botanix PHARMACEUTICALS

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)[1]
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

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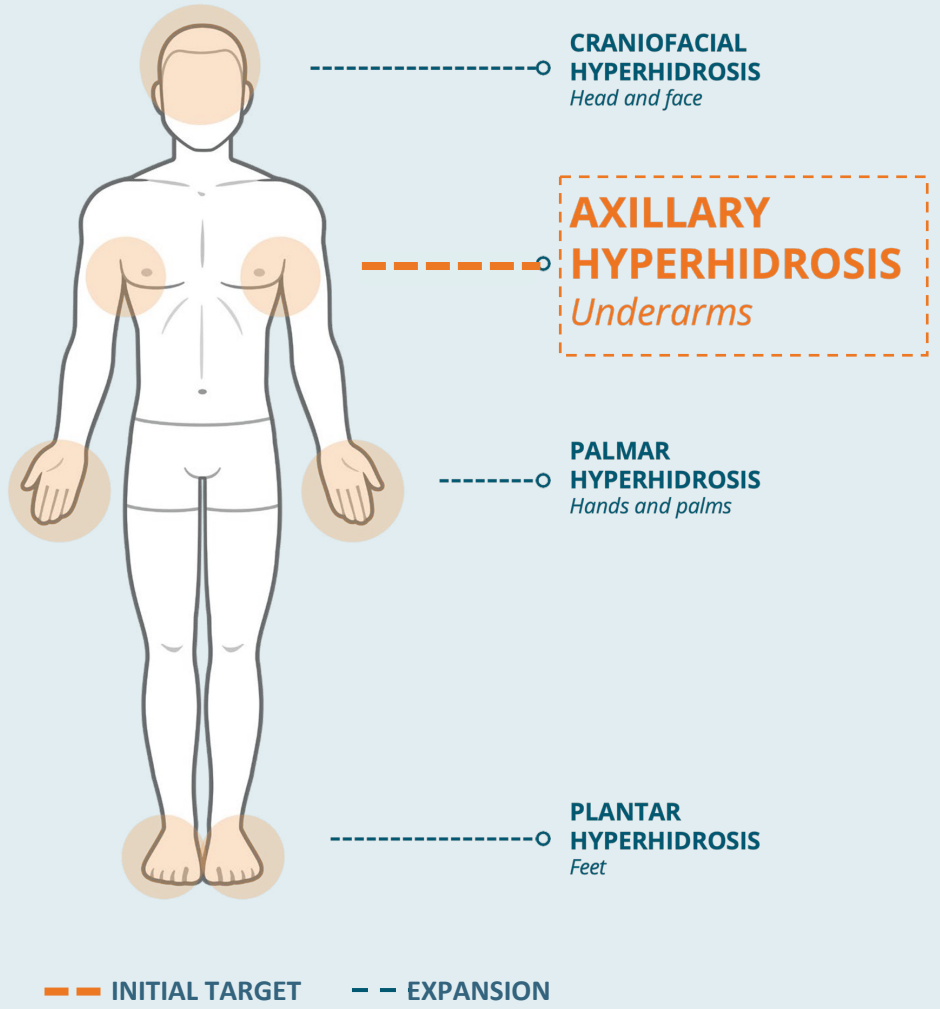
Source: 1. ASX release May 4, 2022

Hyperhidrosis

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

- Hyperhidrosis affects ~16M people in the US[1]
- Results from overstimulation of the nervous system (a physiological not psychological condition)[1]
- 90% of axillary (underarm) patients also have it in a second region[1]
- The most common age of onset for axillary hyperhidrosis patients is 12–17[2]
- **Market for treatments is ~$US1.6B per annum—projected to grow to $US2.8B by 2030[2]**



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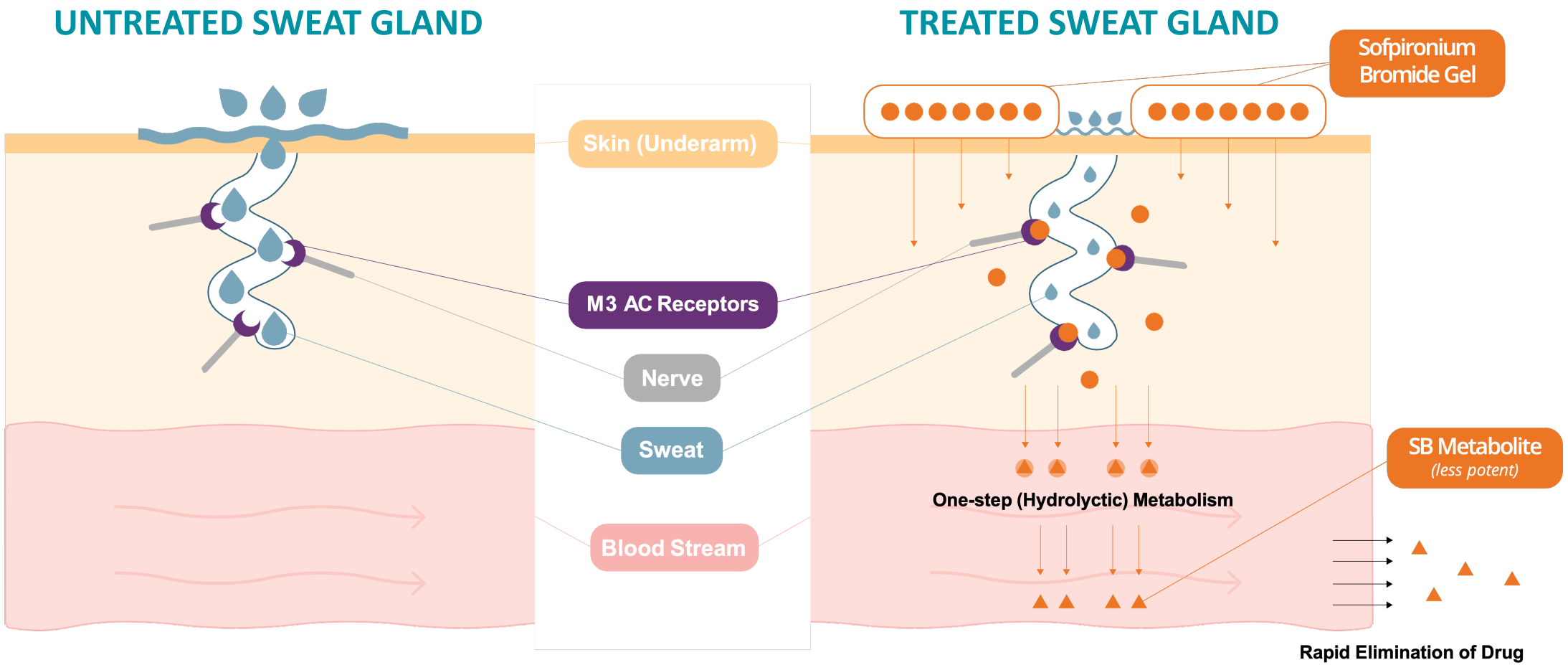
Source: 1. Doolittle, J. et al. Arch Dermatol Res, 2016. **2.** Hamm H. et al. Dermatology. 2006.

Sofdra™ mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion



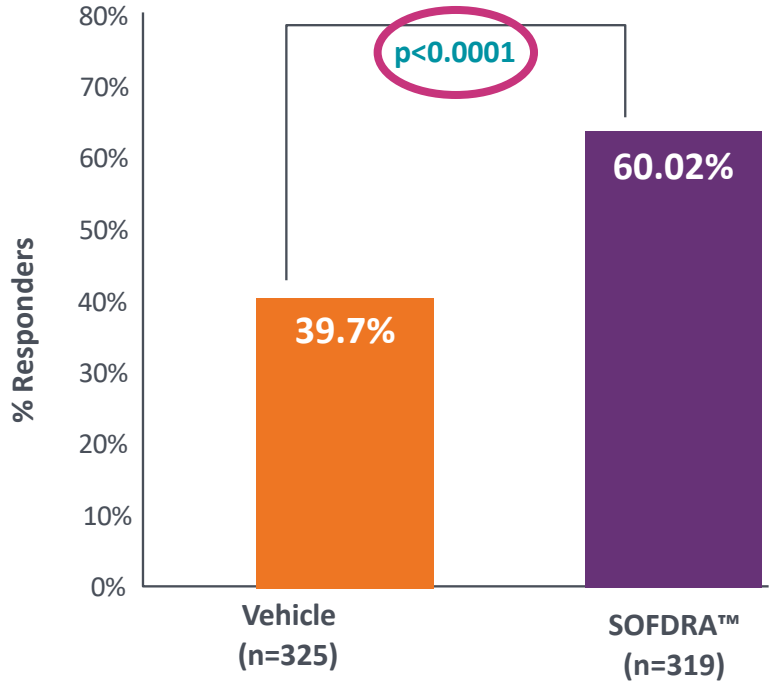
M3 AC Receptors = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

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

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[1]

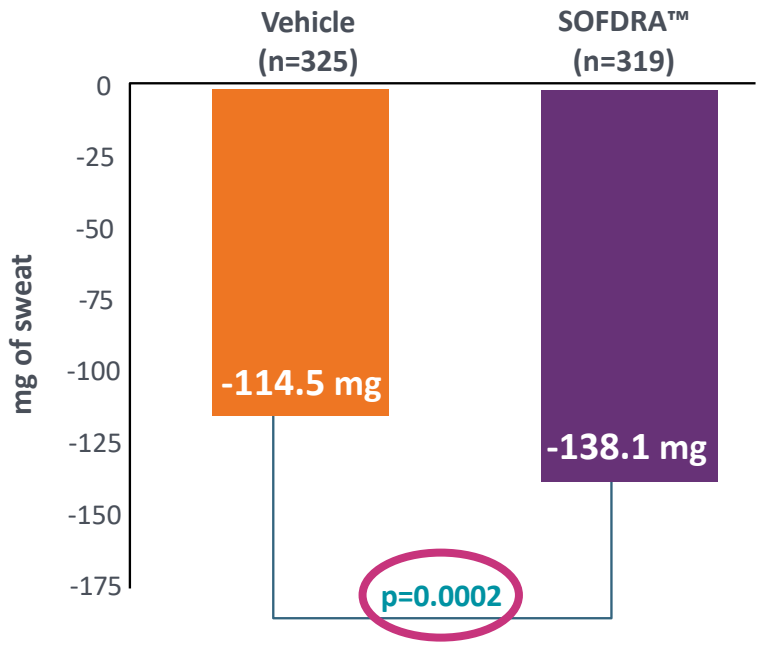


SB = Sofpironium Bromide

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[1]



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

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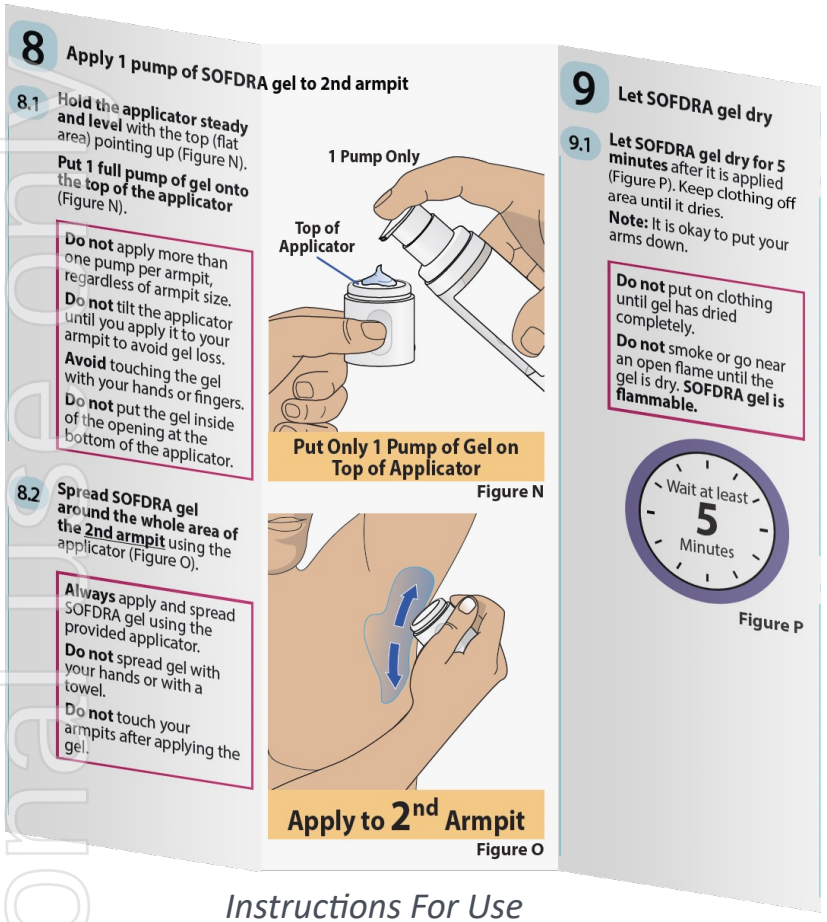
Source: 1. Data on File.

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



Instructions For Use

- 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

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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

ANTIPERSPIRANTS | NEW CHEMICAL ENTITIES | OLDER PRESCRIPTION PRODUCTS | INVASIVE PROCEDURES | SURGERY

OTC

Degree | Old Spice

CLINICAL STRENGTH

CERTAIN DRI ANTIPERSPIRANT | SWEAT BLOCK

SOFDRA

ALUMINUM CHLORIDE

DRYSOL™

REFORMULATED ORAL DRUG INTO A SOLUTION

cuvposa

REFORMULATED ORAL DRUG INTO A WIPE

Qbrexza (glycopyrronium) cloth

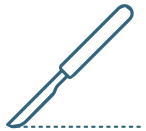
BOTOX INJECTION

BOTOX Cosmetic onabotulinumtoxinA

HEAT ENERGY DEVICE

miraDry

CUTTING NERVES



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[1]

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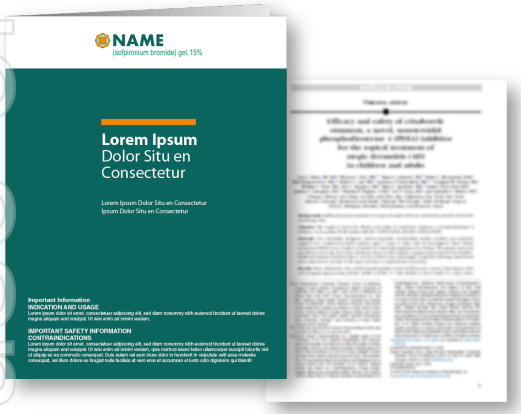
Source: 1. Doolittle, J. et al. Arch Dermatol Res, 2016.

Engagement with dermatologists supported by nonpersonal tactics

CLINICAL RE-PRINT

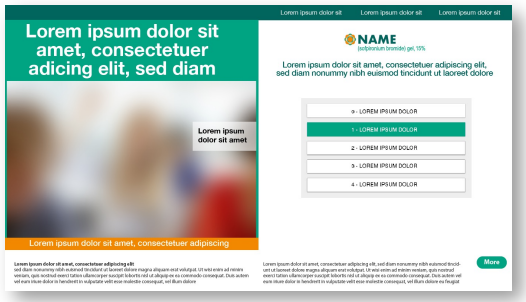
Arm field force with data



Article reprint with branded cover to facilitate early interactions with dermatologists

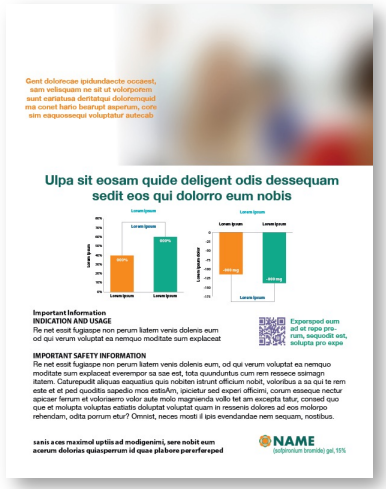
WEBSITE

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

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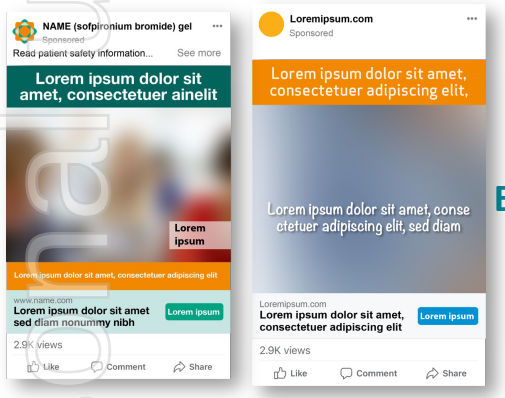
Engage consumers where they are already active

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

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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

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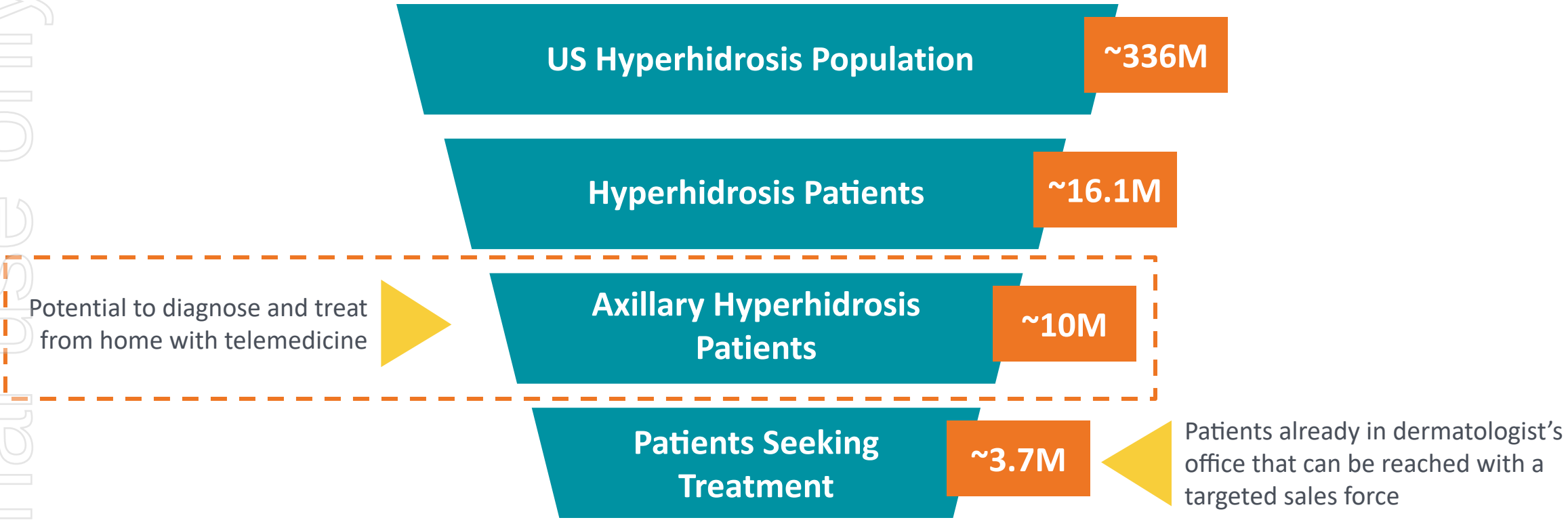
*PDUFA Goal Date; scope of HCP tactics may evolve depending on date of product approval
**Expected date that SB Gel will be available for sale at Hub; to be confirmed once Hub vendor is contracted

Digital strategy—expands the addressable patient population



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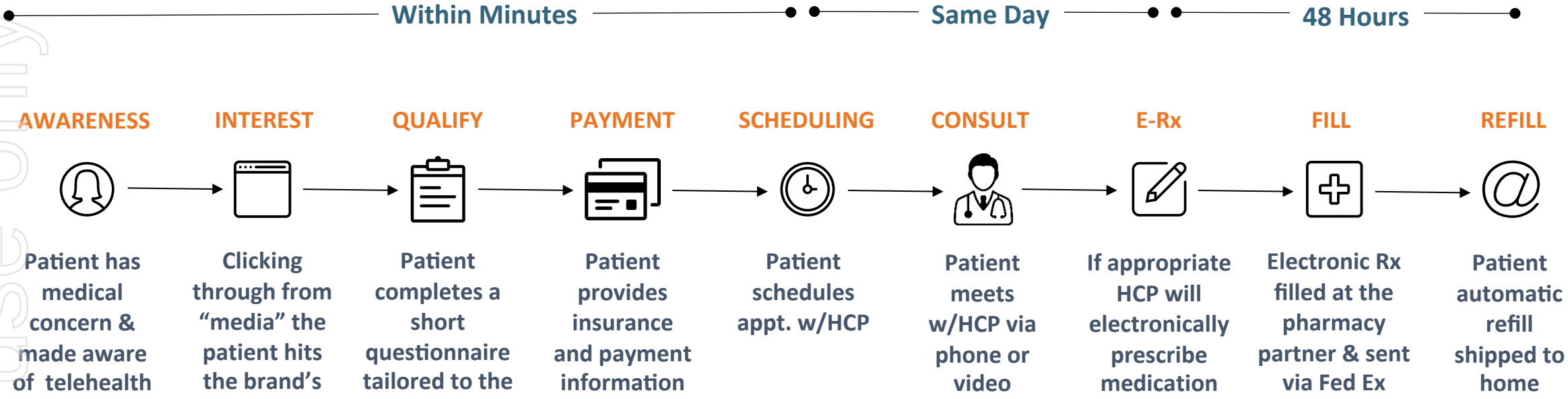
Source: 1. International Hyperhidrosis Society, **2.** Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research

Telehealth experience significantly speeds time to therapy



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

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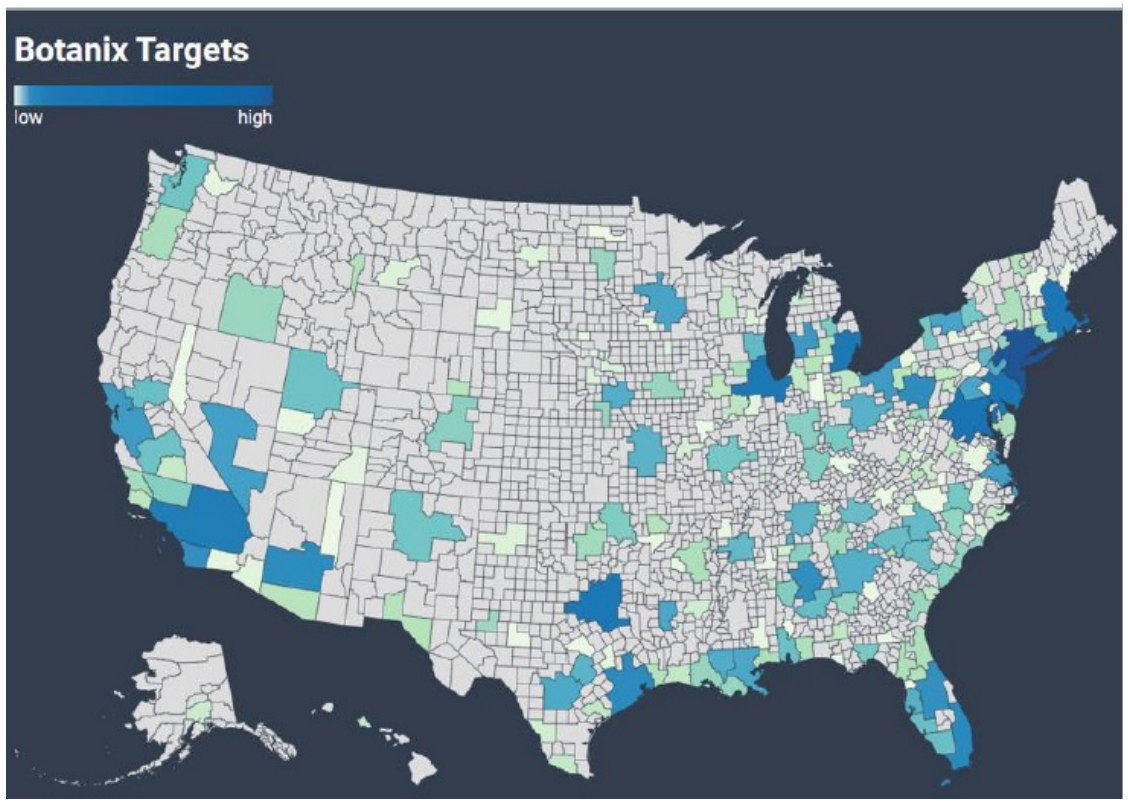
Target most productive prescribers & expand reach via digital

- 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



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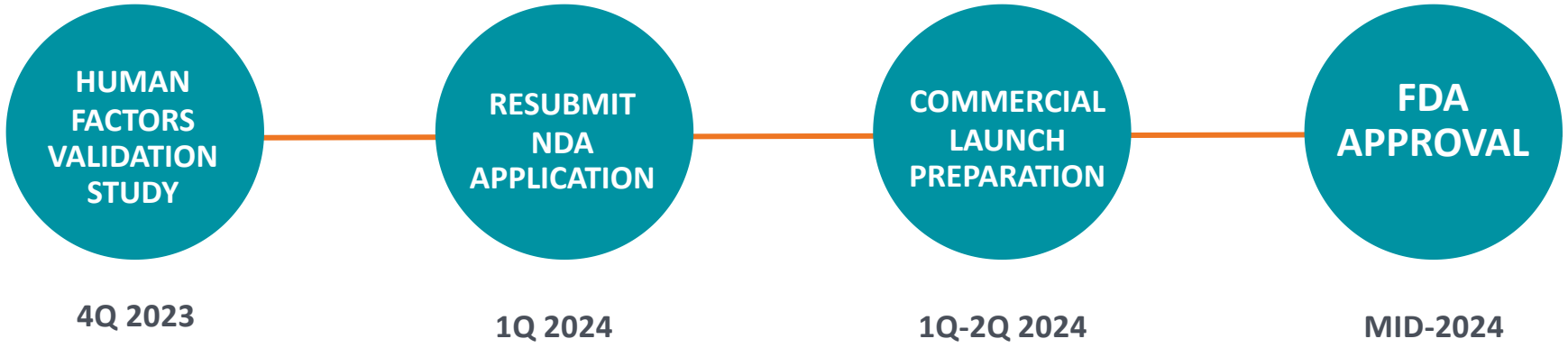
Focused pre-launch period ahead

- 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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