

# AGM Presentation

November 2023

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# Botanix – Accelerating towards commercialization of SOFDRA™

## DERMATOLOGY FOCUS

New treatments for underserved common skin diseases, with a first focus on excessive sweating (“primary axillary hyperhidrosis”)

## 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 successful development and commercial launches of more than 30 dermatology drugs

## NEW PRODUCT “SOFDRA”

SOFDRA is the first and only new chemical entity for primary axillary hyperhidrosis (5% product already approved in Japan with solid sales)<sup>1</sup>

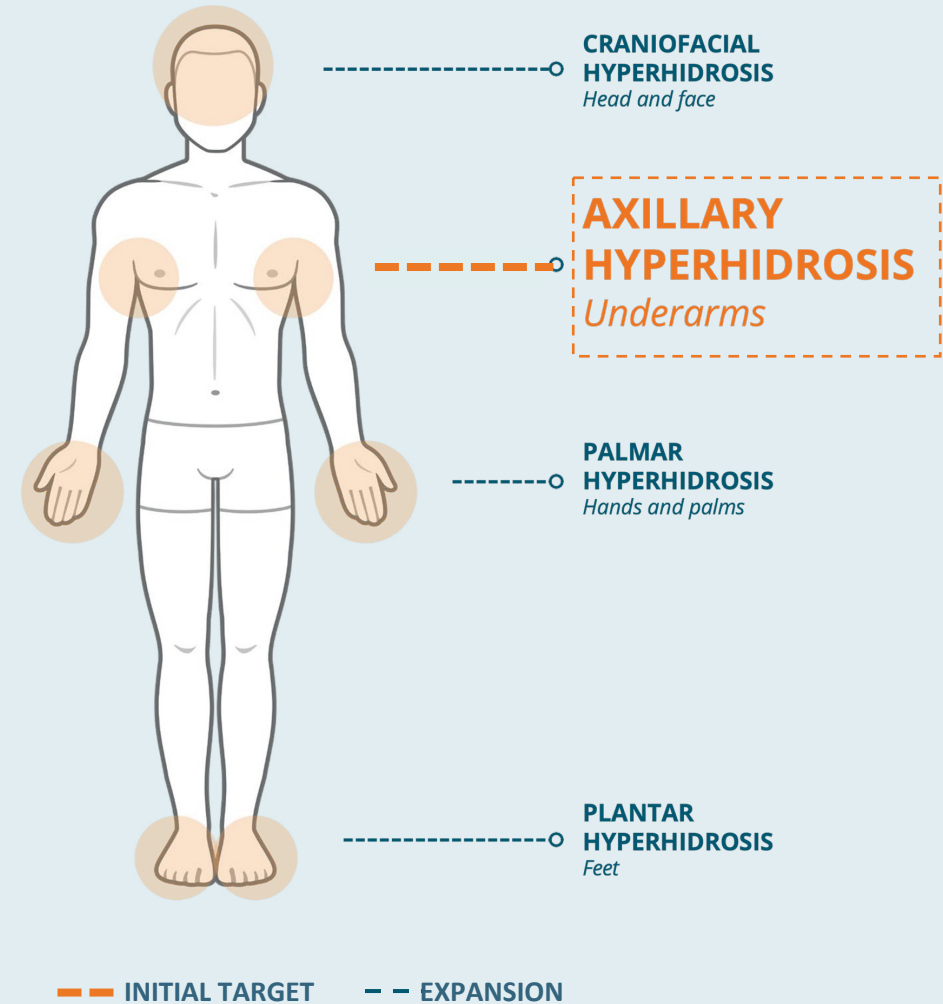
## TARGETING MID-24 FDA APPROVAL

Submission of final component required for approval (the ‘Instructions for Use’) on target for Q1 CY2024, targeting FDA approval in mid-CY2024

# 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<sup>2</sup>**



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING



PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS

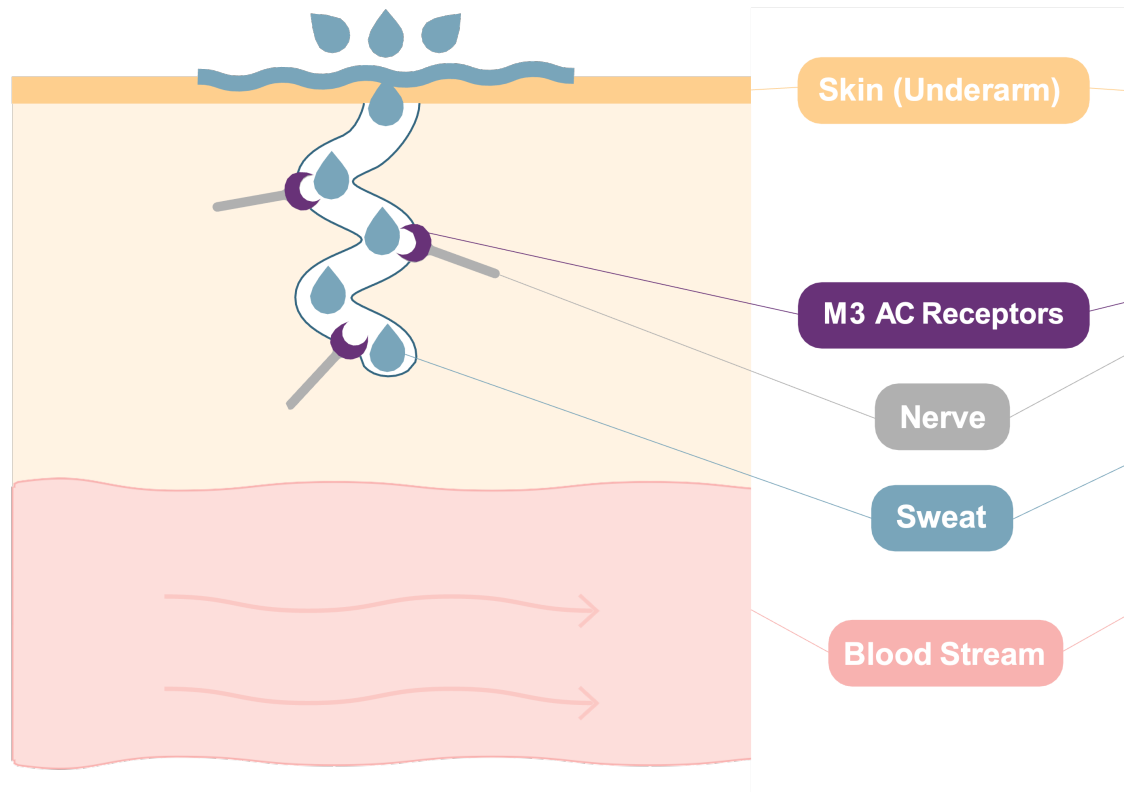


HIDE UNDER  
DARK-COLOURED,  
BULKY CLOTHES

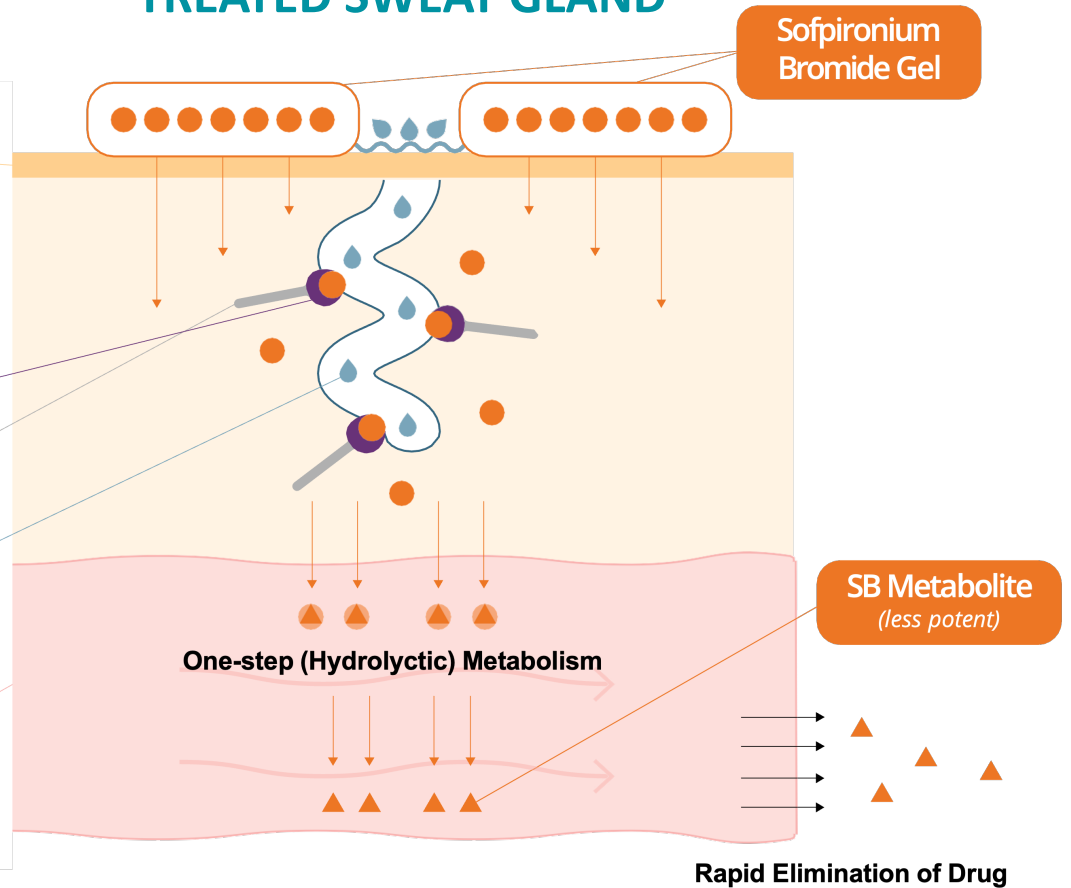
# Sofdra™ mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion

## UNTREATED SWEAT GLAND



## TREATED SWEAT GLAND



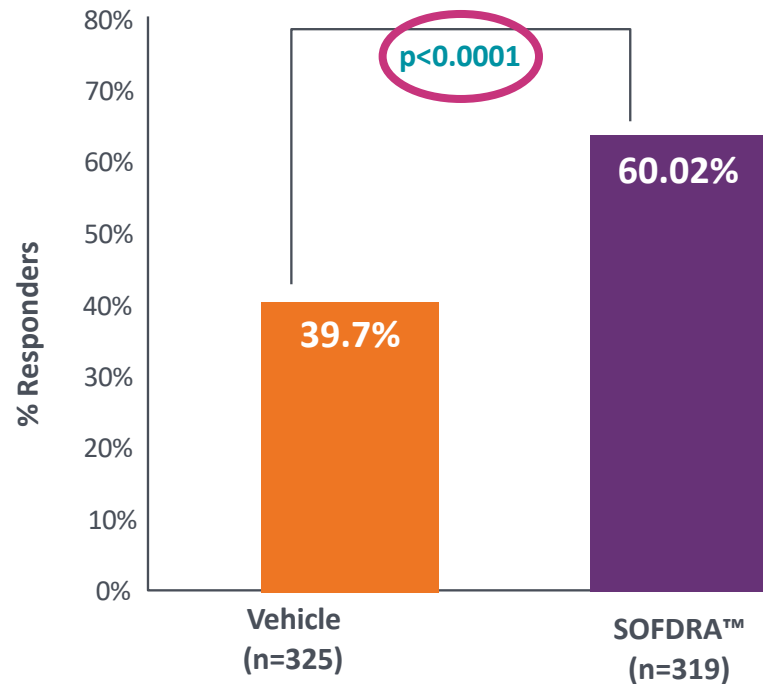
**M3 AC Receptors** = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

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

# 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>

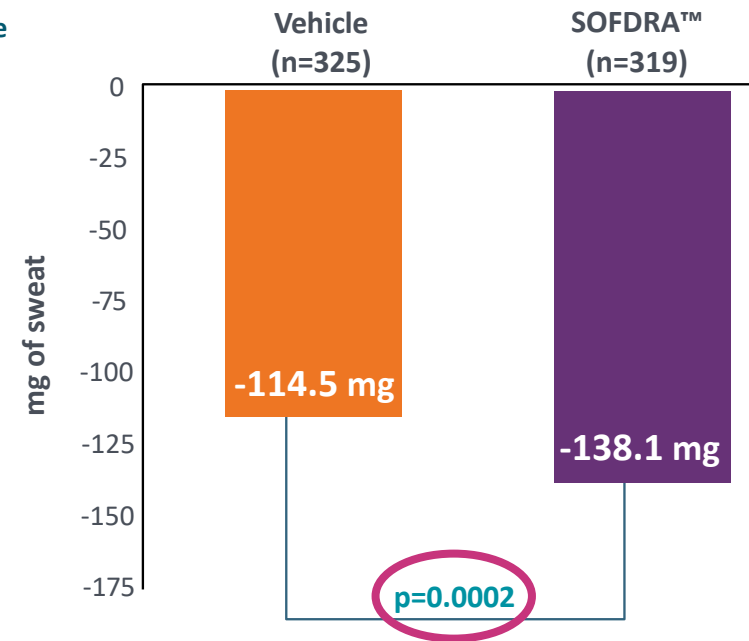


SB = Sofpironium Bromide

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>



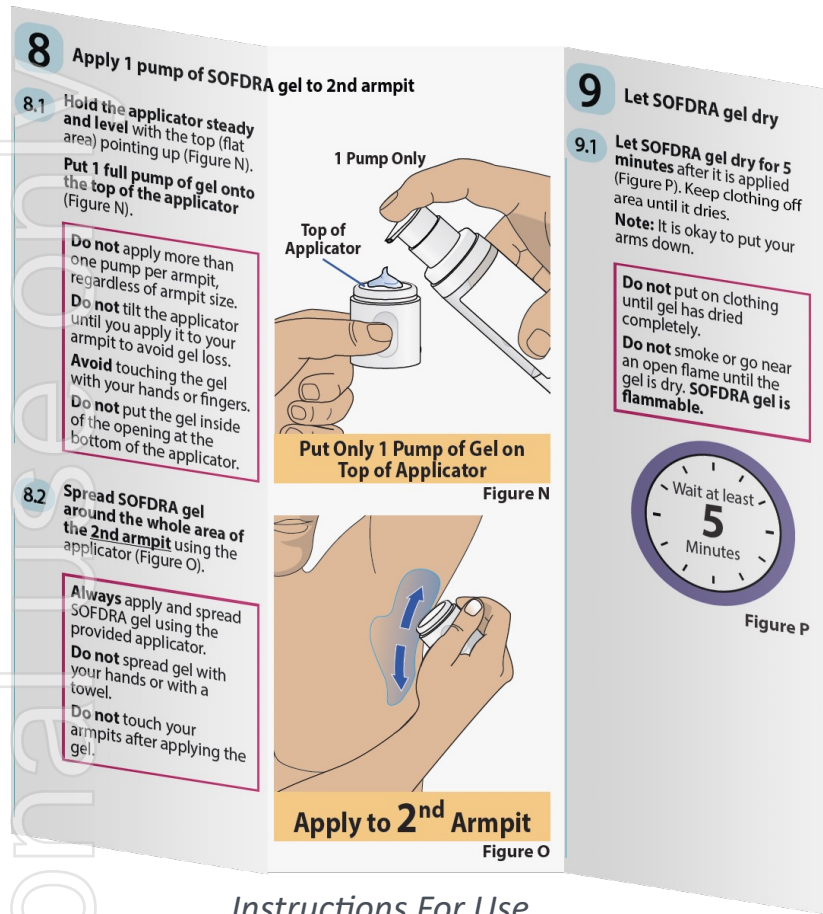
GSP (Gravimetric Sweat Production) is an objective measurement of underarm sweat production (mg/ 5 min)

# FDA Communication

Efficacy, safety and manufacturing all acceptable, one issue to address - patient use instructions

- ❖ The only area identified by FDA was related to the patient *Instructions for Use*
- ❖ No efficacy, safety, or manufacturing issues were raised, and no additional clinical studies are required by FDA to support NDA approval
- ❖ No new review issues are anticipated as part of the resubmission review and the requested activities can be quickly addressed
- ❖ Botanix will meet with FDA in November/December to confirm resubmission guidance
- ❖ On track to resubmit the NDA by early Q1 CY2024, with a target approval of mid-CY2024
- ❖ Anticipated delay in launch from 1Q CY2024 of 3-6 months, with no change in large market opportunity

# Instructions for Use revision – well advanced and on target



- ❖ Revised the Instructions For Use to further simplify the guidance for application ✓
- ❖ Updated bottle label and carton to prominently display “wash hands with soap and water immediately after use” ✓
- ❖ Conducted a *pilot* human factors study to demonstrate the revised Instructions For Use are reliably followed ✓
- ❖ Filed an end-of-review meeting request with FDA to be held end of November/start of December CY 2023 ✓
- ❖ Preparing to commence human factors *validation* study to confirm revised Instructions for Use are reliably followed underway
- ❖ Preparing resubmission to FDA once completed study results are available targeted for early Q1 CY2024 underway



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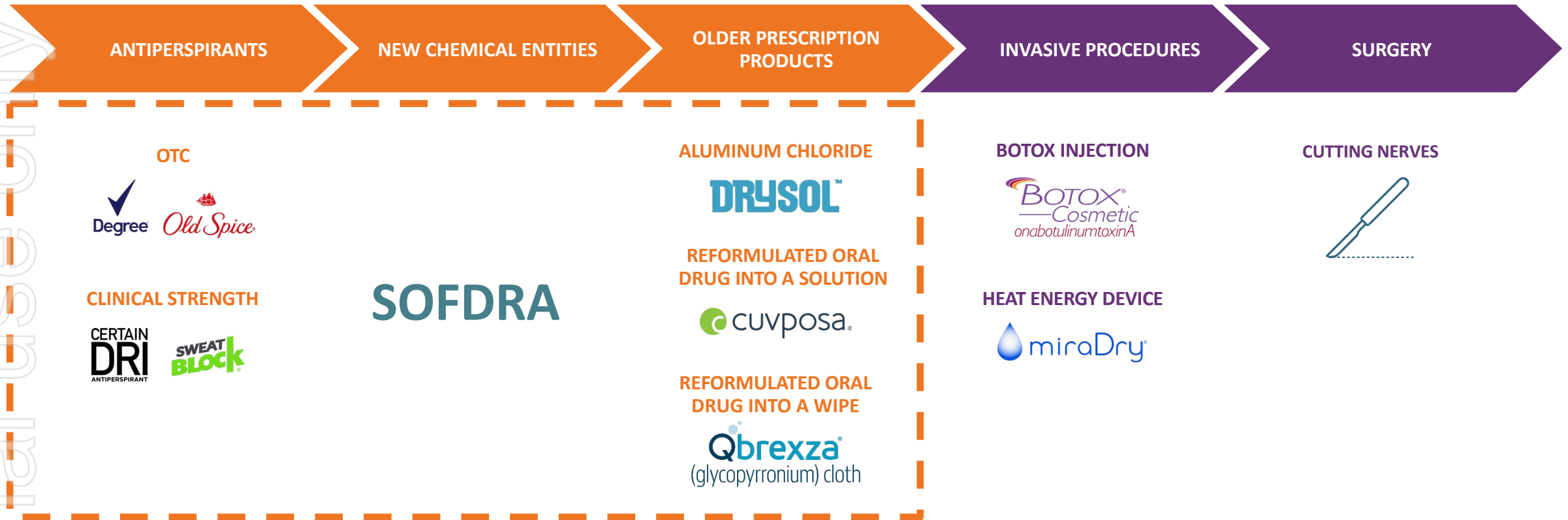
## Commercial preparation for Sofdra™ launch

# Sofdra™ launch strategy

Rapidly establish Sofdra as a safe and effective first-line topical treatment of primary axillary hyperhidrosis, in patients 9 years of age and older

- Drive dermatology adoption through comprehensive engagement around a compelling clinical story
- Engage and motivate patients to take control of their hyperhidrosis and visit a physician for appropriate diagnosis and prescription
- Ensure favorable coverage with payers
- Provide patient access and immediate fulfillment through telemedicine and a dedicated pharmacy network, to drive trial and usage
- Hire and train a highly effective sales force and target accordingly

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

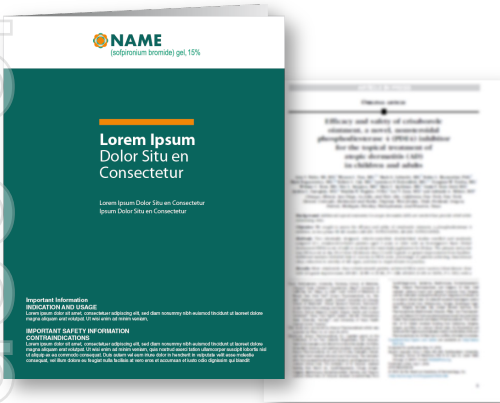


Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would pay anything for a treatment to stop their excessive sweating<sup>1</sup>

# Engagement with dermatologists supported by nonpersonal tactics

## CLINICAL RE-PRINT

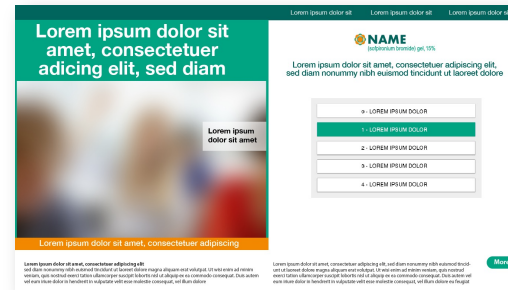
Arm field force with data



Article reprint with branded cover to facilitate early interactions with dermatologists

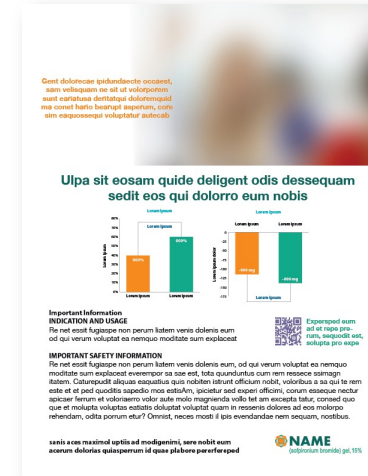
## WEBSITE

Support field force interactions through print/digital channels



Provide full information on including core data and other dermatology resources to increase brand awareness

## JOURNAL AD



Print and digital journal advertisements create and reinforce awareness among dermatologists

## BANNER ADS



Strategically placed banner ads, to drive physicians to branded website

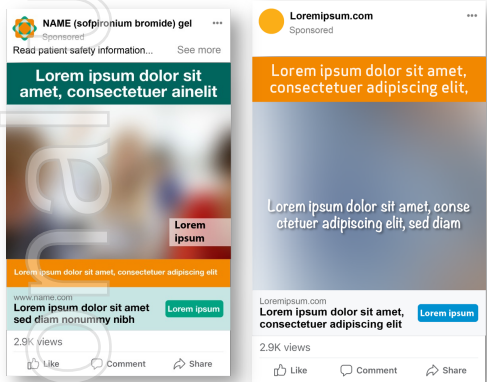
# Engage consumers where they are already active

Launch integrated DTC campaign to drive targeted awareness and motivate patients to take action; drive rapid uptake of prescriptions

## DIGITAL



Branded banner ads and updated website  
Customized branded banner ads that drive target to website and online self-test



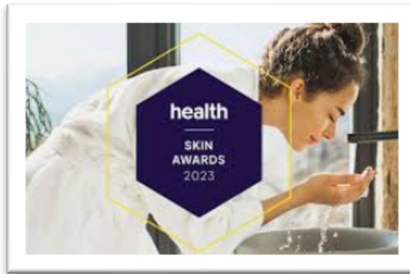
Branded/unbranded social media  
Connect with patients and create a community

## TRADITIONAL



Branded campaign ads  
Advertisements designed for direct response placed in strategically targeted print/digital publications

## PR



Drive positive discussion and coverage in consumer media. Strengthen relationships with community influencers. Establish Botanix as a leader and partner to the HH community



# Ensuring favorable Payer coverage leading up to and post launch

## Maximize coverage through strategic contracting

### Pre-Approval Period

#### Confirm anticipated Payer management

- ❖ Confirm current management approach for HH therapies
- ❖ Identify potential contracting opportunities
- ❖ Clinical presentations as requested

### PDUFA–Launch Period

#### Execute contracts

- ❖ Pricing and Product Fact Sheet
- ❖ Formulary kit
- ❖ Sales force training materials (Implementation Guides)
- ❖ Execute contracts with prioritized Payer accounts

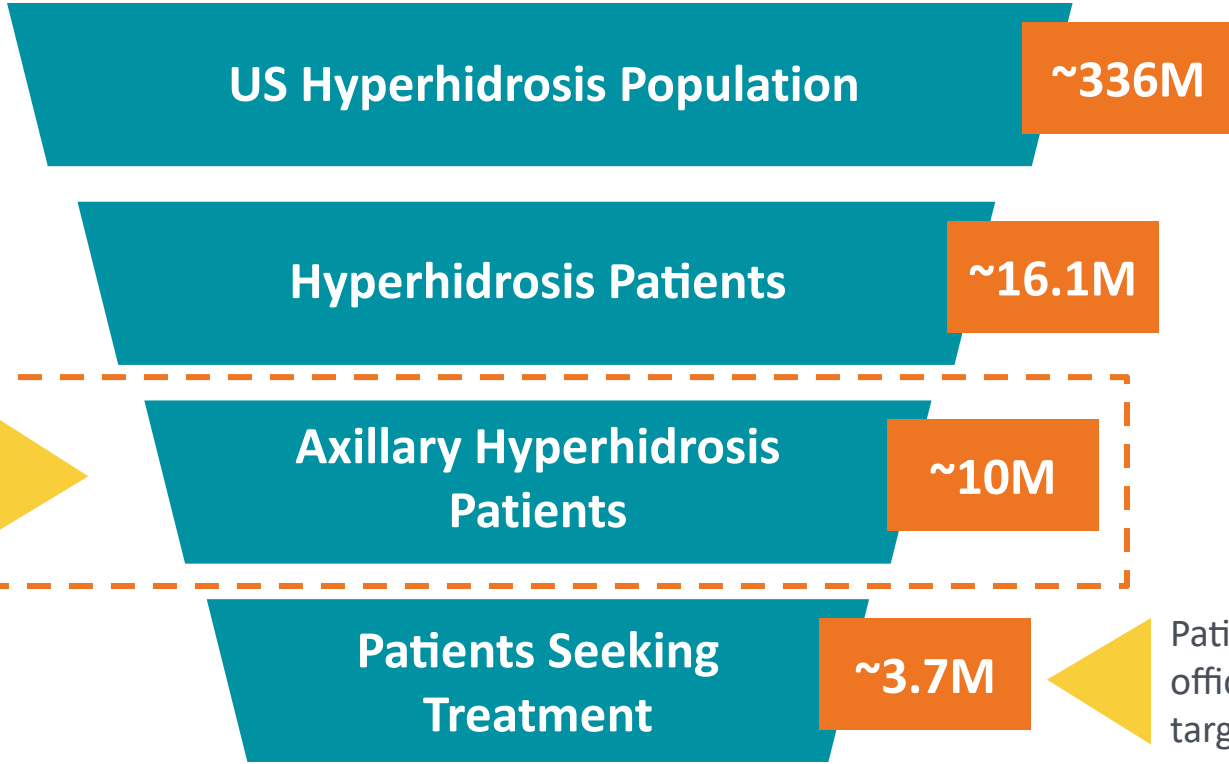
### Post-Launch Period

#### Contract for Favorable Coverage and Support Pull-Through

- ❖ Capitalize on formulary “wins” with sales force
- ❖ Continue discussions and execute contracts with prioritized accounts

# Digital strategy—expands the addressable patient population

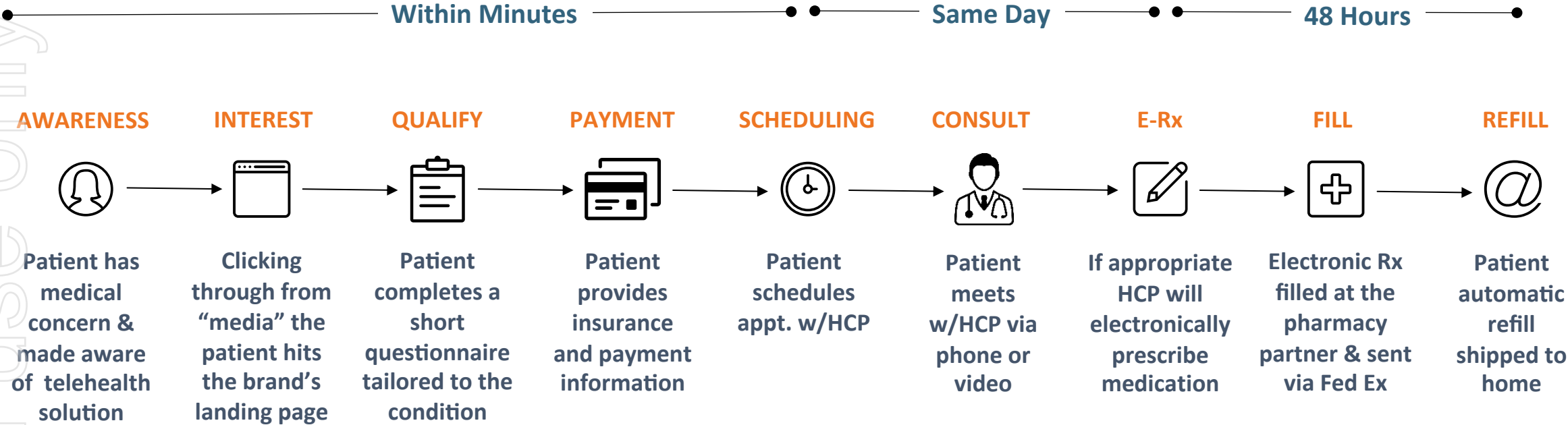
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Potential to diagnose and treat from home with telemedicine

Patients already in dermatologist's office that can be reached with a targeted sales force

# Telehealth experience significantly speeds time to therapy

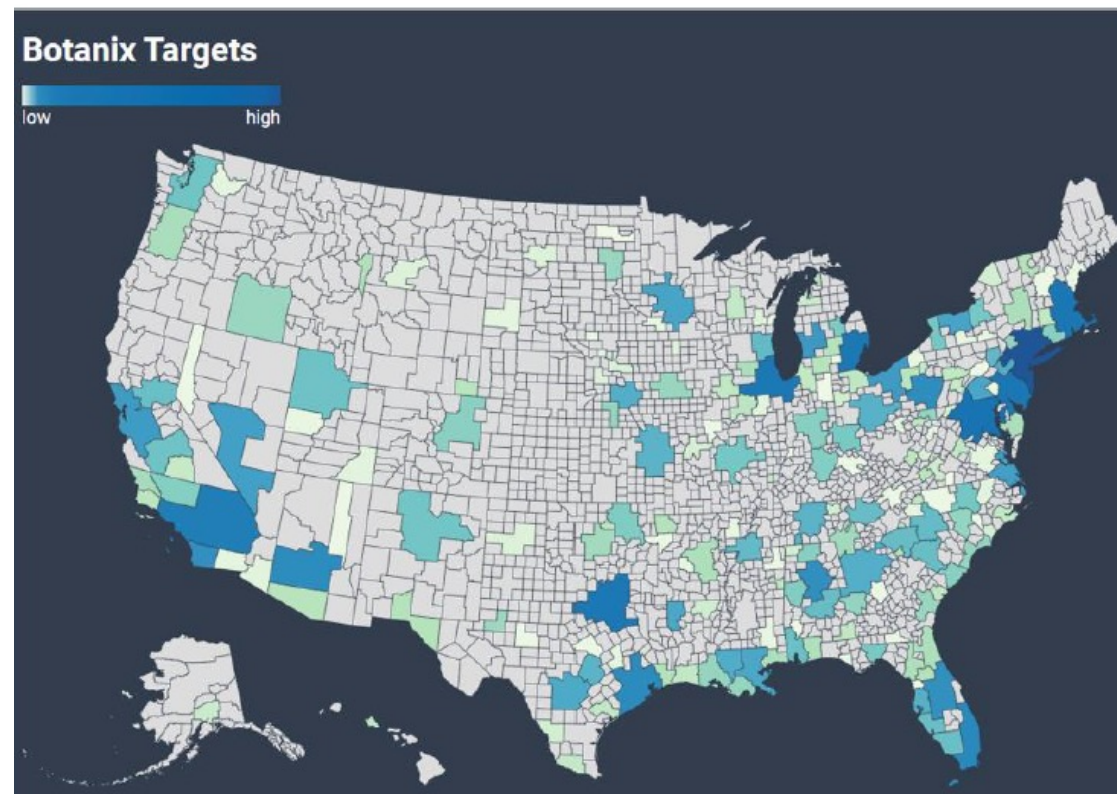


**MOVE FROM THE CURRENT STATE OF WEEKS / MONTHS TO HOURS FOR A PRESCRIPTION**



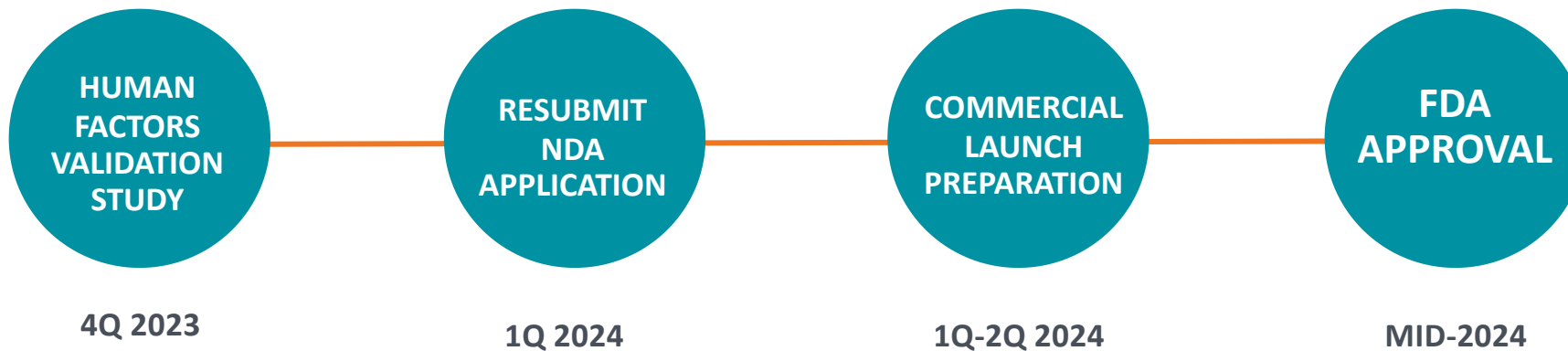
# Target most productive prescribers & expand reach via digital

- ❖ Rapid scale-up of a new 20 - 30 rep field force to reach 4,500 high prescribing dermatologists
- ❖ Top sales professionals identified
- ❖ Recruiting ongoing for post approval start



# Focused pre-launch period ahead

- ❖ FDA submission on track for 1Q CY2024, with approval targeted for mid-CY2024
- ❖ Only remaining issue to be addressed for FDA approval relates to patient Instructions for Use – no efficacy, safety or manufacturing issues
- ❖ Commercial preparation accelerating, given de-risking of FDA approval
- ❖ Company is funded to approval and has multiple commercialization options



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