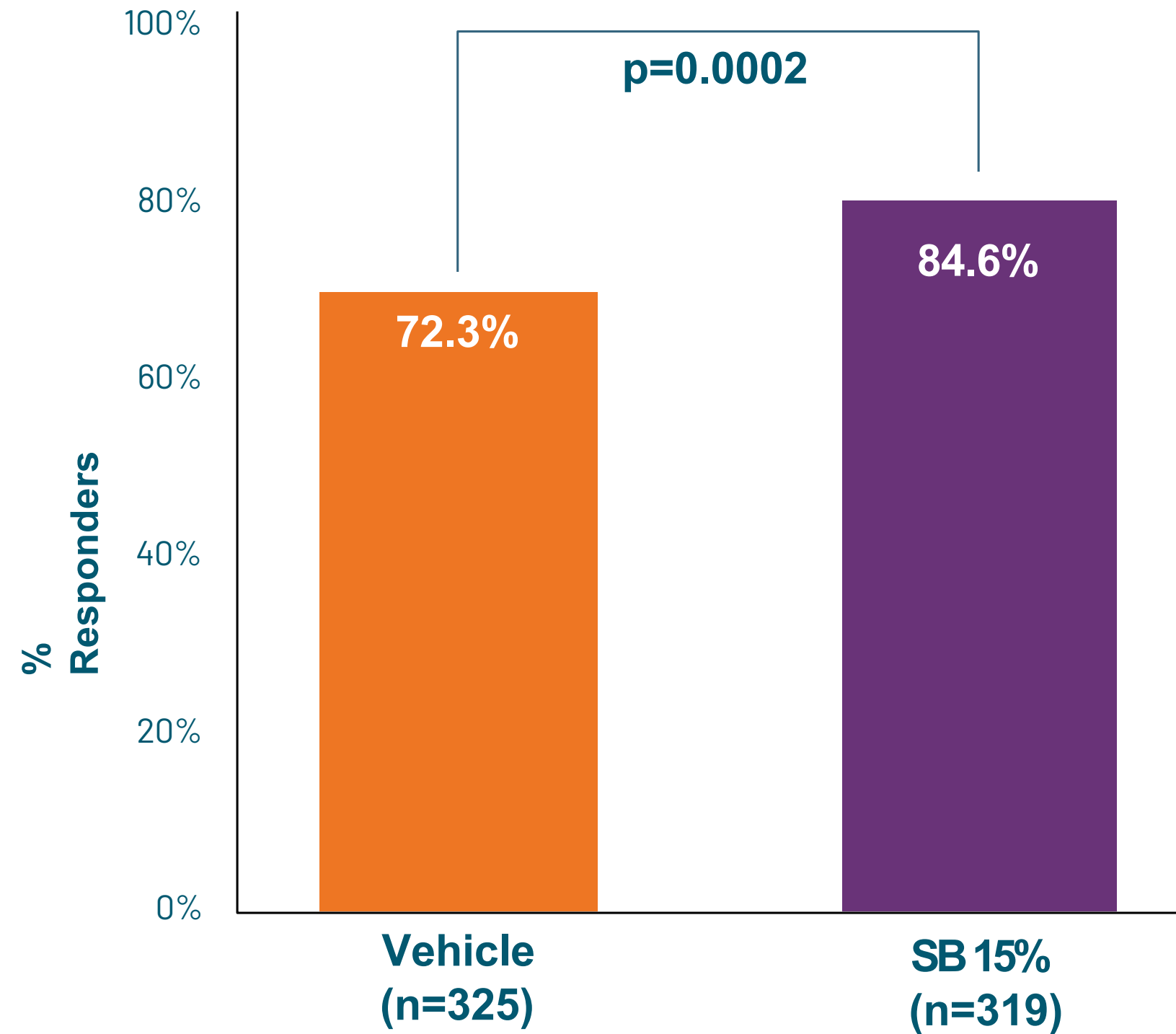
SB = Sofpironium Bromide

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



SB = Solfipronium Bromide

# Hyperhidrosis treatment continuum

No new chemical entities ever approved for hyperhidrosis

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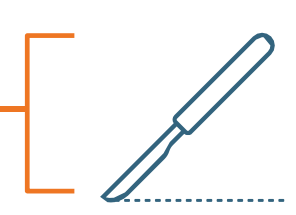
OTC [   ]

Aluminum Chloride

[  Botox injection ]

[  ]

Cutting Nerves



Clinical Strength [   ]

Reformulated oral drug into a solution

[  Heat energy device ]

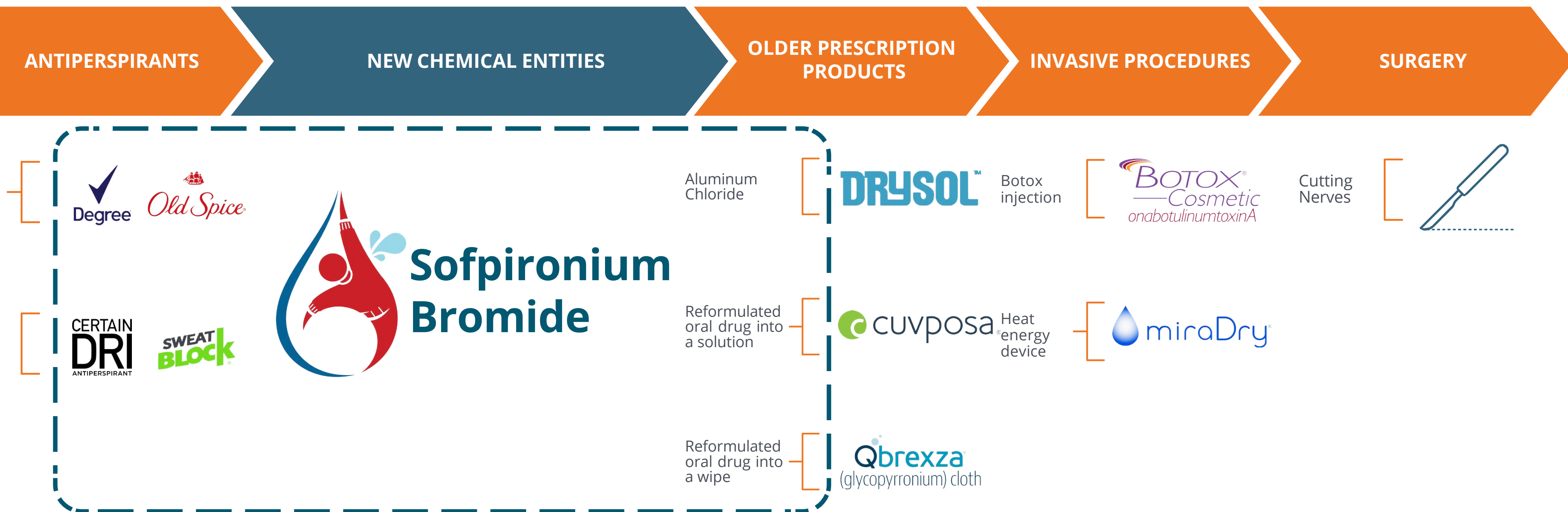
[  ]

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 sweating<sup>1</sup>**

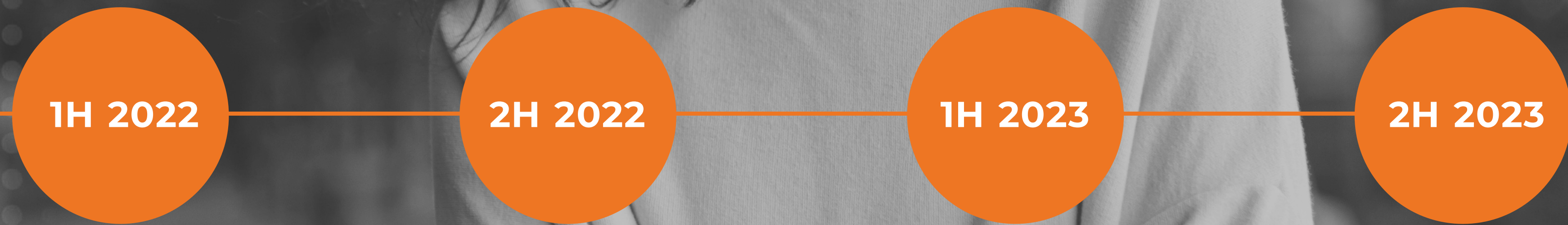
Sources: 1. Doolittle, J. et al. Arch Dermatol Res, 2016.



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# Key Upcoming Milestones

Rapid pathway to approval and revenue



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

- Commercial manufacturing for launch
- FDA approval

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

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

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# Cannabinoid dermatology programs



# Synthetic cannabinoids are well suited to treat skin diseases and infections

## Botanix's studies show that synthetic cannabidiol:<sup>1</sup>

- ✓ is safe and well tolerated
- ✓ has broad anti-inflammatory properties
- ✓ has a strong and consistent impact on skin lesions
- ✓ has antimicrobial properties – kills Staph aureus<sup>2</sup>
- ✓ has potential for widespread use across human and animal health
- ✓ has anti-inflammatory and antimicrobial properties important for dermatology conditions including acne, rosacea and dermatitis

1. See ASX announcement "Antimicrobial Platform Update and Launch of BTX 1801 Study" (13 March 2020) and The Antimicrobial Potential of Cannabidiol, Communications Biology 4, Article number: 7 (2021) Blaskovich, M et al  
2. Staphylococcus aureus (S. Aureus) is a common bacterium that lives on skin & nasal passages.. It can cause skin infection & serious or life-threatening infection.



# BTX 1702: high impact of rosacea on patients and significant market opportunity

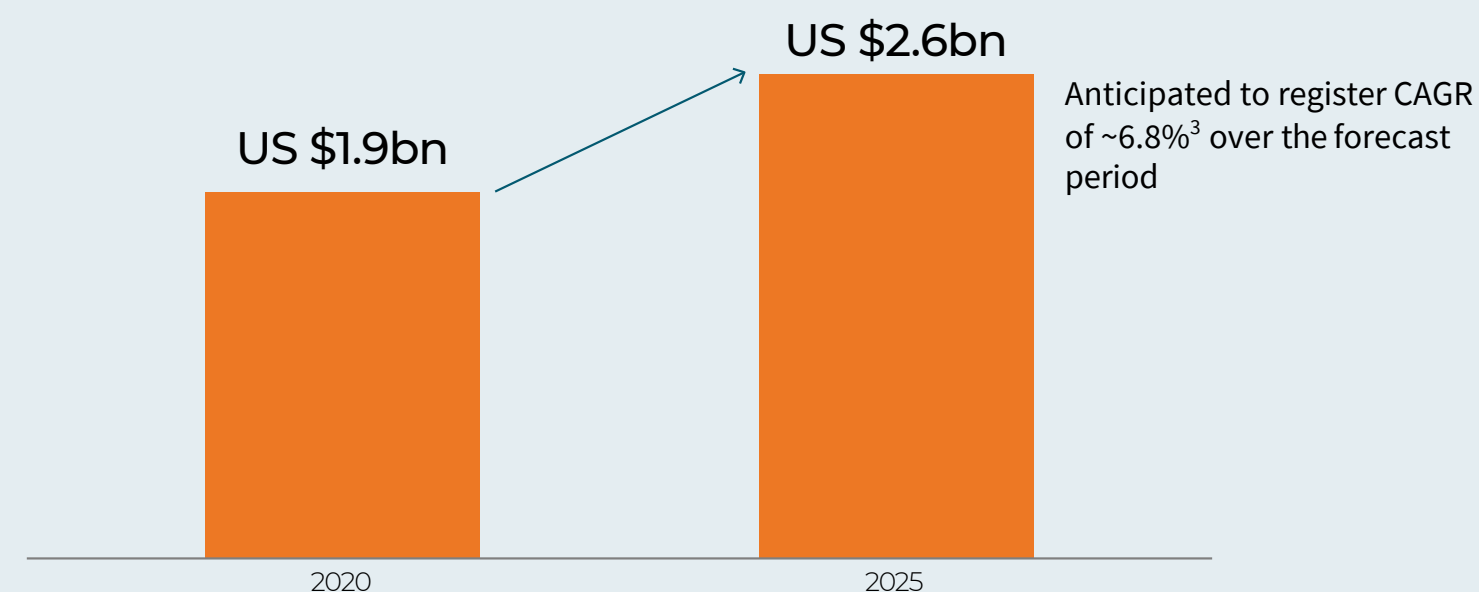
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- Papulopustular rosacea is a highly visible chronic skin disease characterised by redness (inflammation) and acne-like-break-outs<sup>1</sup>
- Patients diagnosed with Rosacea tend to have higher incidences<sup>2</sup> of:

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

## A rapidly growing market: Rosacea market projected to grow to US\$2.6bn by 2025<sup>3</sup>



- Affects ~5.5% of the global population<sup>4</sup>, ~430m individuals, women are more likely to be affected than men
- 85% of patients are > 30 years old<sup>5</sup>
- Currently over 16m Americans affected<sup>6</sup> by rosacea, with ~5m medical treatment prescriptions<sup>7</sup> in the US alone
- Active treatment seekers looking for new solution to rosacea

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

Improved data capture design with dose ranging over 8 week treatment period



- Study designed to enable increased data capture and provide insights to support broader dermatology program
- All sites using Canfield imaging technology supporting clinical assessment, tracking and analysis

## 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 1204A: Atopic dermatitis

Canine study, will inform licensing in animal health and potential launch of late-stage Phase 2b human clinical program

## PROOF OF CONCEPT CANINE STUDY

### Three dose groups, ~36 dogs:

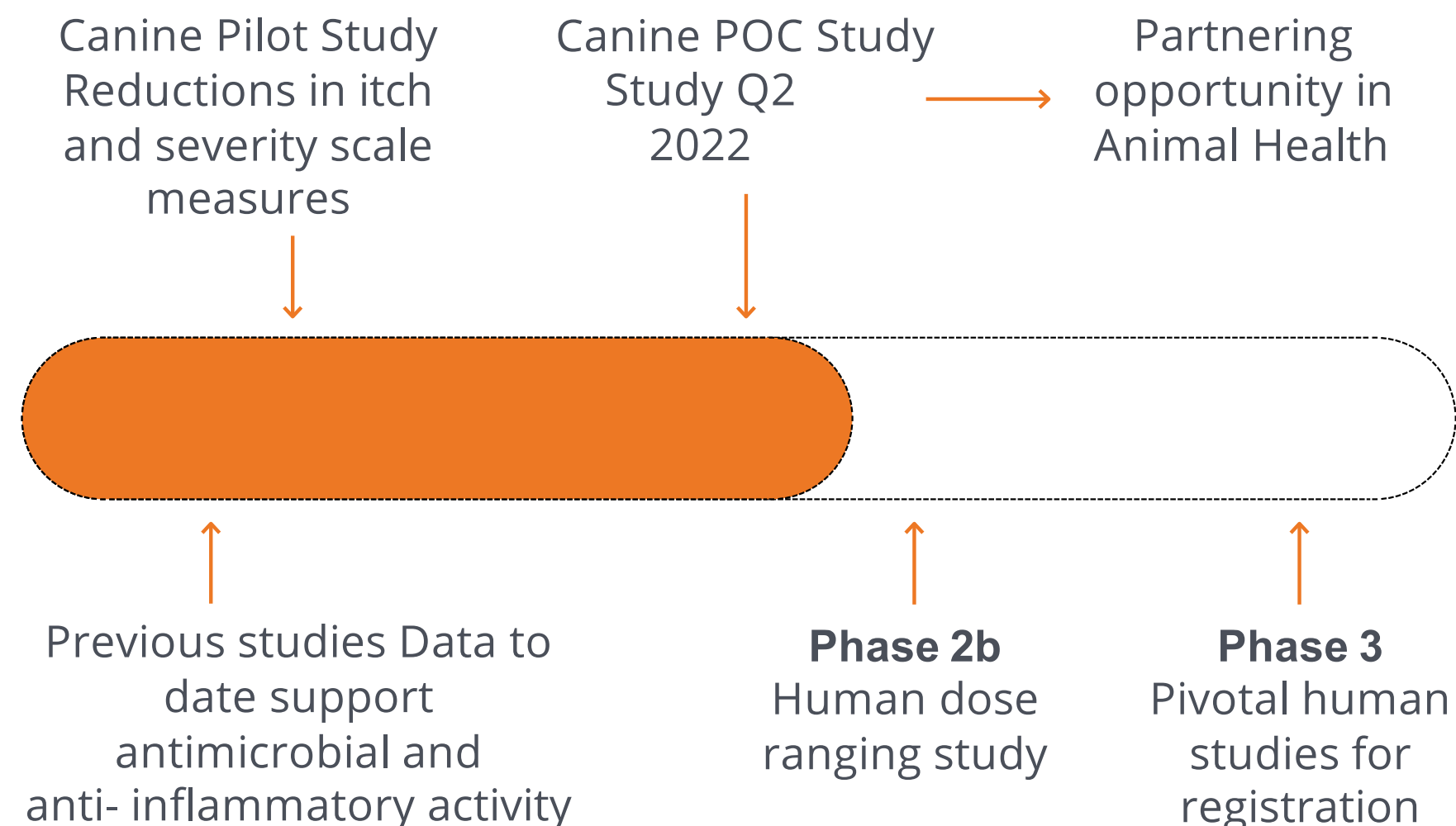
- BTX 1204A high dose: 12 dogs
- BTX 1204A low dose: 12 dogs
- Vehicle: 12 dogs

**Sites:** 3 Australian sites

**Treatment period:** Twice daily treatment for 28 days

**Endpoints:** Treatment effectiveness using Enhanced Pruritus Score<sup>2</sup>; Canine Atopic Dermatitis Extent and Severity Scale Index<sup>3</sup>

## PLANNED PATHWAY TO APPROVAL



**Successful outcome opens up partnering opportunity and supports progression to Phase 2b human study in atopic dermatitis.**

1. ASX 29 Sep 2021: Launch of canine atopic dermatitis program  
2. Enhanced Pruritus Score (EPS): designed to measure the severity of itching in dogs  
3. Canine Atopic Dermatitis Extent and Severity Index (CADESI-04): simplified scale for assessing skin lesions of atopic dermatitis in dogs

# BTX 1503: Acne in preparation for Phase 3 and future filing

Successful End-of-Phase 2 FDA meeting and completion of rosacea BTX 1702 study will inform final design for Phase 3 acne study

## DEVELOPMENT UPDATE

- ✓ End of Phase 2 meeting with FDA successfully completed, supported by overall efficacy and safety, and significance of Australian data on further analysis<sup>1</sup> in 2020 of late 2019 Phase 2 study data<sup>2</sup>.
- ✓ FDA highlighted excellent safety profile of BTX 1503, allowing several waivers for studies typically required for dermatology drug registration
- ✓ Co-primary efficacy endpoints<sup>3</sup> agreed for Phase 3
- ✓ Important milestone providing clarification on activity to move forward
- ✓ Confirmed drug development plan to support filing and registration for treatment of moderate and severe acne

Planning underway for Phase 3 clinical studies to be informed by completion of BTX 1702 Phase 1b/2 study

## SIZEABLE ACNE PRESCRIPTION MARKET



**22m** total prescriptions in 2019 growing ~5% year-on-year<sup>4</sup>



**US\$5.1bn** in sales in 2019<sup>4</sup>



**>2m** p.a. active, diagnosed acne patients under HCP care<sup>5</sup>



**~40m to ~50m** acne sufferers<sup>6</sup> (~10m mod-to-severe)



**60%** of acne patients are managed by 5,000 HCPs<sup>7</sup>

1. ASX 4 Mar 2020, Additional BTX 1503 data analysis 2. ASX 22 Oct 2019 BTX 1503 data and progression to Phase 3 3. Co-primary efficacy endpoints: (1) Absolute change from baseline in inflammatory and absolute change from baseline in non-inflammatory lesion at Week 12; (2) Proportion of patients with an Investigators Global Assessment (IGA) of "clear" or "almost clear" and at least a 2-grade improvement in IGA from baseline at Week 12

4. Symphony Health Solutions, METYS, data ending December 2019 – weighted; 5. Symphony Health Solutions, MAT, ending April 2019; 6. AAD. Acne Stats and Facts. <https://www.aad.org/media/stats-numbers>; 7. Symphony Health Solutions, IDV Vantage, February 2019 HCPs: Healthcare Professionals

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# Cannabinoid antimicrobial programs





# BTX 1801: demonstrated clinical efficacy vs *Staph aureus* in Phase 2a study

Staphylococcus aureus (*Staph aureus* or 'staph') is a common bacterium that lives on skin and in nasal passages. It can cause skin infection and serious or life-threatening blood stream infections, pneumonia or bone and joint infections



## EFFICACY

- ✓ Efficacy of ointment and gel formulations demonstrated for primary endpoint at Day 12<sup>1</sup>
- ✓ Eradication rates as high as 76.2% at Day 7, with eradication effects extending through to Day 28, despite no treatment after Day 5



## SAFETY & TOLERABILITY

- ✓ Safe and generally well tolerated at doses of active drug up to 20%
- ✓ All 66 participants successfully completed the BTX 1801 study
- ✓ No severe adverse events reported<sup>2</sup>

1. BTX 1801 Phase 2a Clinical Study - BOT data on file  
2. The incidence of adverse events was low, mild in severity and occurred at similar rates across the different treatment groups with no severe events reported

# BTX 1801: Haemodialysis patients with central venous catheters at risk of bloodstream infections

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## Haemodialysis

Replicates the functions of the kidneys in patients with kidney failure, by using a machine to filter and clean the blood



## Rationale for selection

Infection is a leading cause of death with 20% to 40% of haemodialysis patients eventually dying from an infection<sup>1</sup>



## Significant health risks

Risks for central venous catheter-related complications were as high as 30% and 38%, at 1 and 2 years respectively<sup>2</sup>

Central venous catheter patients (approx. 160,000) make up more than 70% of blood infections in the dialysis population<sup>2</sup>

**11.8%**

of patients were re-admitted within 12 weeks of hospitalisation related to Staph aureus infections<sup>1</sup>

**US\$734M**

Market for nasal decolonisation of haemodialysis patients at risk of blood stream infection by 2030<sup>3</sup>

**~US\$32k**

Mean cost (per episode) of treating Staph aureus blood stream infections, including re-admissions and outpatient costs<sup>1</sup>

**US\$1bn**

Estimated annual cost of treating bacteraemia in haemodialysis patients with central venous catheters<sup>2</sup>

1. 'Mortality in dialysis patients: analysis of the causes of death', Mailloux LU, Bellucci AG, Wilkes BM, Napolitano B, Mossey RT, Lesser M, Bluestone PA. AJKD. 1991 Sep;18(3):326-35  
2. 'Complications From Tunneled Hemodialysis Catheters: A Canadian Observational Cohort Study', (2019) Poinen, K. et al AJKD Volume 73 Issue 4 Pages 467-475

# BTX 1801: Phase 2 study preparing to launch in 2Q 2022

Targeting nasal decolonisation of Staph 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 Australian sites

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

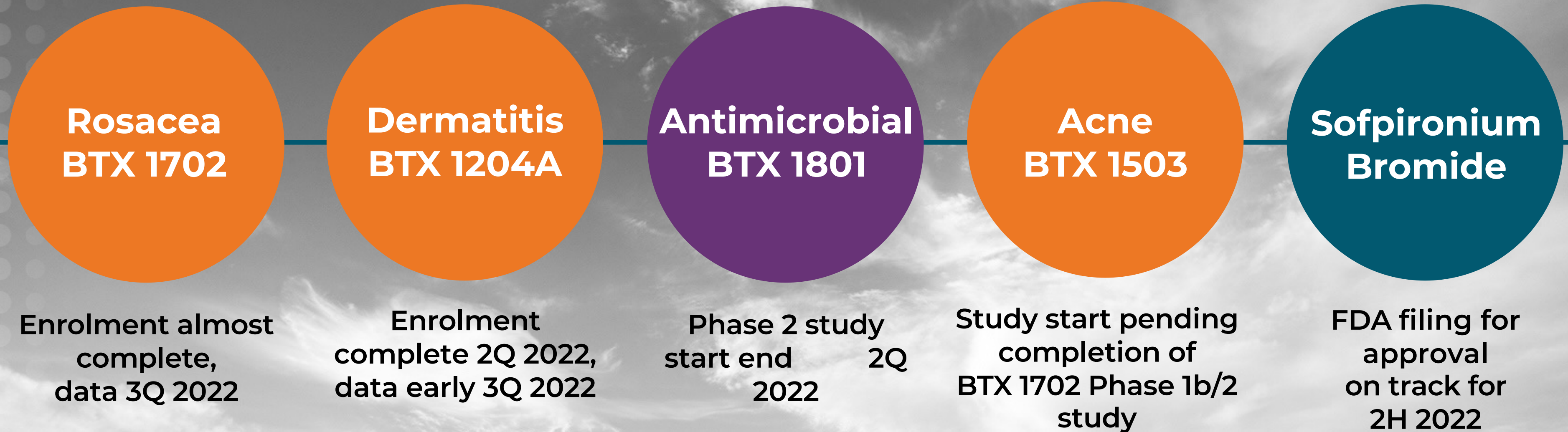
**Endpoints:** eradication of Staph aureus in the nares of subjects

## FDA incentives provide accelerated development and increased market exclusivity

- |                            |   |   |
|----------------------------|---|---|
| ✓ QIDP <sup>1</sup> 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 |
| LPAD <sup>2</sup> status   | > | Allows smaller, fewer and / or shorter clinical trials for FDA approval   |

Botanix plans to apply for all three programs to accelerate development, reduce clinical costs and increase exclusivity

# Executing on key commercial and clinical milestones



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