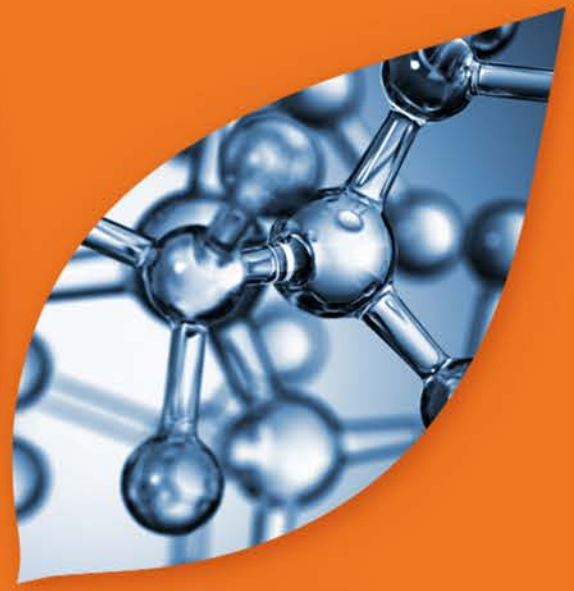
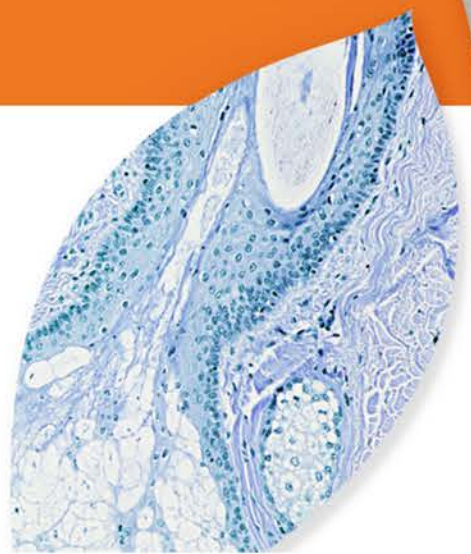
Investor Event: Physician Symposium on AMZEEQ® and ZILXI™

October 1, 2020

VYNE™ THERAPEUTICS





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Agenda

01 **Welcome and Opening Remarks**
Dave Domzalski | Chief Executive Officer

02 **AMZEEQ® Commercial Strategy**
Matt Wiley | Chief Commercial Officer

03 **The AMZEEQ® Experience**
Dr. Ted Lain | Sanova Dermatology
Dr. Julian Moore | Hollywood Dermatology

04 **AMZEEQ® Q&A**
All Speakers

05 **Commercial Strategy / Market Opportunity for ZILXI™**
Matt Wiley | Chief Commercial Officer

06 **KOL Presentation on ZILXI™**
Dr. Linda Stein Gold | Henry Ford Health System

07 **ZILXI™ Q&A**
All Speakers

08 **Closing Remarks**
Dave Domzalski | Chief Executive Officer

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Ted Lain, MD MBA FAAD

- Board-certified Dermatologist and Chief Medical Officer at Sanova Dermatology in Austin Texas. specializing in diagnosis and treatment of disorders of the hair, skin and nails.
- Joint medical/masters in business administration degrees from Baylor College of Medicine and Rice University in Houston, TX.
- Specializes in diagnosis and treatment disorders of the skin, hair and nails. Physician Trainer for Allergan on BOTOX Cosmetic, JUVEDERM, and VOLUMA.

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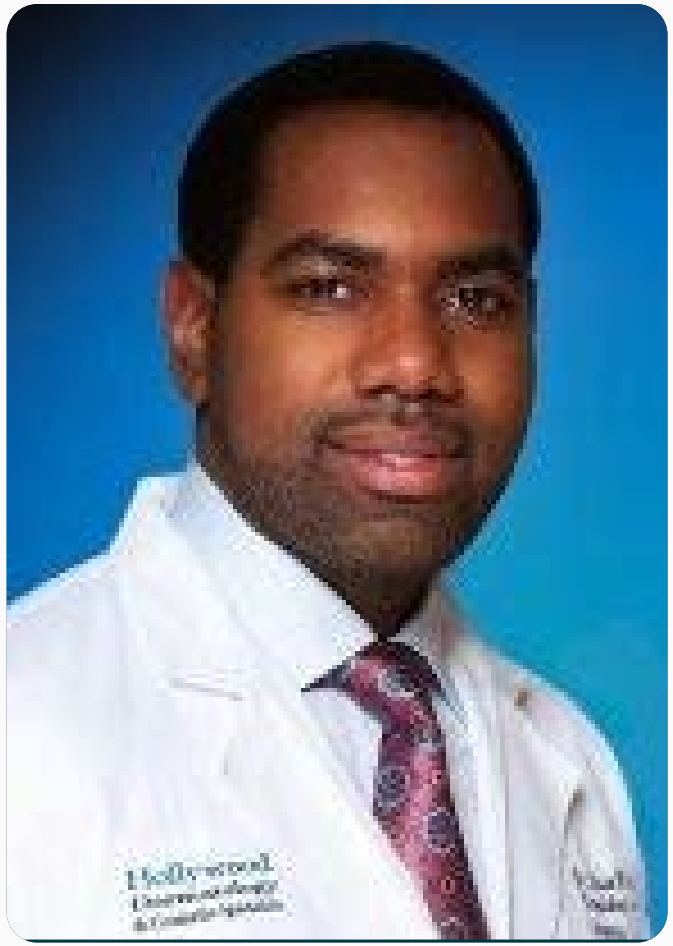

Julian Moore, DO FAAD

- Board certified dermatologist at Hollywood Dermatology and Cosmetic Surgery Specialists in Hollywood FL.
- Assistant Director of the Larkin/Nova Southeastern University Dermatology Residency Training Program.
- Specializes in acne, eczema and psoriasis, as well as skin cancer detection and treatment.
- Doctorate in Medicine from the New York College of Osteopathic Medicine.
- Post-Doctoral NIH Fellowship in Dermatology and Cutaneous Malignancy at Mount Sinai Icahn School of Medicine.

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Linda Stein Gold, MD FAAD

- Director of Dermatology Clinical Research at Henry Ford Health System in Detroit.
- Division Head of Dermatology at Henry Ford Health System in West Bloomfield, Michigan.
- Medical degree from the University of Pennsylvania School Of Medicine.
- Active in clinical research on dermatologic conditions such as chronic plaque-type psoriasis, actinic keratosis, atopic dermatitis, acne vulgaris, seborrheic dermatitis, and rosacea.
- Treasurer of the National Acne and Rosacea Society.
- Member of the National Psoriasis Foundation Medical Board.

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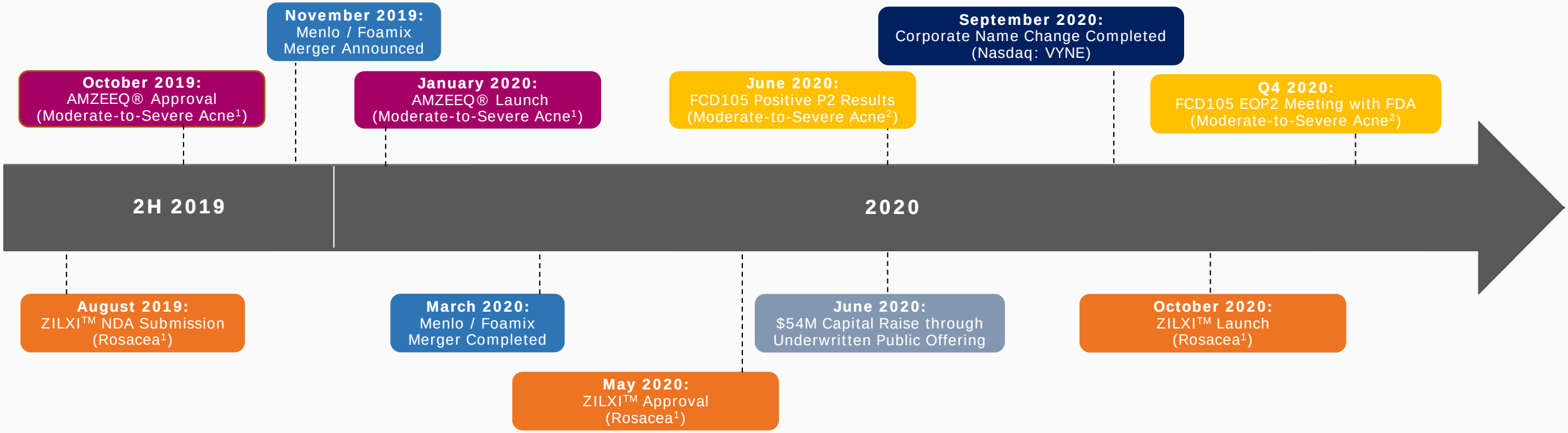
Multiple Milestones Achieved in Last 12 Months



1. Please see Important Safety Information on slides 43 55 and 106
2. Safety and efficacy of this investigational product have not been established. There is no guarantee that pipeline products will receive FDA approval or become commercially available.

Key Priorities

- **AMZEEQ®:**
  - Continue to progress trial and utilization of AMZEEQ®; Gain market share
  - Increase awareness and efficiently mobilize patients through digital and social media
  - Expand payor acceptance and reimbursement
- **ZILXI™:**
  - Address the unmet need within the disease state and capitalize on patient dissatisfaction with currently marketed products within the category
  - Leverage physician experience with AMZEEQ® and our MST™ technology to drive rapid uptake of ZILXI™
  - Gain broad payor acceptance and reimbursement
- **FCD105:**
  - Continue to progress this potentially best-in-class treatment for patients with acne
    - Q4 2020: End-of-Phase 2 Meeting
    - 1H 2021: Phase 3 Initiation Anticipated
- **Manage OPEX through prudent resource prioritization and rationalization**

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VYNE Investment Highlights

- ✓ Commercial stage company focused on large and growing markets in dermatology
- ✓ Two commercial products: AMZEEQ® and ZILXI™ employ proprietary differentiated MST™ technology
- ✓ Strong intellectual property with latest patent into 2037 and barriers to genericization inherent among topical medications
- ✓ Addition of FCD105 expands potential product offering and enhances company position as a scaled leader in dermatology
- ✓ Portfolio synergies allow for leverageable commercial infrastructure
- ✓ Experienced management team demonstrating execution capabilities with AMZEEQ® ramp
- ✓ Well capitalized with $100M in cash as of June 30th and ~168M shares outstanding
- ✓ Broad investor base with a healthy mix of institutional and retail investors

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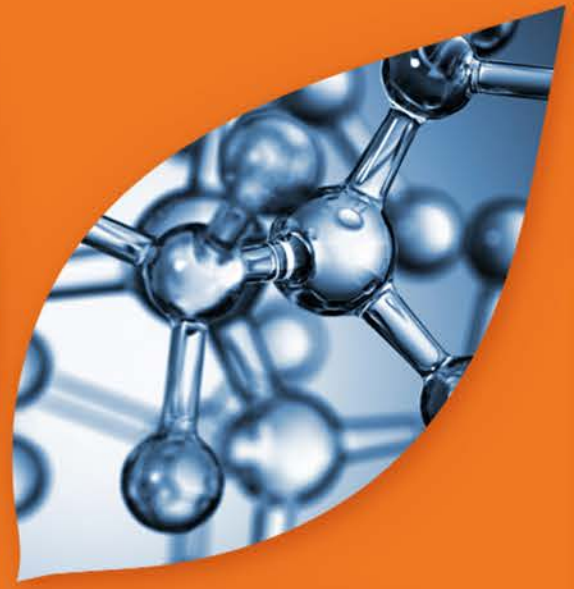
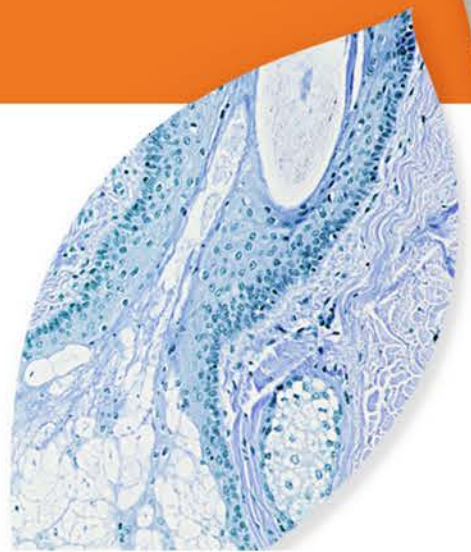
Physician Symposium on AMZEEQ® and ZILXI™

Matt Wiley, CCO

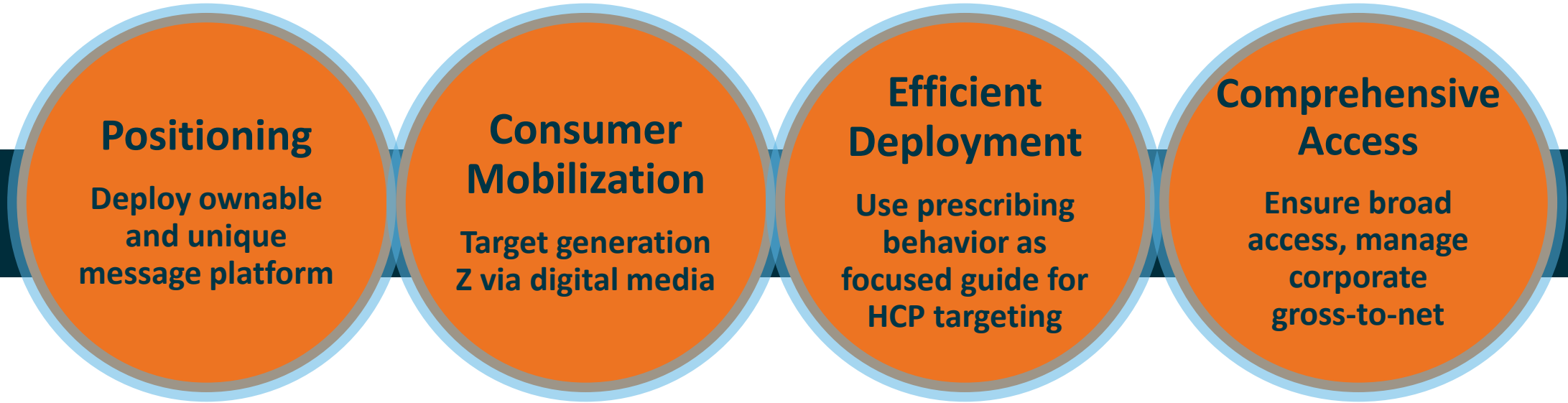
October 1, 2020





VYNE™ THERAPEUTICS

AMZEEQ® (minocycline) topical foam, 4% Commercial Strategy



AMZEEQ Positioning

Novel, ownable product positioning rooted in novel delivery/MST™ and first to market topical minocycline while the competition all positions around safety, efficacy and convenience

Efficacy, safety, convenience

Aczone 7.5% (dapsone) Gel, 7.5%

AKLIEF TRIFAROTENE 50

Altreno (tretinoin) Lotion, 0.05%

EPIDUO FORTE

FABIOR (tazarotene) Foam, 0.1%

Retin-A (tretinoin)

Once-daily Seysara (sarecycline) tablets

VS.

Novel delivery, MST

amzeeq® (minocycline) topical foam,4%

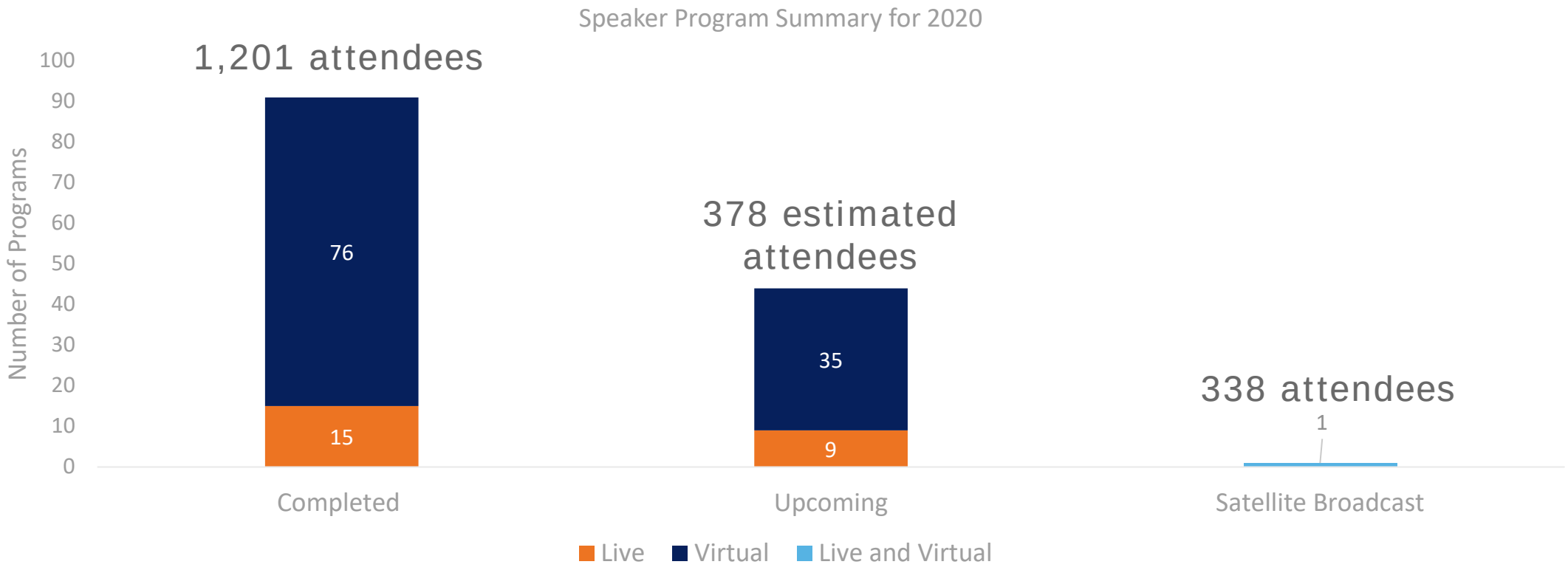
Core Selling Asset

The Core Visual Aid (CVA): Primary Promotional Asset Presents AMZEEQ Through A Simple, Motivating Story

- **Minocycline:** antibiotic of choice for moderate-to-severe acne
- **MST:** Overcoming challenges with formulating topical minocycline
- **AMZEEQ:** Redefining topical therapy for inflammatory lesions of non-nodular moderate to severe acne vulgaris
- **Efficacy** of AMZEEQ
- **Proven Safety**
- **Tolerability**
- **Easy to use**, once-daily formulation
- **Affordable** for patients

Speaker Program Metrics

AMZEEQ speaker programs expected to reach ~2,000 attendees in 2020

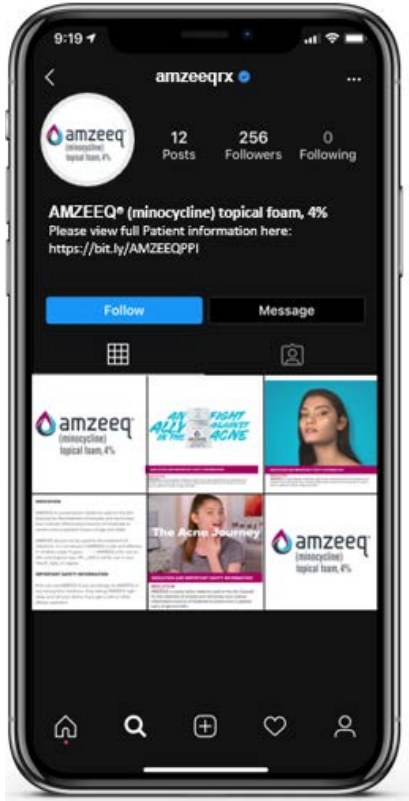


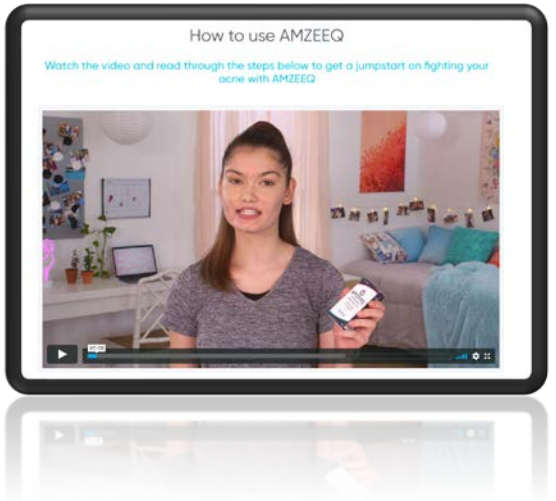
Source: VYNE Data on File as of mid-September 2020
Note: some attendees may not be unique if they attended two or more programs.

Consumer Approach

Stimulating Generation Z interest through trusted digital sources

- Increase presence in top search engines
- Launch of AMZEEQ Facebook and Instagram channels
- Acne influencer partnership for “in real life” promotion





Source: VYNE data on file

Reach on Targets

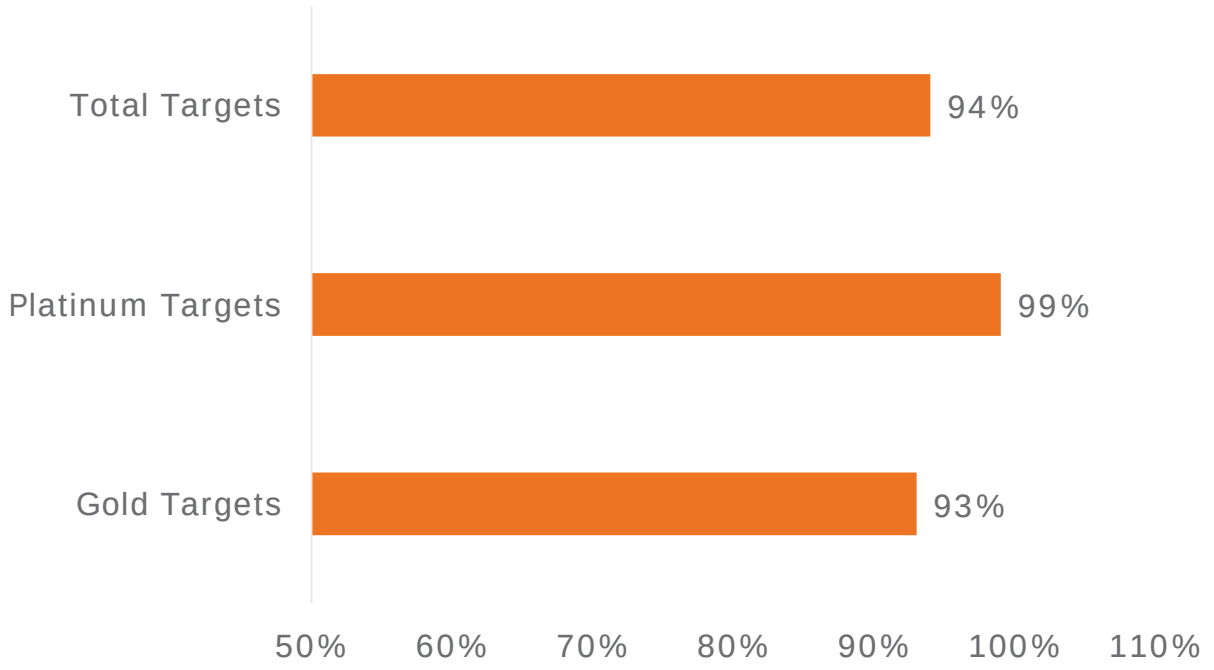
51 representatives deployed covering 67% of diagnosed acne patients and 73% of acne TRxs[1]

Targeting focused on select HCPs prioritized based on acne patient volume, acne TRx volume, preference for brands and early adoption

Launch to date, representatives have reached 94% of all targets

- 99% of platinum targets
- 93% of gold targets

Reach by Target Segment[2]



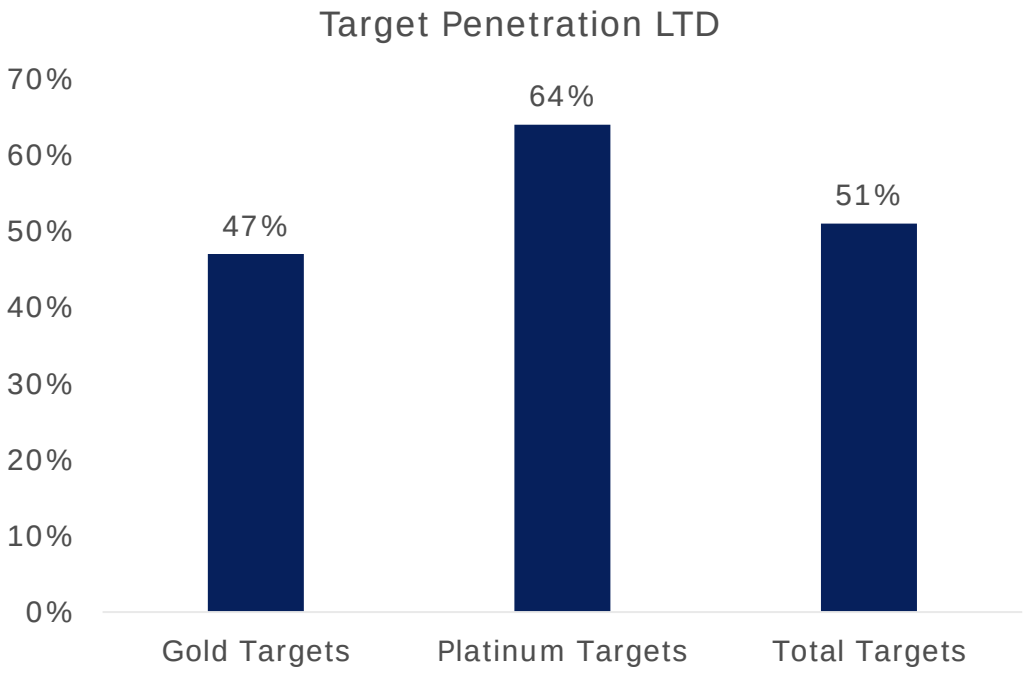
Sources:

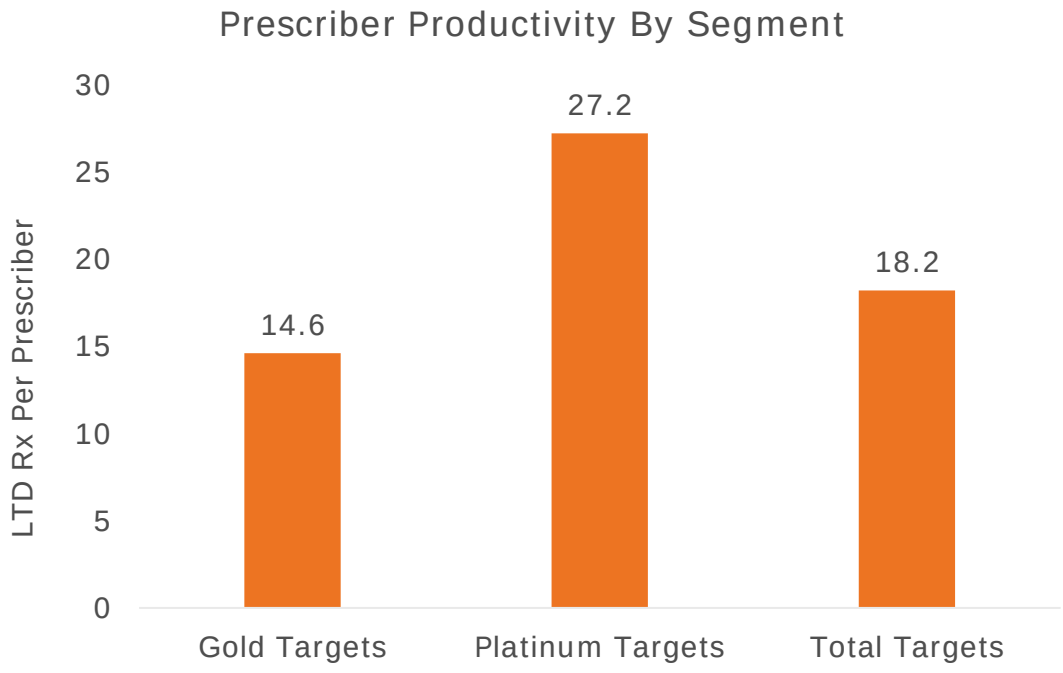
(1) Symphony Integrated Dataverse (IDV) Patient Claims Database, Time Period: 24 months ending Feb '19

(2) VYNE Data on File, data as of 9/22/20

AMZEEQ Target Penetration and Productivity

Launch-to-date (LTD), 64% of platinum targets have prescribed at least 1 Rx and on average prescribed ~27 Rx's



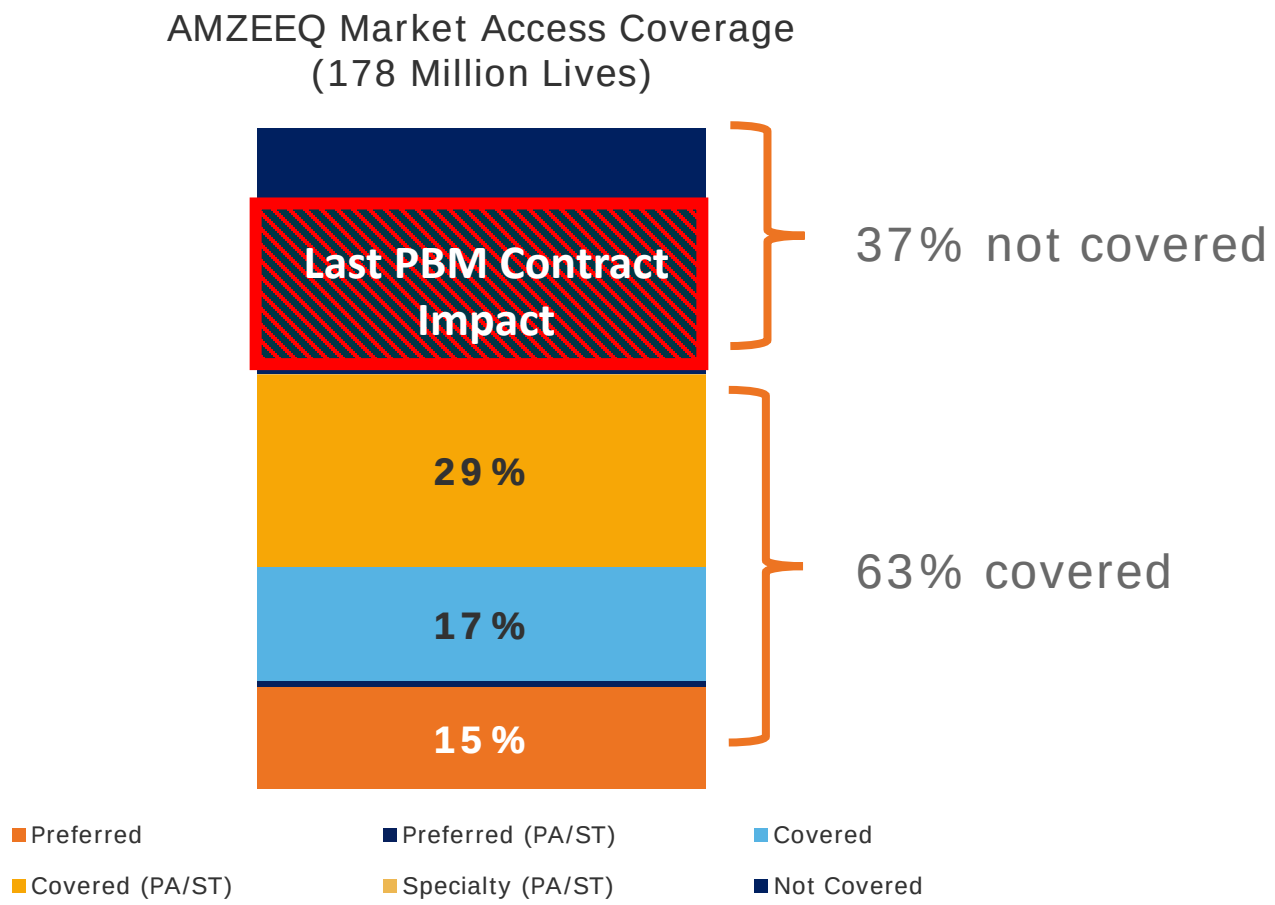


Source: Symphony Vantage Prescriber Insights – LTD as of 1/10/20 to 9/4/20

Source: Prescriber Segment 3Q Target List, AMZEEQ® Weekly TRx by Segment LTD as of 9/4/20

Market Access

AMZEEQ market access at 63% of covered lives to date

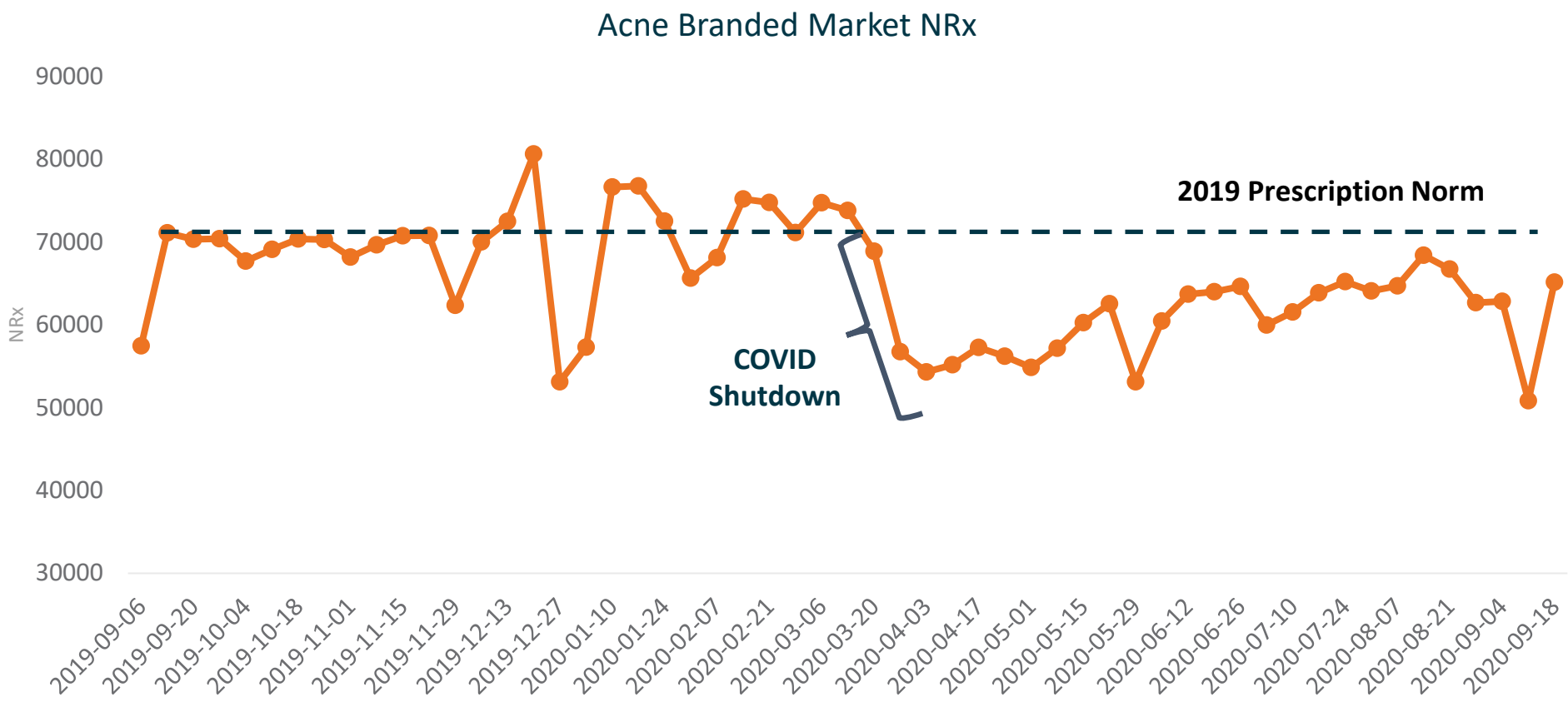


- Approximately 1/3rd of AMZEEQ covered lives has no utilization management
- 42m of the 65m lives not covered are due to one major PBM
- If successful, contract negotiations with other PBMs could bring the total covered lives to >80% by the end of the year

Source: MMIT July 16th, 2020

Acne Branded Market Performance

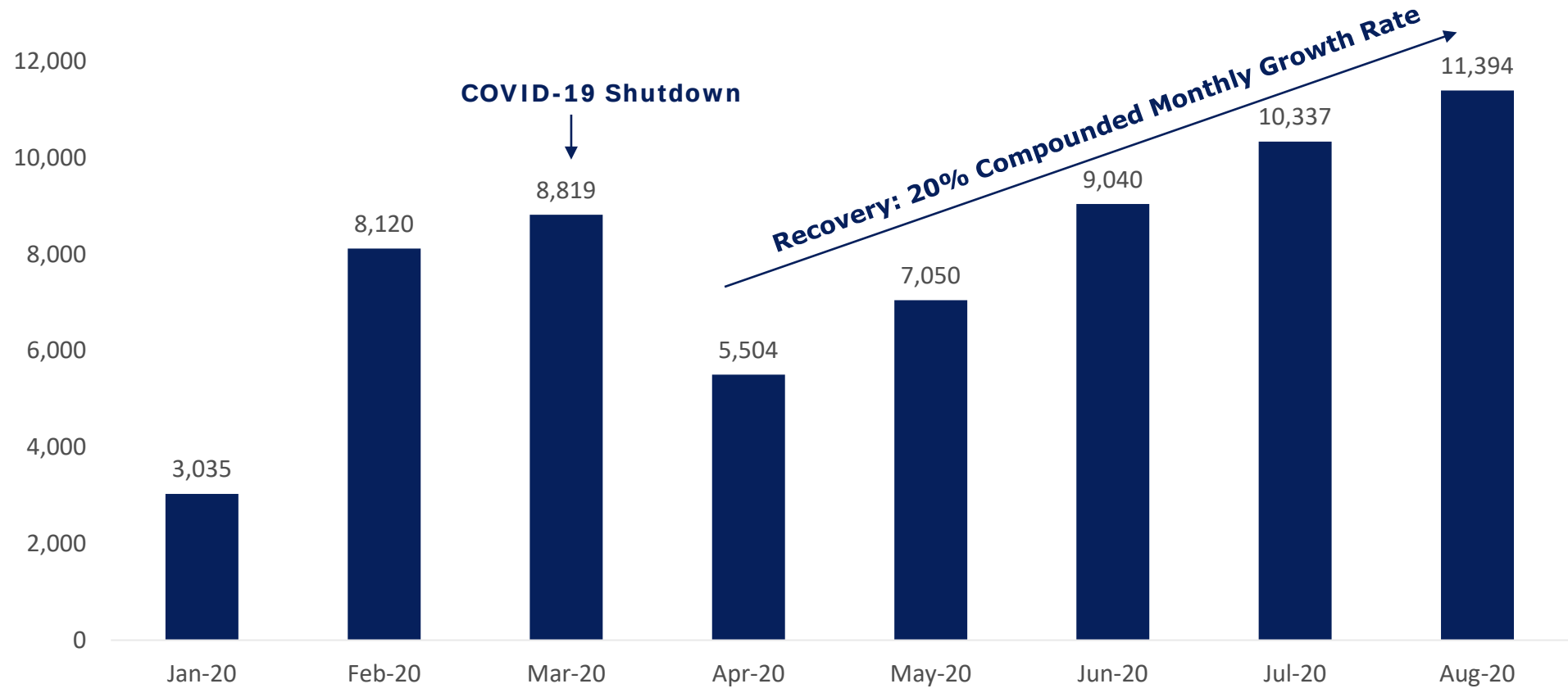
The total branded acne market retracted due to COVID-19 shutdowns in April and May; now recovering to near September 2019 levels.



Source: METYS, unweighted 091820

AMZEEQ Monthly TRxs

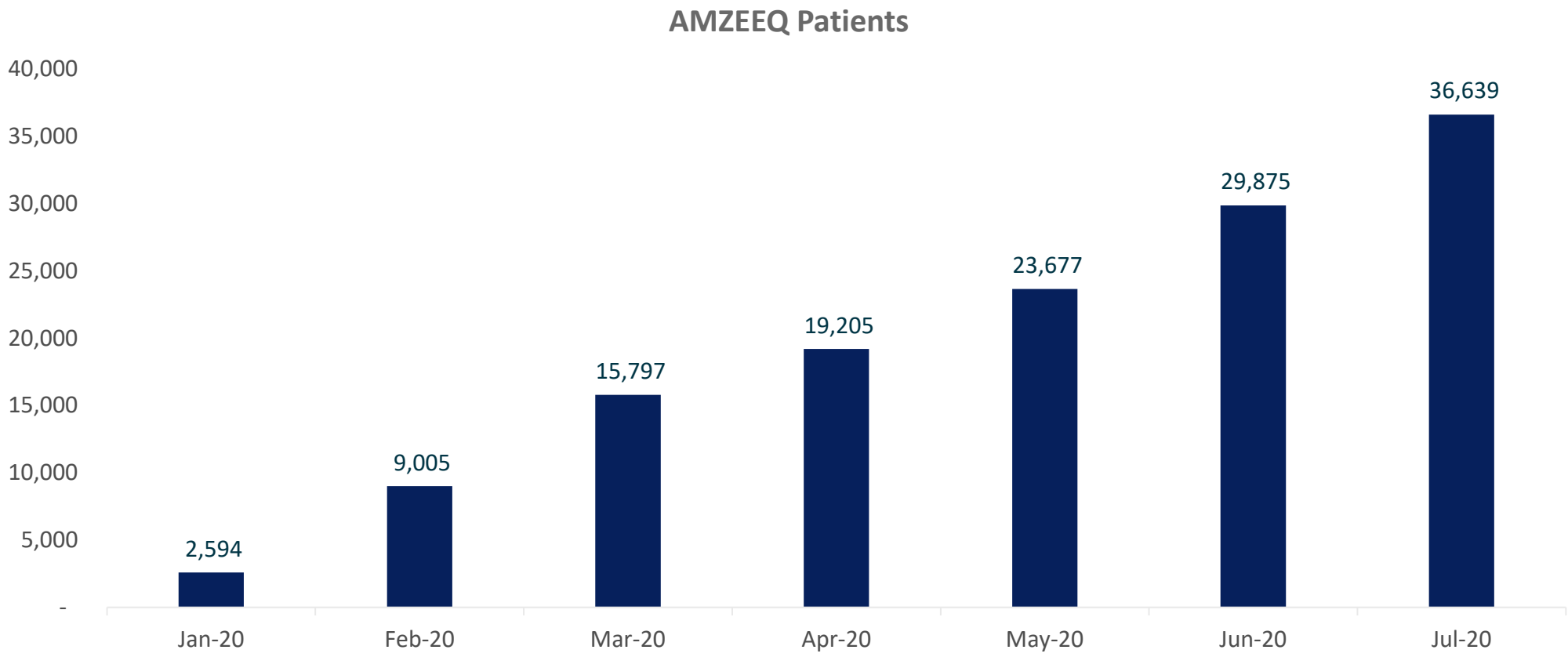
AMZEEQ TRxs have had a nice growth recovery since the late March shutdowns



Symphony METYS – LTD as of 1/10/20 through August 2020

Cumulative Unique Patients

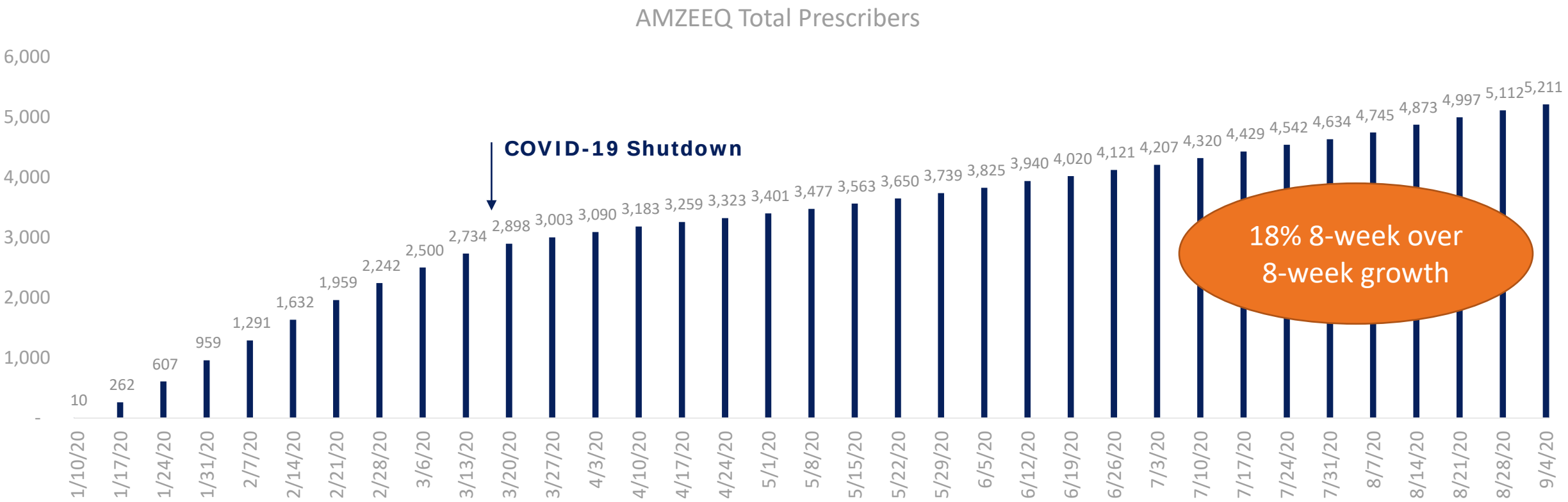
Patient exposure to AMZEEQ growing steadily over time, with over 36k patient exposures through July



Source: AMZEEQ Patients Monthly YTD Vantage Payer Landscape September 2020

AMZEEQ Weekly Total Prescribers

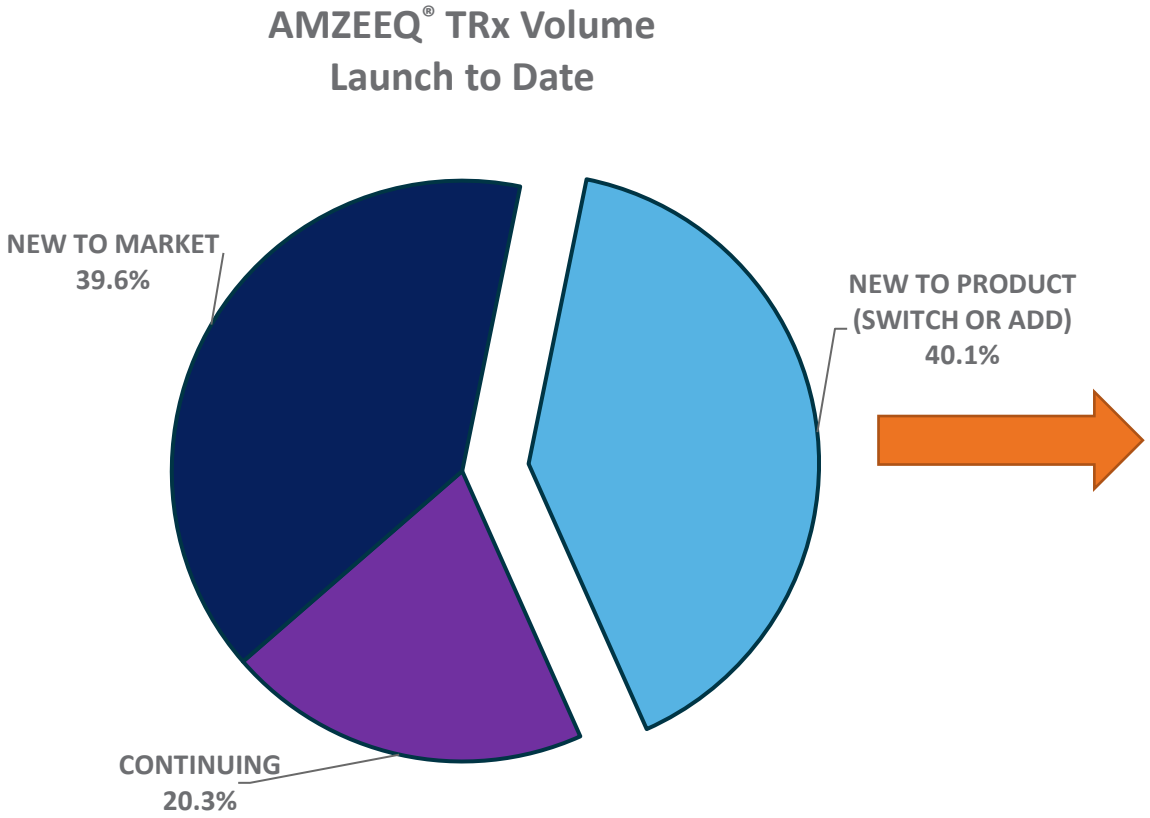
Continued week over week (WoW) growth of total prescribers despite absence of face-to-face selling during COVID-19

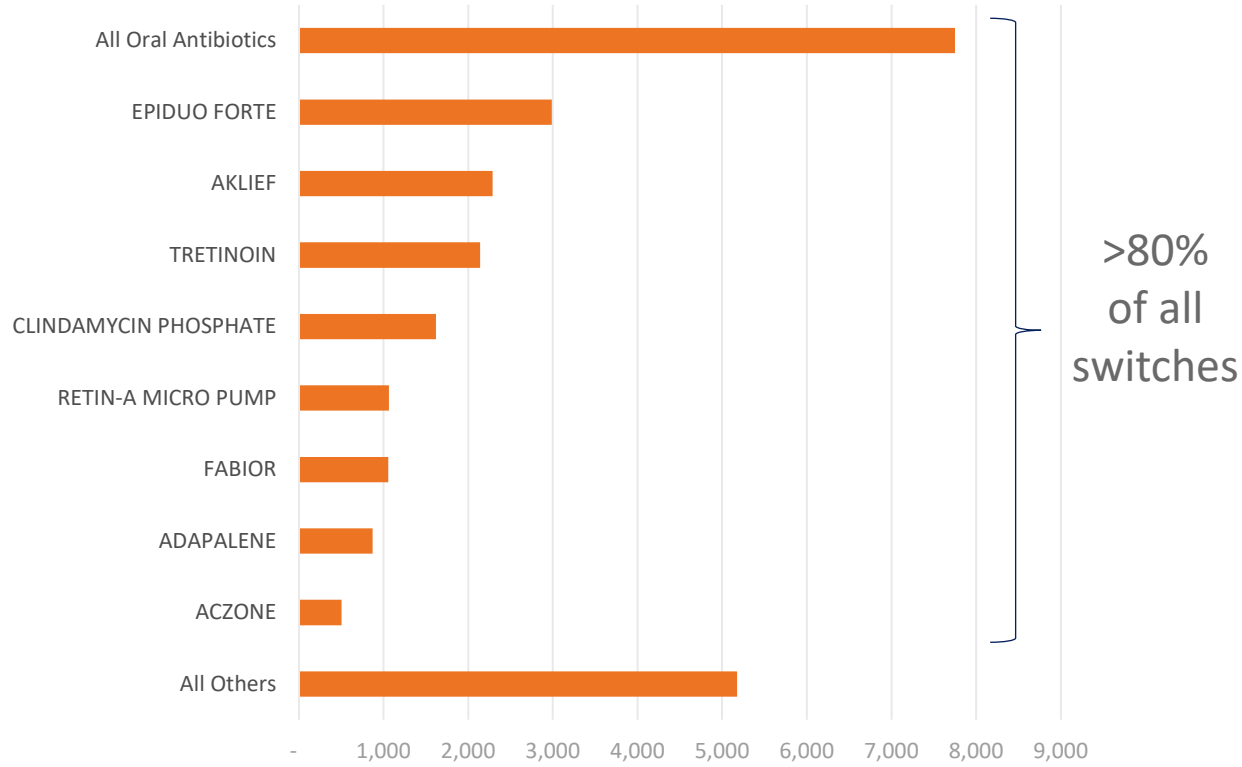


Source: Symphony Vantage Prescriber Insights – LTD as of 1/10/20 to 9/4/20, cumulative prescriber count

AMZEEQ New to Product and Switch Metrics

Roughly half of all new AMZEEQ patients are new to prescription therapy, while the balance is either switched or added to existing therapy. Approximately 20% of all AMZEEQ volume is due to refills.

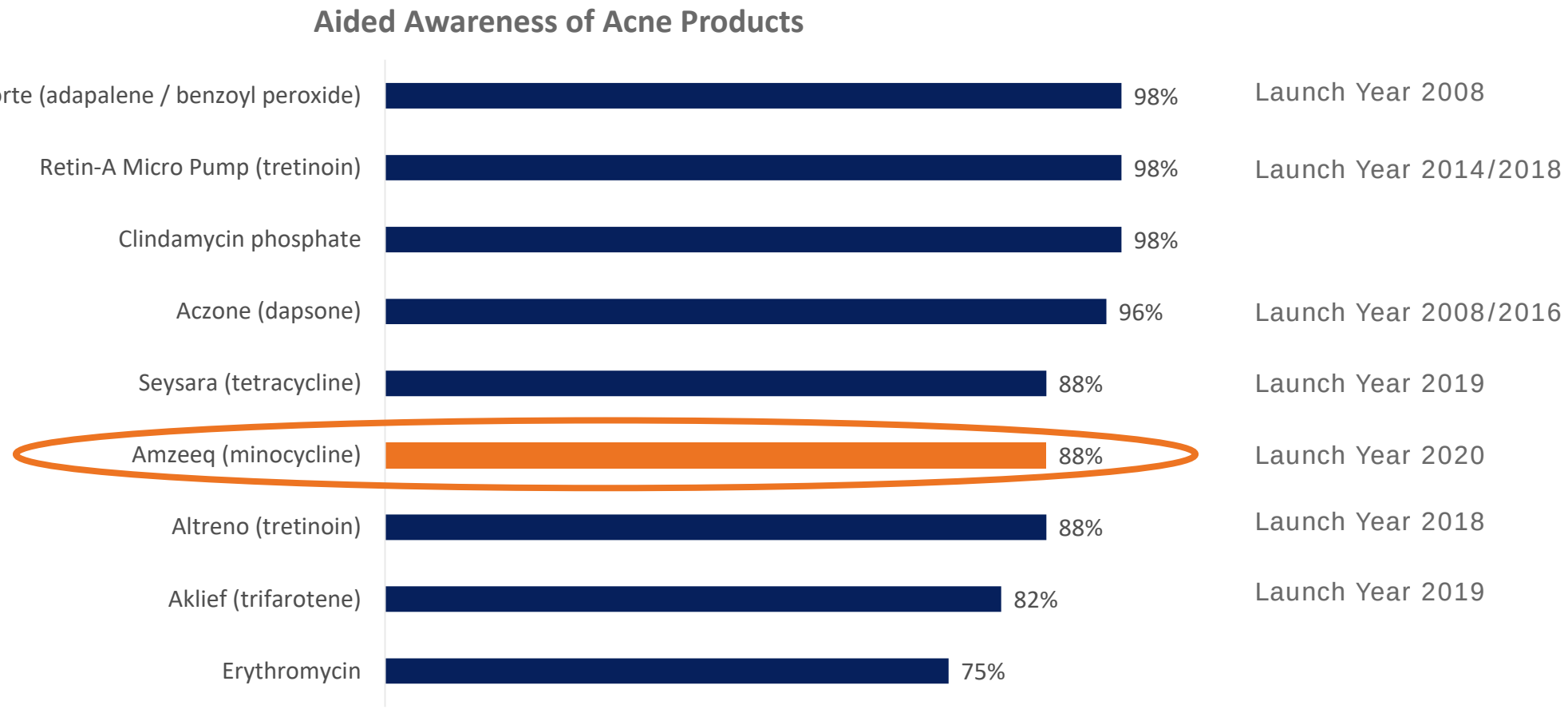




Source: Symphony Metys – LTD as of 1/10/20 to present

HCP Awareness of Acne Treatments

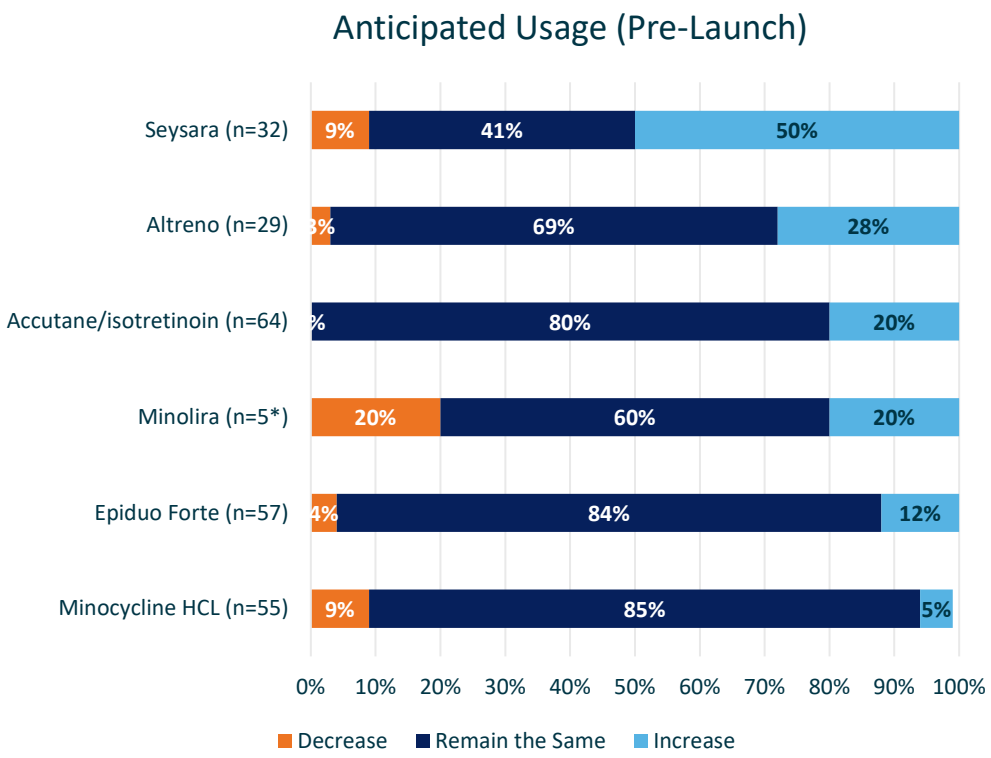
After only 9 months, nearly 90% of targeted HCPs are aware of AMZEEQ

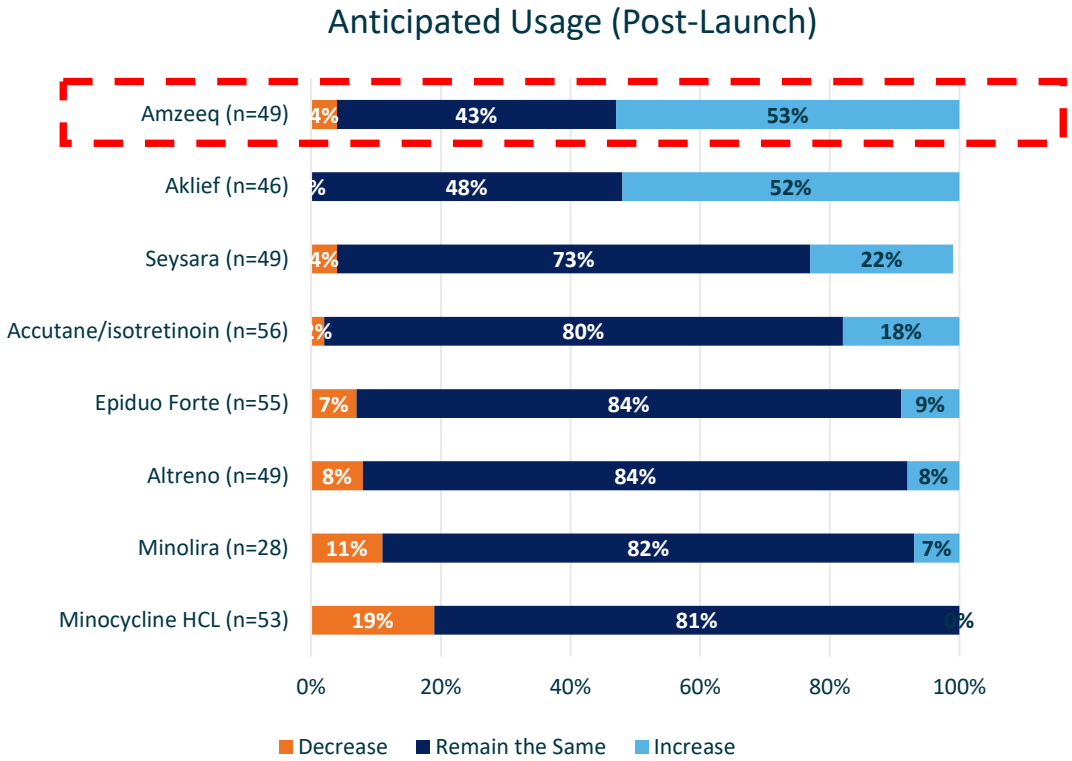


Source: Ipsos Acne Attitude, Trial and Usage (ATU) Report Wave 1 Dec 10, 2019 and wave 2 partial analysis September 30th, 2020
Q105. Which of the following OTC or prescription medications for moderate to severe acne are you aware of?
Note: Partial Sample Only. Data may shift. On list HCPs only. N=56

Future Anticipate Usage

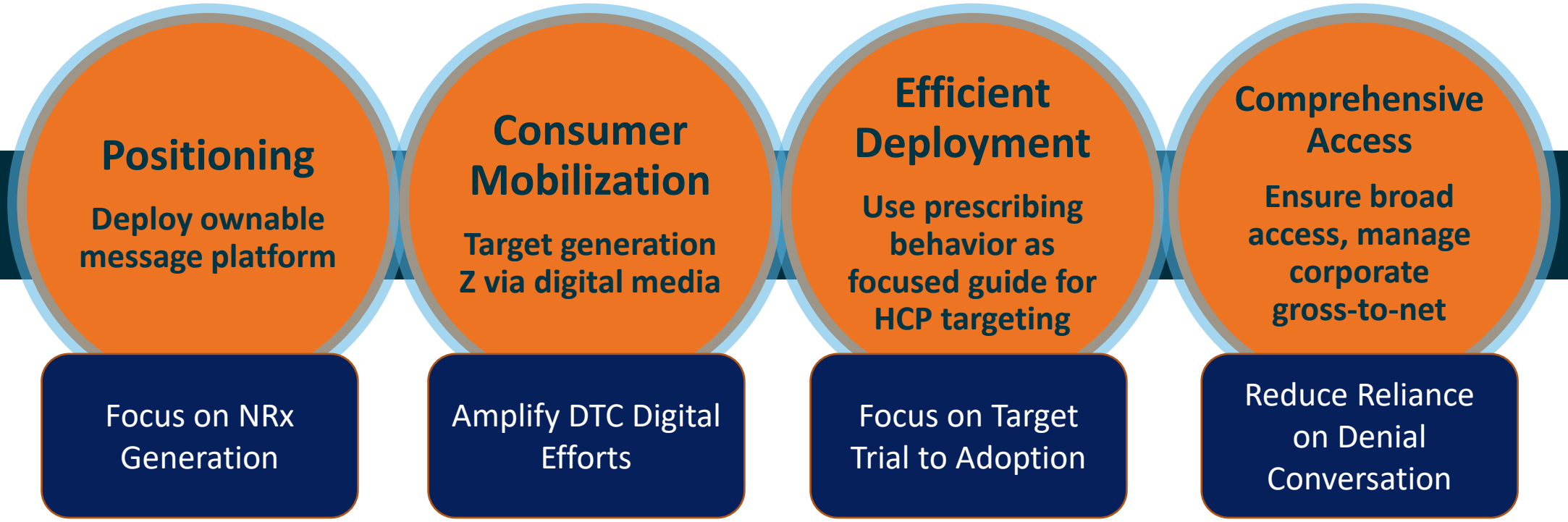
Over 50% of physicians expect their usage of AMZEEQ to increase over the next 6 months.





Source: Attitude, Trial and Usage Study Wave 1 2019 and Wave 2 September 2020
*CAUTION: LOW BASE SIZE / INELLIGIBLE FOR SIGNIFICANCE TESTING
Q130. Over the next 6 months, how do you anticipate your use of the following medications for the treatment of moderate to severe acne to change, if at all? PARTIAL DATA SHOWN FOR WAVE 2; SUBJECT TO REVISION IN FINAL DELIVERABLES

AMZEEQ 2021 Emphasis Areas



AMZEEQ® (MINOCYCLINE) TOPICAL FOAM, 4%: A DERMATOLOGIST POINT OF VIEW

Dr. Ted Lain (Sanova Dermatology)

CONSULTANT DISCLOSURES

- This is an event hosted by VYNE. It is not a CME-accredited program.
- Dr. Lain is a consultant for VYNE and is receiving compensation for his presentation at today's event.
- Dr. Lain also is a speaker for VYNE and is compensated for this role.

APPROACH TO THE ACNE PATIENT

GOAL
01

ACHIEVE THEIR DESIRED OUTCOME

i.e., how much are they willing to do to get to better/clear skin

GOAL
02

OPTIMIZE COMPLIANCE

Will they tolerate retinization? Initial flaring? Take an antibiotic for 2-3 months?

GOAL
03

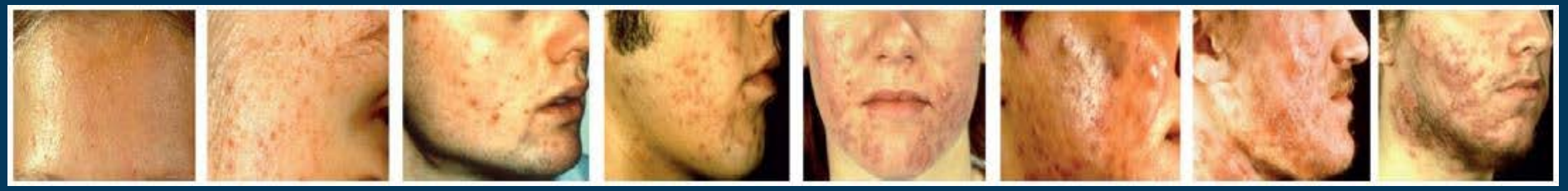
CONSIDER THE MOST LIKELY DRIVER TO INFORM TREATMENT SELECTION

hormonal vs complexion vs bacteria

Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

2016 AAD ACNE MANAGEMENT GUIDELINES

Treatment recommendations for acne vulgaris



	Mild	Moderate	Severe
1st Line	• BPO • Topical retinoid • Topical combination therapy[a] – Antibiotic + BPO – Retinoid + BPO – Antibiotic + retinoid + BPO	• Topical combination therapy[a] – Antibiotic + BPO – Retinoid + BPO – Antibiotic + retinoid + BPO • Oral antibiotic + topical retinoid + BPO • Oral antibiotic + topical antibiotic + topical retinoid + BPO	• Oral antibiotic + topical combination therapy[a] – Antibiotic + BPO – Retinoid + BPO – Antibiotic + retinoid + BPO • Oral isotretinoin
Alternate	• Add topical retinoid or BPO • Consider alternate retinoid • Consider topical dapsone	• Consider alternate combination therapy • Consider change in oral antibiotic • Add combined oral contraceptive or oral spironolactone (females) • Consider oral isotretinoin	• Consider change in oral antibiotic • Add combined oral contraceptive or oral spironolactone (females) • Consider oral isotretinoin

- Currently recommended topical antibiotics include clindamycin and erythromycin **(not recommended as monotherapy because of risk of resistance)**
- Recommended systemic antibiotics include minocycline and doxycycline

AAD=American Academy of Dermatology; BPO=benzoyl peroxide. [a]As a fixed combination product or as separate component.

Zaenglein AL, et al. *J Am Acad Dermatol.* 2016;64:945-973.e33.

MY COMMON SELECTIONS

TOPICALS

- **Retinoids**
- Aklief, Arazlo, Epiduo Forte, Tretinoin .05% cream, Differin.1% gel

- **Non-retinoids:**
- Amzeeq, Aczone, Azeleic Acid, BPO-Clindamycin

SYSTEMICS

- Tetracycline class: Seysara, Doxycycline>>>Minocycline
- Other abx: Amoxil, Bactrim, Clindamycin
- Spironolactone
- Accutane

UNCONVENTIONAL

- Sebacia, Blu-U +/- pdt, peels/facials

Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

WHAT HAS AMZEEQ REPLACED IN MY ALGORITHM?

Clindamycin alone

BPO + Clindamycin

Aczone

Oral antibiotics

Delay isotretinoin use…

Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

FOCUS ON AMZEEQ COMPELLING FACTORS

- Minocycline taken internally has possible side effects & therefore limitations – dizziness, nausea, drug-induced lupus, pigment deposition
  - We know tetracycline-class antibiotics are anti-inflammatory as well as antibiotic
- Antibiotic stewardship & lack of bacterial resistance in *in vitro* studies of AMZEEQ
- No efficacy/tolerability trade-off
- Easily applied to face and trunk

Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

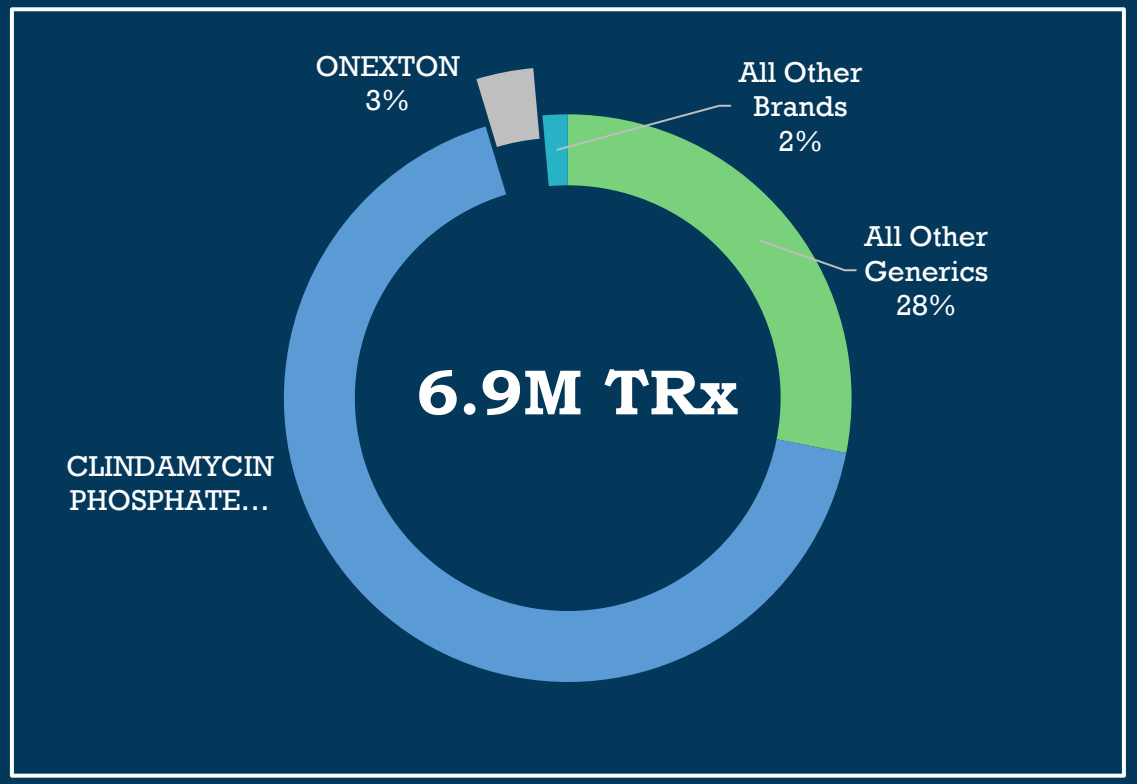
FOCUS ON AMZEEQ COMPELLING FACTORS

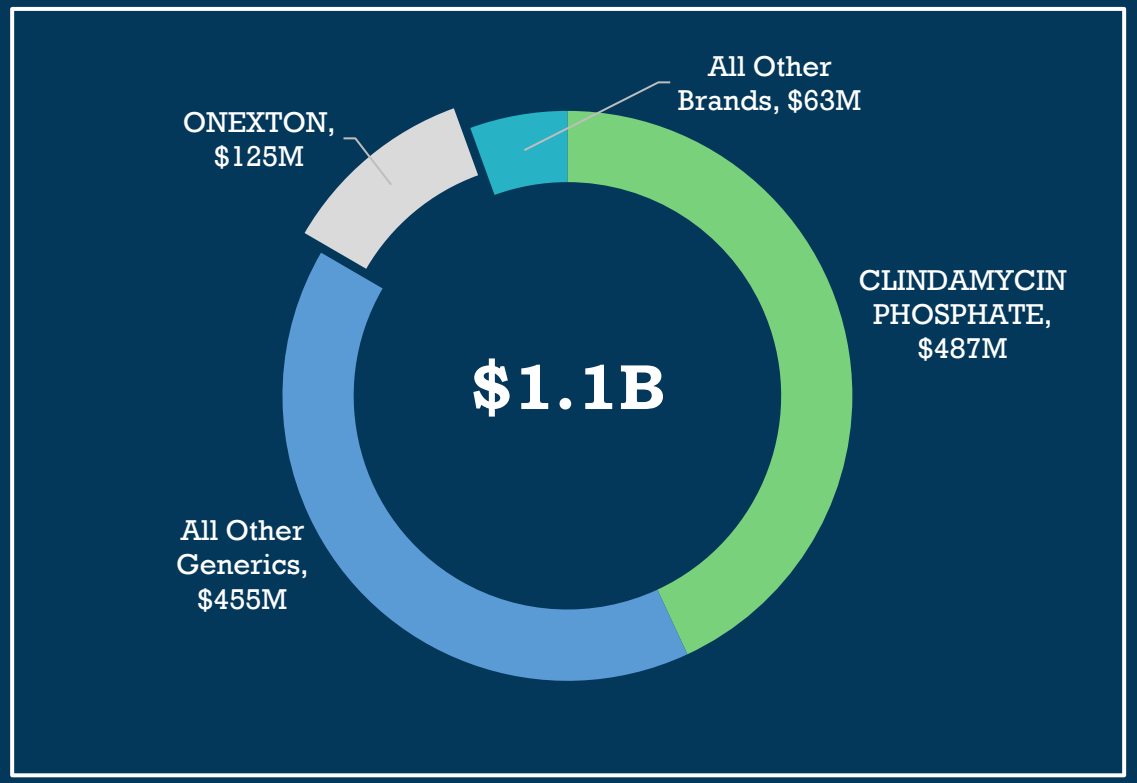
- Numerous studies show community resistance to topical clindamycin has skyrocketed
- "the resistance of *P. acnes* to clindamycin increased from 4% in 1999 to 90.4% in 2016"*
- Hence the need for addition of Benzoyl Peroxide
- Yet prescription numbers for clindamycin lotion/foam/gel are consistently high

* Xu H, Li H. Acne, the Skin Microbiome, and Antibiotic Treatment. Am J Clin Dermatol. 2019;20(3):335-344. doi:10.1007/s40257-018-00417-3

TOPICAL ANTIBIOTIC MARKET VOLUME

~7M topical erythromycin and clindamycin products prescribed in 2019, generating >$1B.





Source: Symphony METYS, unweighted.

Note: All Topical Clindamycin & Erythromycin Products

IGA TREATMENT SUCCESS OF BRANDED COMPETITOR PRODUCTS*

	IGA at Baseline	IGA SUCCESS (Week 12)* Treatment vs Vehicle (%)
AMZEEQ Minocycline foam 4%	3&4	30.8% vs 19.6%
ARAZLO Tazarotene lotion .045%	3&4	29.6% vs 19.5%
AKLIEF Trifarotene Cream .005%	3	42.3% vs 25.7%

* IGA/EGSS Treatment Success rate from individual clinical study with the best clinical response as per the Prescribing Information for the respective product. No head-to-head studies have been conducted and therefore the comparisons are presented for illustrative purposes only.

TOLERABILITY IN PHASE 3 TRIAL WAS EXCELLENT

Study 22 Assessment*	FMX101 (n=737) – n (%)				Vehicle Foam (n=747) – n (%)			
	0=None	1=Mild	2=Moderate	3=Severe	0=None	1=Mild	2=Moderate	3=Severe
Erythema	515 (82.7)	100 (16.0)	11 (1.8)	0 (0.0)	514 (82.5)	98 (15.7)	11 (1.8)	0 (0.0)
Dryness	568 (90.7)	53 (8.5)	5 (0.8)	0 (0.0)	550 (88.3)	68 (10.9)	4 (0.6)	1 (0.2)
Hyperpigmentation†	536 (85.6)	75 (12.0)	14 (2.2)	1 (0.2)	515 (82.7)	90 (14.4)	17 (2.7)	1 (0.2)
Skin Peeling	607 (97.0)	18 (2.9)	1 (0.2)	0 (0.0)	587 (94.2)	33 (5.3)	2 (0.3)	1 (0.2)
Itching	588 (93.9)	30 (4.8)	7 (1.1)	1 (0.2)	577 (92.6)	40 (6.4)	6 (1.0)	0 (0.0)

*Based on safety population. Prospective assessment of cutaneous tolerability.
†The term hyperpigmentation was most commonly used to describe localized post-inflammatory darkening of the affected skin.

AMZEEQ PATIENT SELECTION

01.

Patients sensitive to side effects

- Teenage girls
- Adult women

02.

Patients needing combination therapy

- Teenage girls
- Adult women

03.

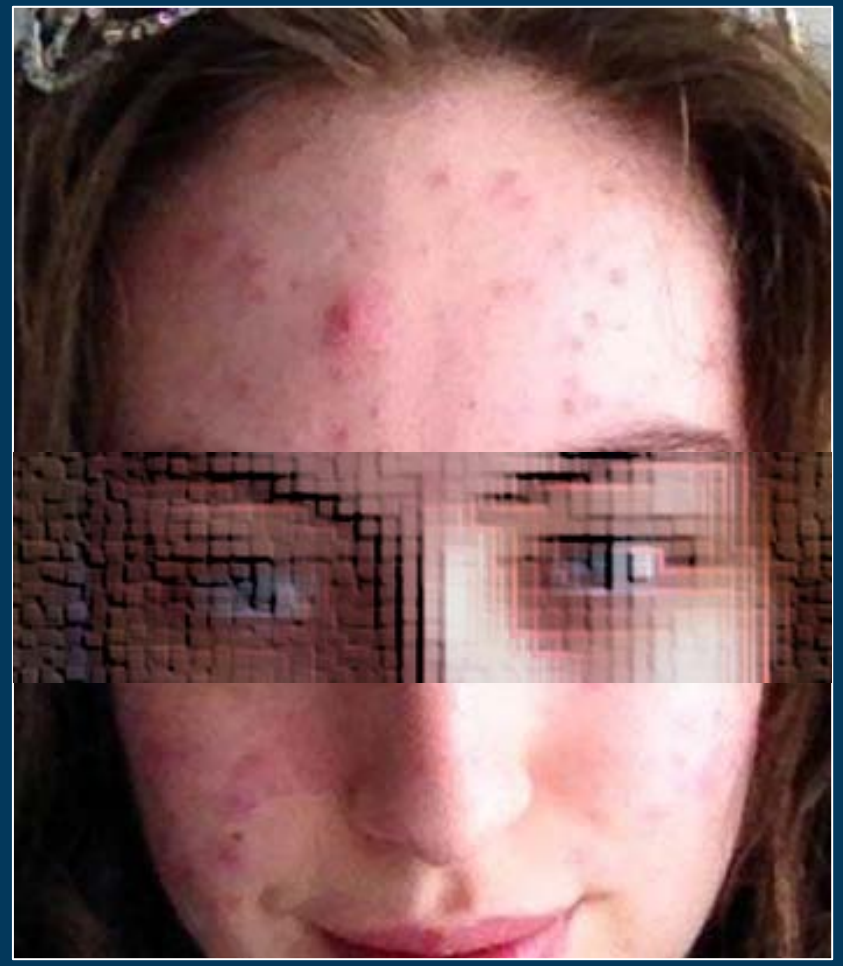
Patients wanting/needing to avoid systemic therapy

Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

REPRESENTATIVE EXAMPLES OF ACNE PATIENTS

17-YEAR OLD FEMALE

with mixed acne, anxious about her skin texture and tone, scratches at her acne bumps and wears copious makeup



TREATMENT CONSIDERATIONS

- Birth Control vs Spironolactone vs Oral antibiotic
- AM: ACZONE
- PM: AMZEEQ

REPRESENTATIVE EXAMPLES OF ACNE PATIENTS

32-YEAR OLD WOMAN

with acne that just started, worse around menses, not responding to multiple OTC treatment options

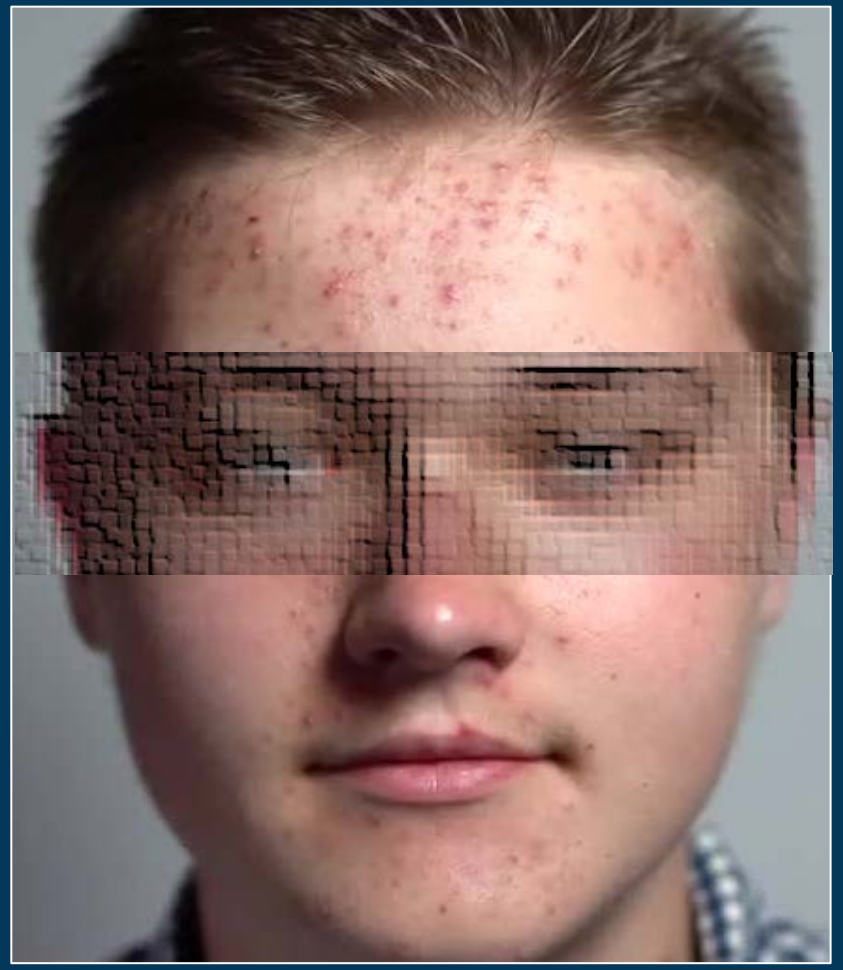
TREATMENT CONSIDERATIONS

- Spironolactone
- Amzeeq either AM or PM

REPRESENTATIVE EXAMPLES OF ACNE PATIENTS

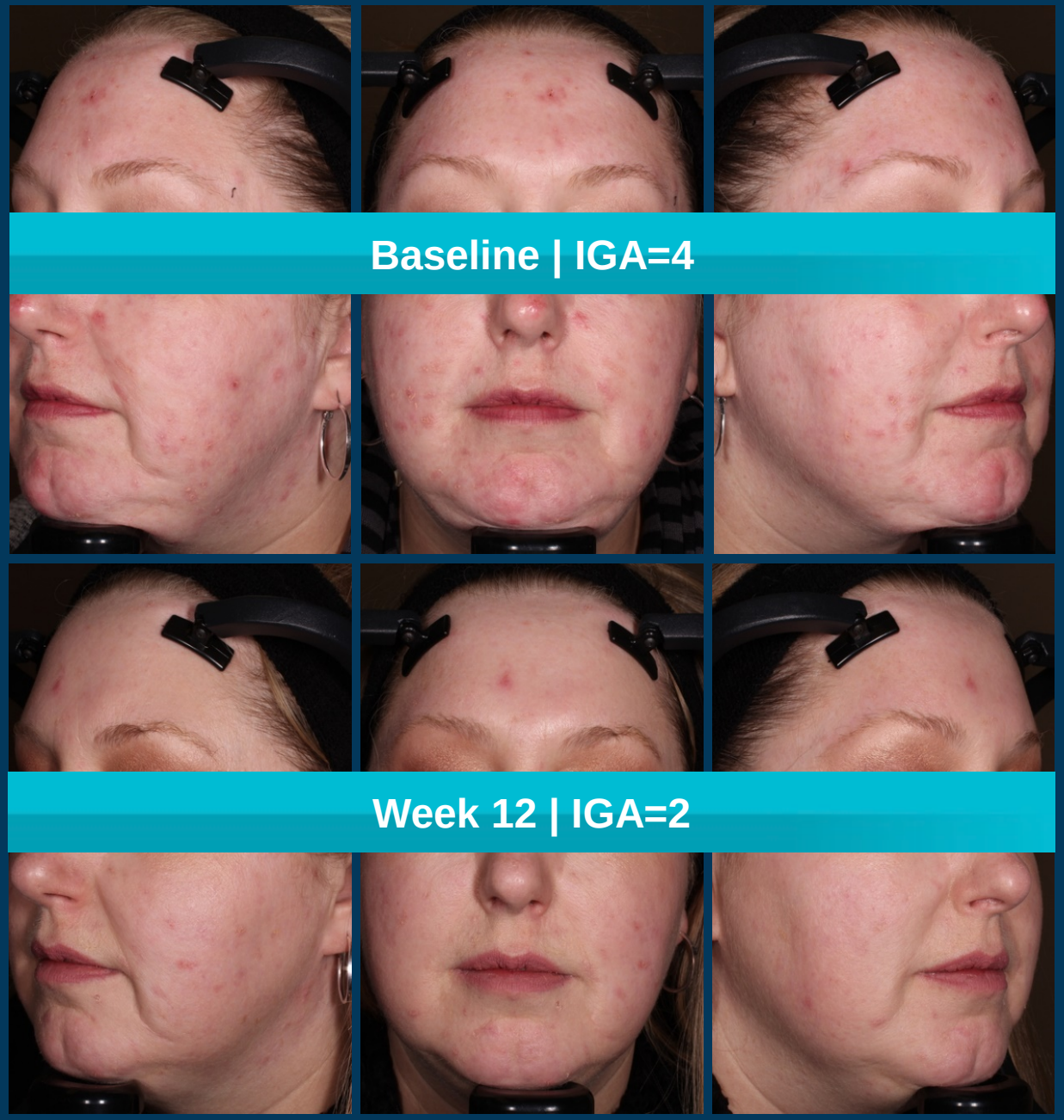
15-YEAR OLD MALE

with mixed inflammatory and non-inflammatory lesions, brought in by Mom, not worried too much about his acne



TREATMENT CONSIDERATIONS

- AM: AMZEEQ
- PM: RETINOID+/- BPO



Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

amzeeq
(minocycline)
topical foam,4%

AMZEEQ CLINICAL TRIAL PATIENT: IMPROVEMENT FROM "SEVERE" TO "MILD

The average percent reduction in inflammatory lesions and percent of patients achieving IGA endpoint success with AMZEEQ vs. vehicle at Week 12 was -43% to -54% and 8.1% to 30.8%, respectively.

IGA endpoint success at Week 12 is defined as an IGA score of 0 or 1 (clear or almost clear), and at least a 2-grade improvement (decrease) from baseline.

Clinical pictures used with permission. Photos from individual patients may not be typical, as individual results vary.

IMPORTANT SAFETY INFORMATION

Indication

AMZEEQ® (minocycline) topical foam, 4% is a topical form of the antibiotic minocycline for the treatment of pimples and red bumps (non-nodular inflammatory lesions) that happen with moderate to severe acne in adults and children 9 years of age and older. AMZEEQ is available by prescription only.

AMZEEQ should not be used for the treatment of infections. It is not known if AMZEEQ is safe and effective in children under 9 years of age. **AMZEEQ is for use on skin only (topical use). AMZEEQ is not for use in the mouth, eyes or vagina.**

Important Safety Information

- AMZEEQ should not be used in people who are allergic to AMZEEQ or any tetracycline medicine. Use of AMZEEQ should be stopped right away if a rash or other allergic symptom occurs.
- AMZEEQ should not be used in women who are pregnant, may become pregnant or are nursing. If a woman becomes pregnant while using AMZEEQ, she should talk to her doctor. Tetracycline medicine when taken by mouth during pregnancy, infancy and/or childhood up to the age of 8 years may permanently discolor teeth (yellow-gray-brown) and may slow the growth of bones.
- AMZEEQ is flammable and fire, flame, and smoking must be avoided when applying and right after applying AMZEEQ.
- People should protect their skin from the sun while using AMZEEQ and avoid sunlight or artificial sunlight such as sunlamps or tanning beds. Use of AMZEEQ should be stopped if skin is sunburned.
- When taken by mouth, minocycline may cause feelings of lightheadedness, dizziness or spinning. People should not drive or operate dangerous machinery if they have these symptoms.

AMZEEQ is a topical foam that contains minocycline, a tetracycline medicine. It is not taken by mouth. However, tetracyclines, when taken by mouth (capsules or tablets), may cause serious side effects, including: diarrhea, including watery or bloody stools; loss of appetite; tiredness; yellowing of the skin or eyes; bleeding more easily than normal; confusion; sleepiness; vision changes, including blurred vision, double vision, or permanent vision loss; unusual headaches; fever; rash; joint pain; body weakness; discoloration or darkening of the skin, scars, teeth, or gums. People should call their doctor right away if these side effects occur.

The most common side effect of AMZEEQ is headache.

These are not all of the possible side effects with AMZEEQ. People should contact their doctor for medical advice about side effects and be sure to tell their doctor about all of their medical conditions and medicines they take before using AMZEEQ.

People are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see Patient Information leaflet.

AMZEEQ®:
(MINOCYCLINE) TOPICAL FOAM, 4%

October 1st, 2020

Presented by

DR. JULIAN O'Neil MOORE

VYNE™ THERAPEUTICS

CONSULTANT DISCLOSURES

- This is an event hosted by VYNE. It is not a CME-accredited program.
- Dr. Moore is a consultant and a speaker for VYNE and is receiving compensation for his presentation at today's event.
- Dr. Moore also is a speaker for VYNE. Dr. Moore is compensated for this role.
- All clinical pictures used in this presentation have been cleared and consented for use by patients.
- Individual results may vary.

HISTORICAL TREATMENT APPROACH

Topicals

ORAL MEDICATION (Antibiotics) RX Topicals

ORAL MEDICATION
Plus Topical or Oral Isotretinoin

EPIDEMIOLOGY OF ACNE VULGARIS IN THE UNITED STATES

50 Million

People have acne vulgaris

Affects roughly 85% of teenagers, but can occur in most age groups, persisting into adulthood

Associated with significant physical and psychological morbidity (e.g. permanent scarring of the skin, poor self-image, depression, anxiety)

Direct and indirect cost is established to be > $3 billion per year

References 1. Zaenglien AL, Pathy AL, Scholosser BJ, et al. Guidelines of care for the management of acne vulgaris. J *Am Acad Dermatol.* 2016; 74(5);945-973. 2. Bicker DR, Lim HW, Margolis DM, et al. The burden of skin diseases: 2004. A joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology. *J Am Acad Dermatol.* 2006;55(3):490-500.

amzeeq™
(minocycline)
topical foam, 4%

Efficacy	Safety	Patient Experience	RESULTS	RESOURCES
Great results Lower Systematic exposure	Minimal Adverse Event Profile 95 % of skin reactions were considered none or mild in the Phase 3 clinical trials.[1]	Less Irritation Ease of use Product feel Overall product satisfaction	Significant reduction in inflammatory lesions	Eligible patients pay as low as $35

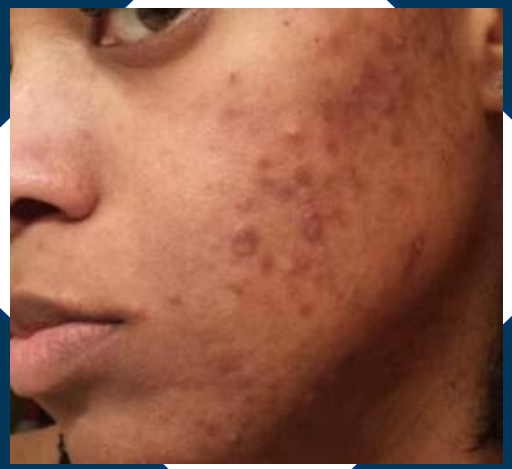
1. Please see important safety information on slide 57

AMZEEQ USE

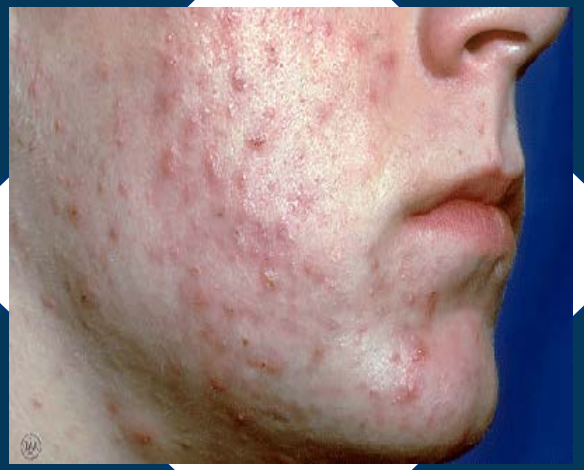
amzeeq™
(minocycline)
topical foam, 4%

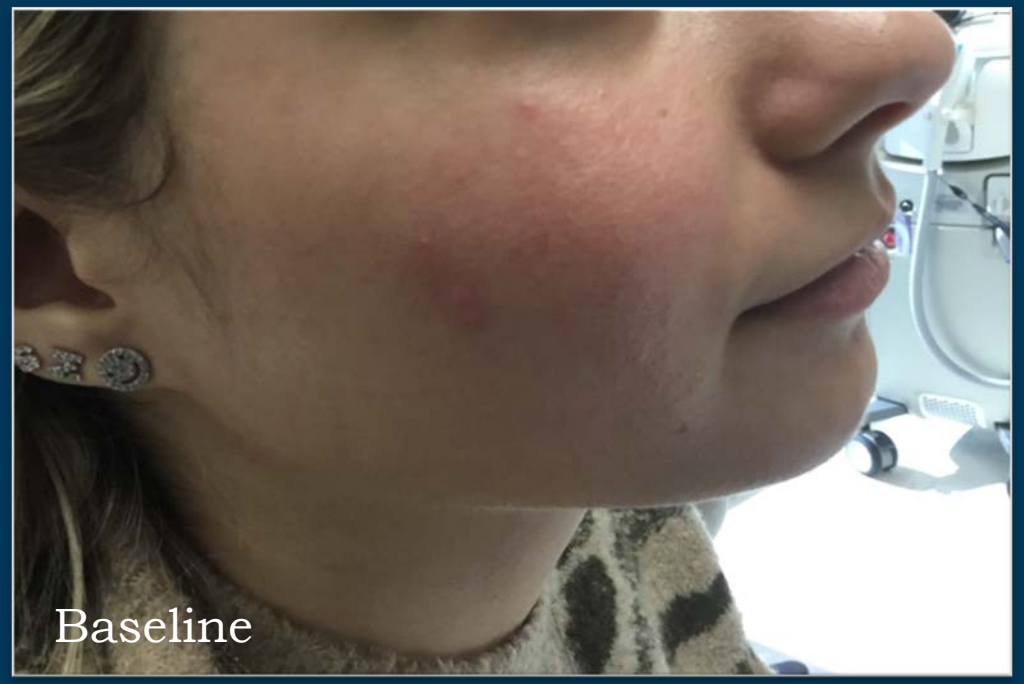
Novel Foam Formulation

MODERATE



SEVERE





Patient 1

Female
Age: 18
White American
Diagnosis: Moderate Acne for 1 Year

Tried & Failed:

OTC Medications
Rx Clindamycin with no improvement. Patient also stated she tried a Retinoid and it made her acne worse.

Treatment:

Amzeeq

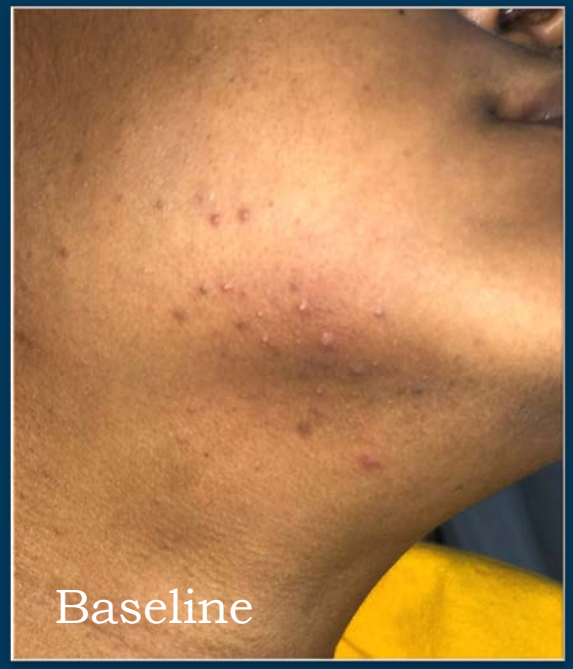
Results

- Reduction in Inflammatory lesions
- Less Dryness
- Clearance achieved and maintained

Patient 2

Female
Age: 21
African American/ Caribbean
Diagnosis: Moderate Acne
> 3 Years

Tried & Failed:
OTC Medications
Clindamycin
Mother against Oral antibiotics (Nurse)



RESULT

- Prescribed Amzeeq QAM. Also prescribed Retinoid/BP QHS.
- Reduction in Inflammatory lesions
- Reduction in Hyperpigmentation
- Well tolerated
- Clearance achieved and maintained

Patient 3

Female
Age: 30
African American

Diagnosis: Moderate/Severe Acne > 3 Years

Tried & Failed:
Clindamycin – Dryness
Doxycycline (Stopped due to Side Effects)

Treatment

Patient using Amzeeq QAM. Patient also using Retinoid/BP QHS.

Result

- Reduction in Inflammatory Lesions
- Less Dryness
- Reduction in Hyperpigmentation

Patient 4

Female
Age: 25
Diagnosis: Moderate Acne > 3 Years
Indian

Tried & Failed:
OTC Medications
Clindamycin

Treatment:
Patient using Amzeeq Q AM.
Patient also using Retinoid/BP
QHS

Result

- Reduction in inflammatory lesions
- Less Dryness
- Reduction in hyperpigmentation

Patient 5

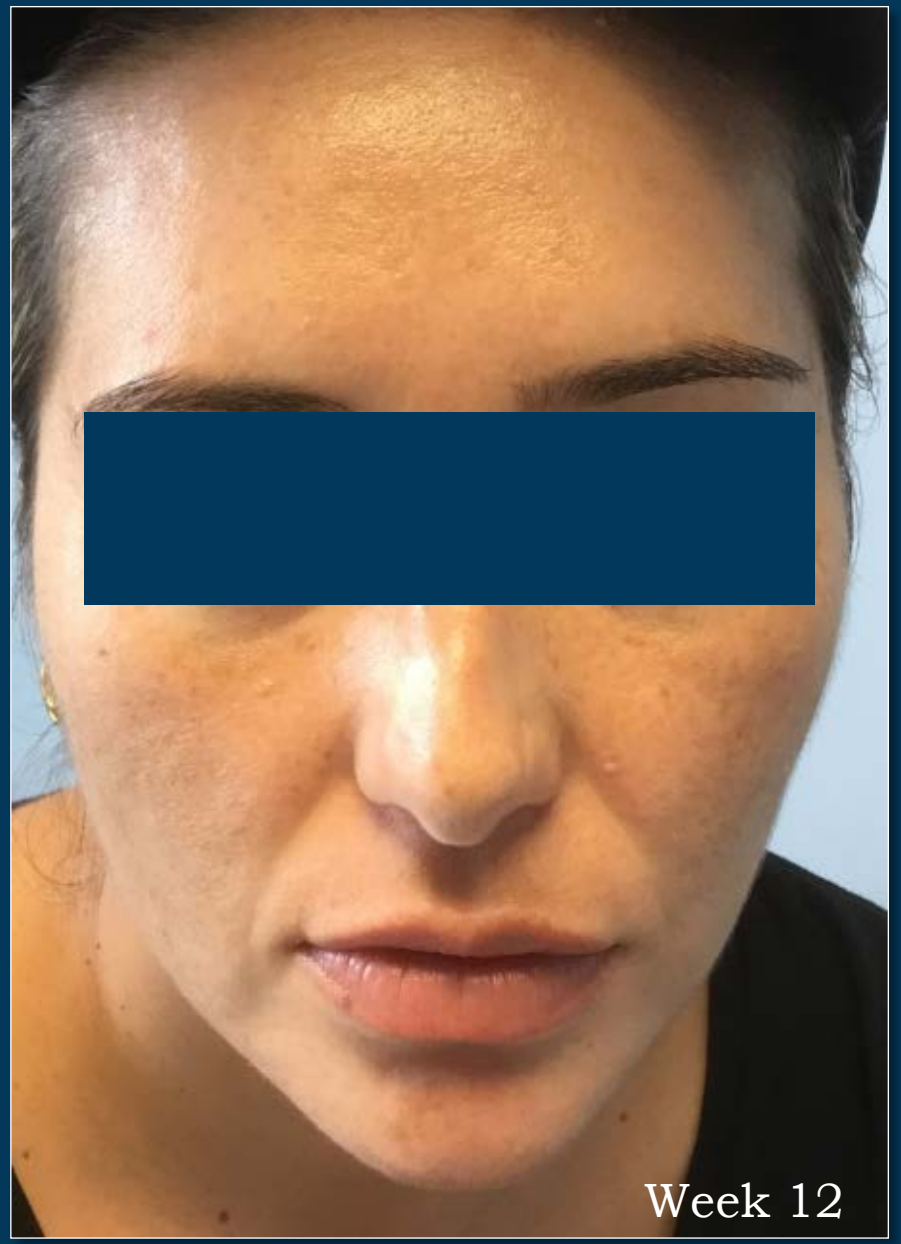
Female Age 33
Latin American
Diagnosis: Moderate Acne > 5Years

Tried & Failed:
Retinoids: Successful but Adverse effects intolerable
Minocycline: Oral and developed hyperpigmentation

Treatment Plan:

Amzeeq QAM and Spironolactone 50mg QD.

Result:
- Reduction in Inflammatory lesions
- Less Dryness
- Patient was compliant with treatment



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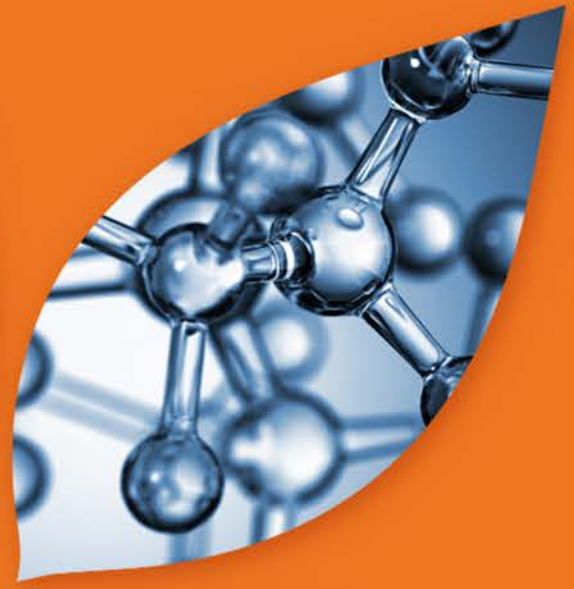
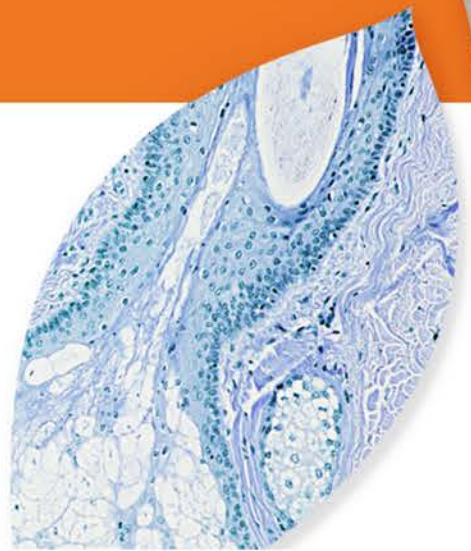
Please see Patient Information leaflet.

Physician Symposium on AMZEEQ® and ZILXI™

Matt Wiley, CCO

October 1, 2020

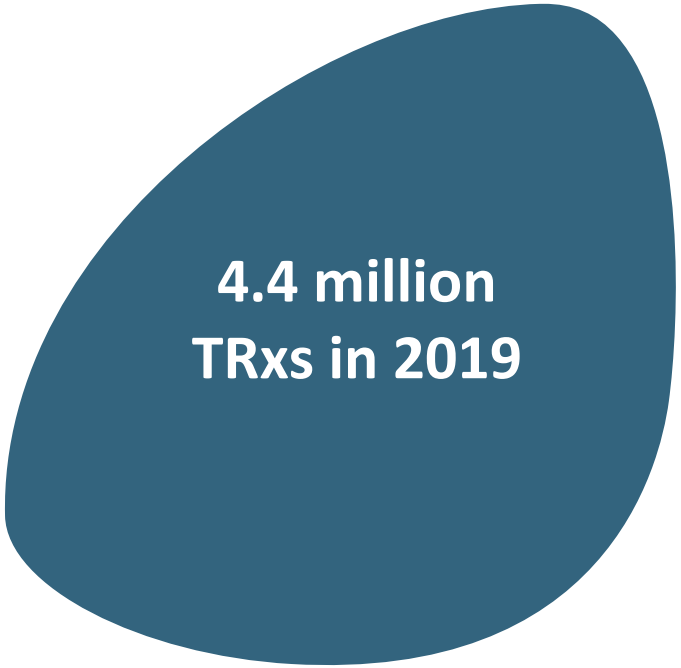


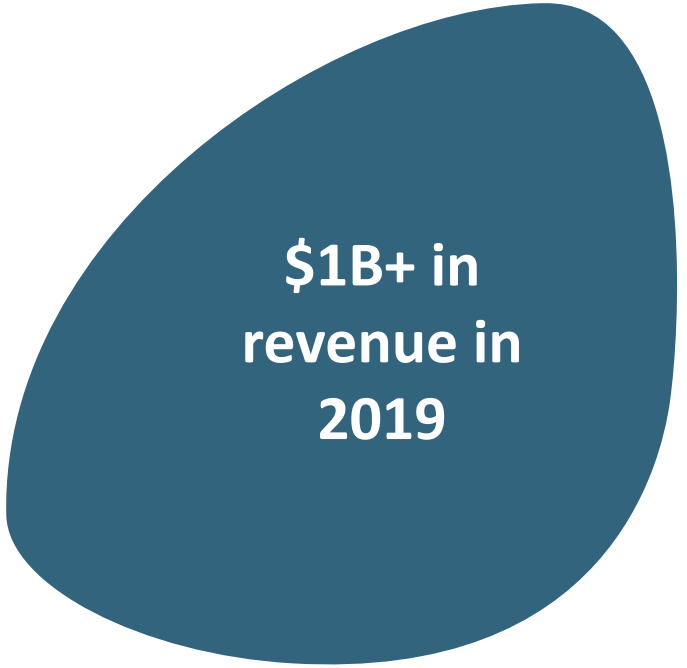


VYNE™ THERAPEUTICS

Rosacea Market Size

Large dynamic and underserved market

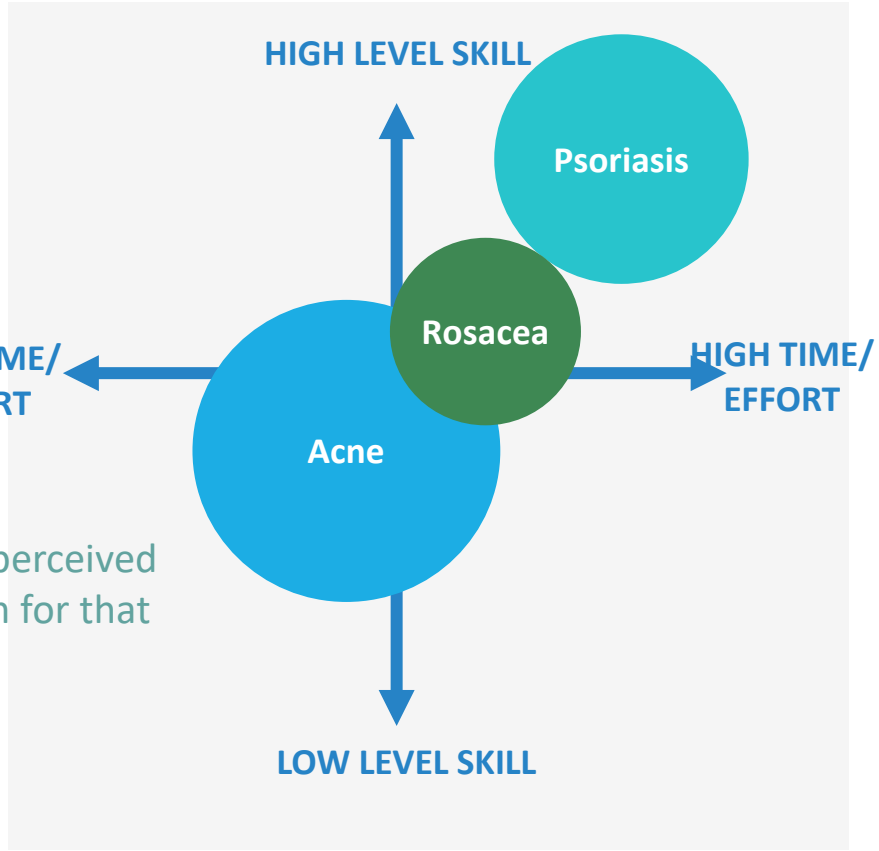




Source: Symphony Health Solutions METYS, data ending DEC'19- weighted

Rosacea Unmet Need: HCP Perceptions

HCPs feel they have a smaller armamentarium to treat rosacea, and less predictability of response relative to other dermatology conditions



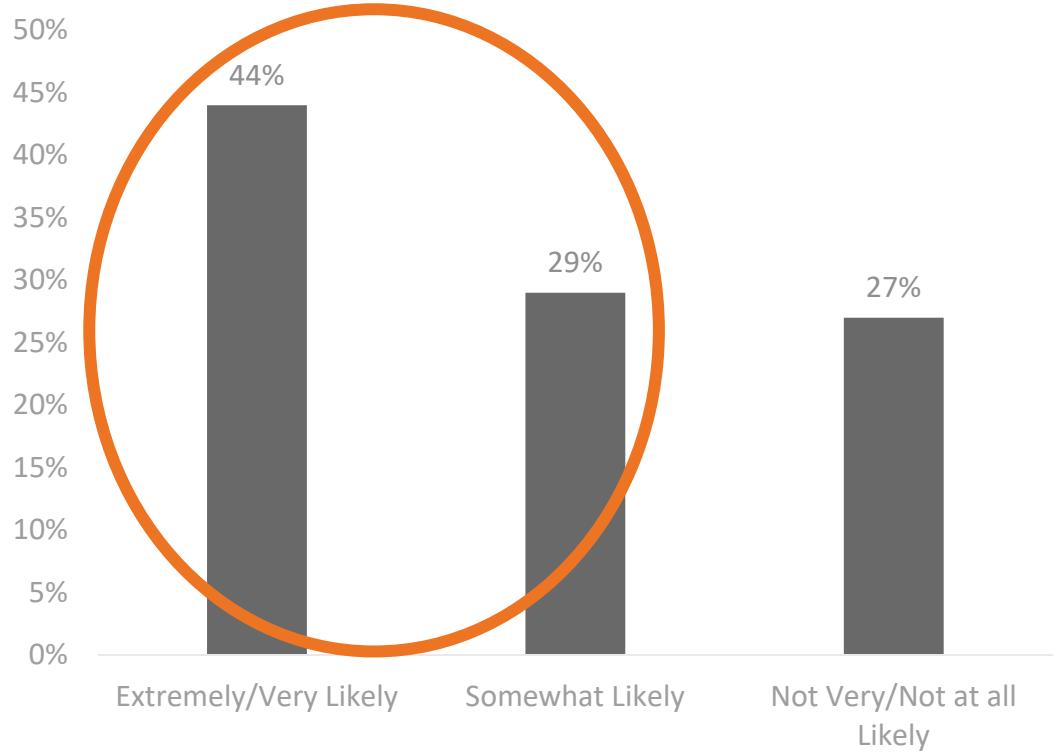
Size of circle indicates perceived size of armamentarium for that condition

SOURCE: Harper Global HCP IDIs March 2019

Rosacea Patient Dissatisfaction

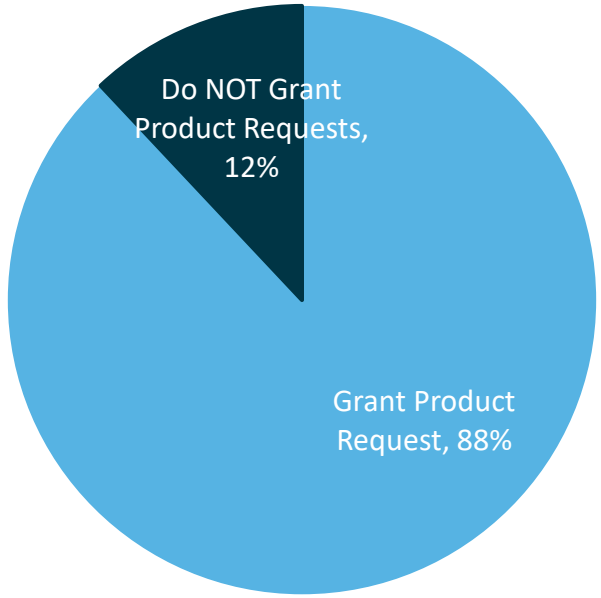
73% of patients have indicated that they are at least somewhat likely to seek a better solution for their rosacea, and HCPs very likely to grant patient requests for a specific product

Patient Likelihood to Seek Better Solution



SOURCE: FMX103 Demand Study, Consumer Arm June 2019
Note: Rx users only n=156 Q.6 - How likely are you to seek a better solution for treating your rosacea?

HCP Action After Patient Requests Product



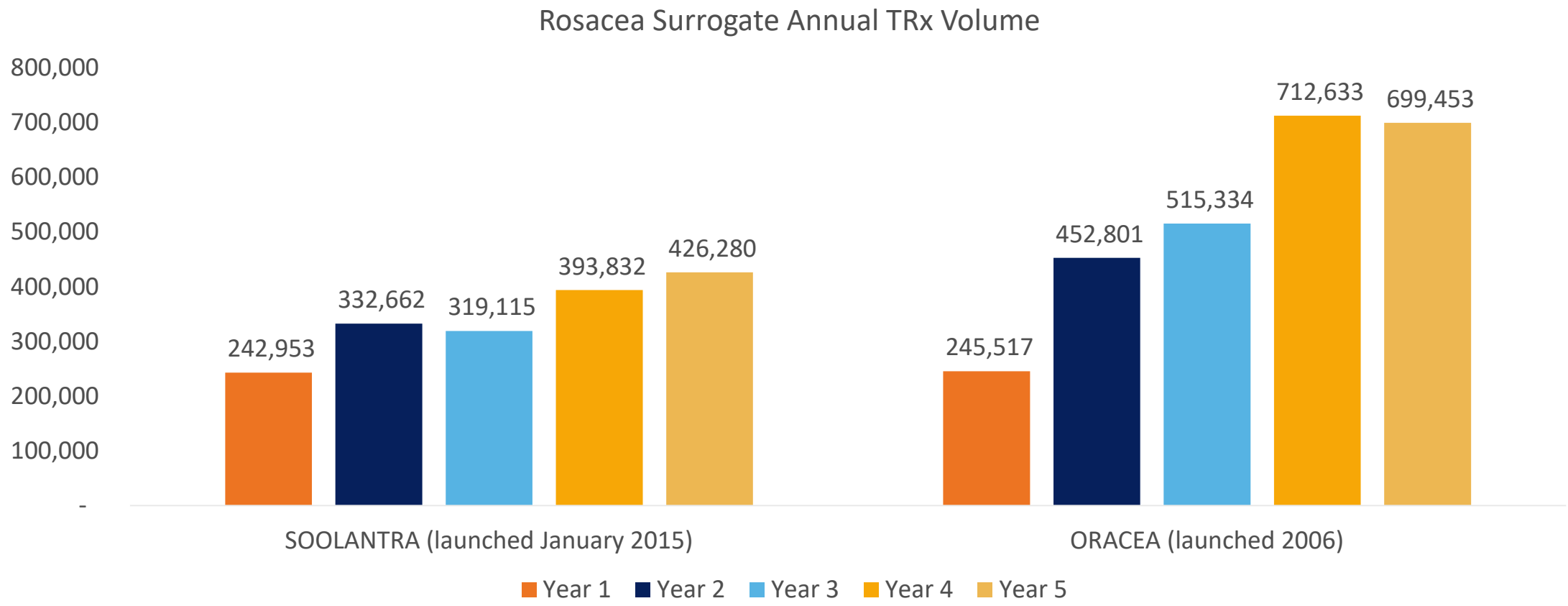
SOURCE: Awareness, Trial and Usage Study, IPSOS, 2020. Q For each medication, how many of those patients' requests did you honor? Note: average of responses Number of requests considered in this analysis=75

Life with Rosacea: Patient Perspective

Source: "11 People Describe What It's Really Like to Have Rosacea" Sarah Jacoby, Self Magazine, May 14, 2018
self.com/story/what-its-really-like-to-have-rosacea

Launch Surrogates

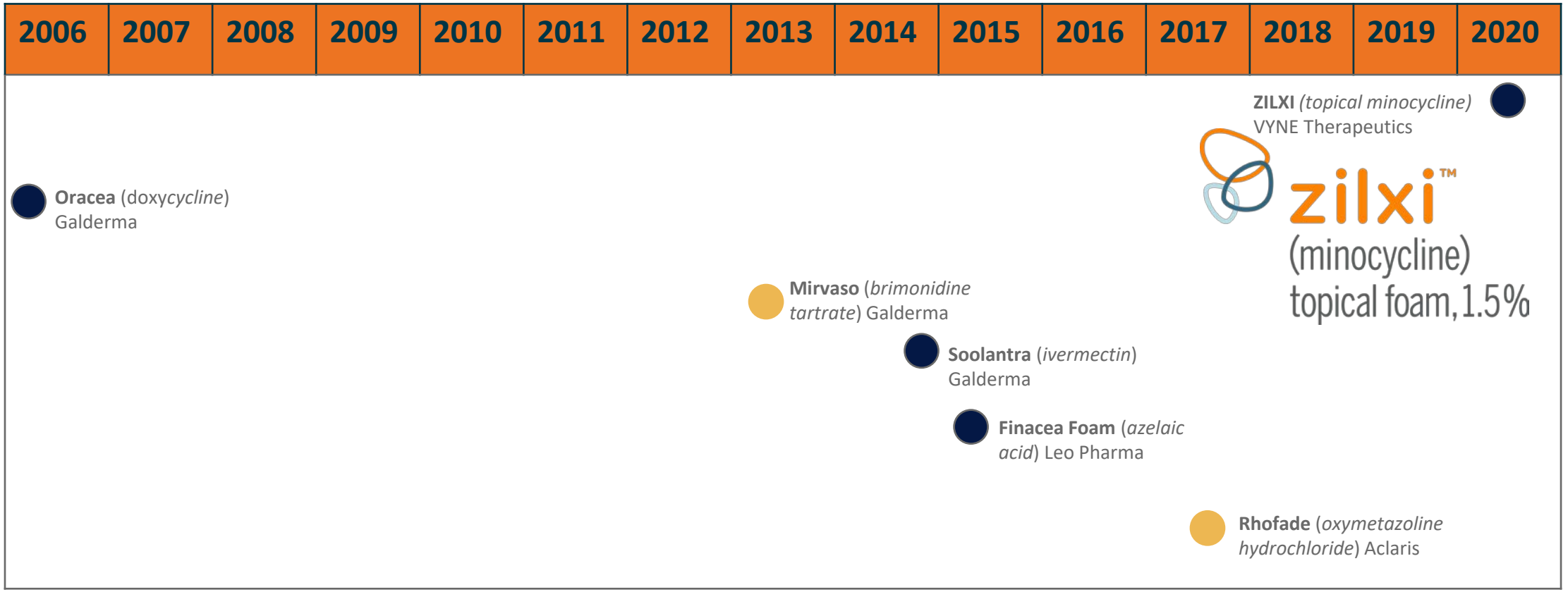
Surrogates suggest strong adoption for launch products in rosacea, generating ~250k prescriptions in first full year.



Source: Source: Symphony METYS, unweighted. Note: Oracea launch curve from Symphony PHAST, unweighted.

Rosacea Marketed Products Overview

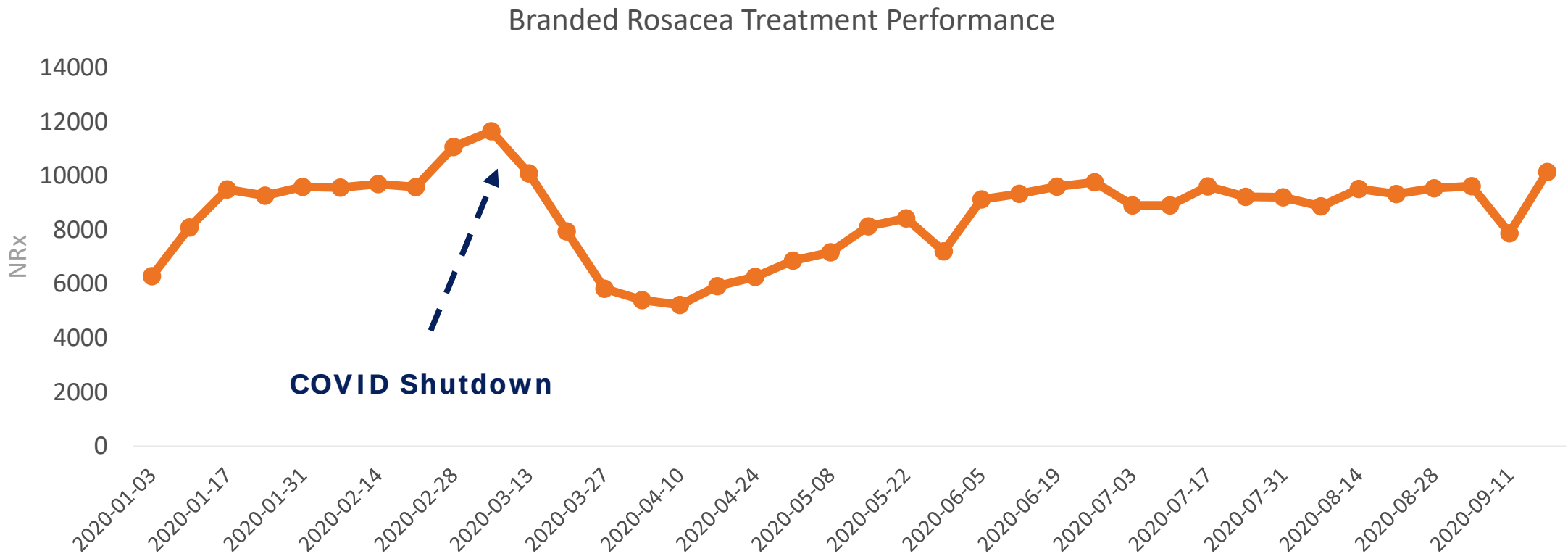
ZILXI is the first new option for papulopustular rosacea in 5+ years.



Sources: Evaluate Pharma Rosacea, Accessed Sep 2019. Package Inserts.

Rosacea Branded Market Performance

Weekly prescriptions recovered since COVID shutdowns

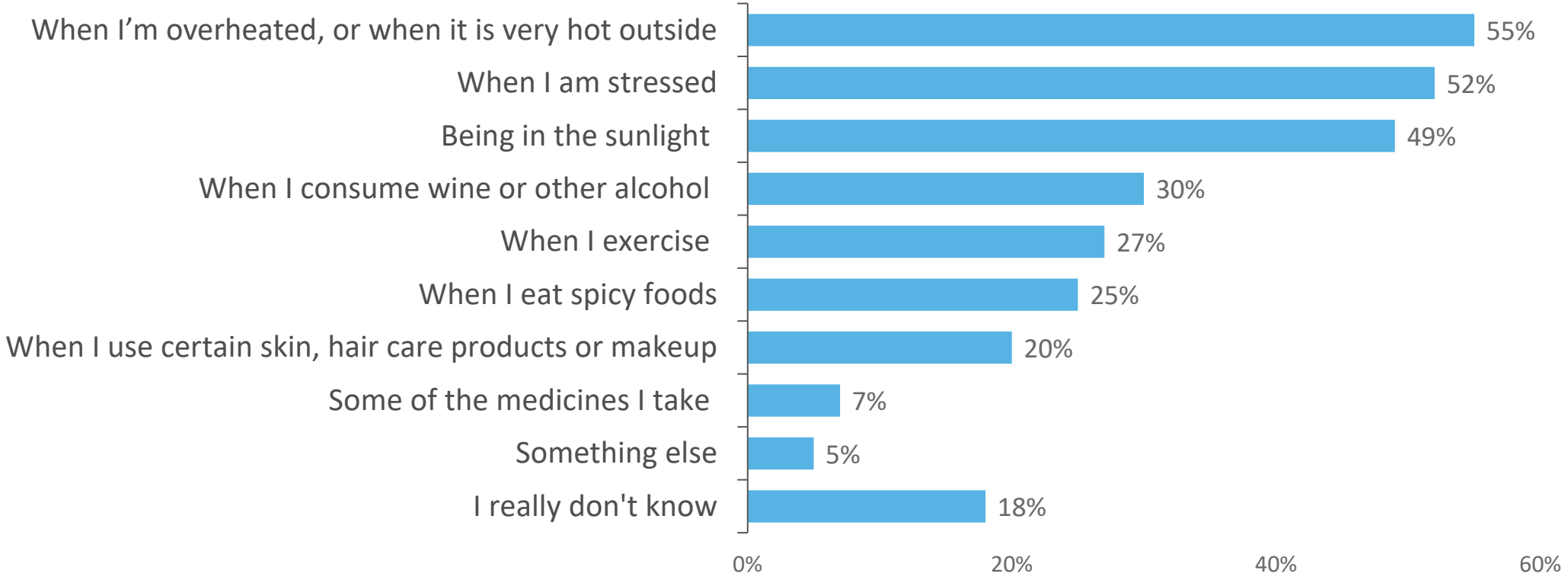


Source: METYS, unweighted 09/18/20

Rosacea Triggers

Heat and stress are biggest triggers of rosacea

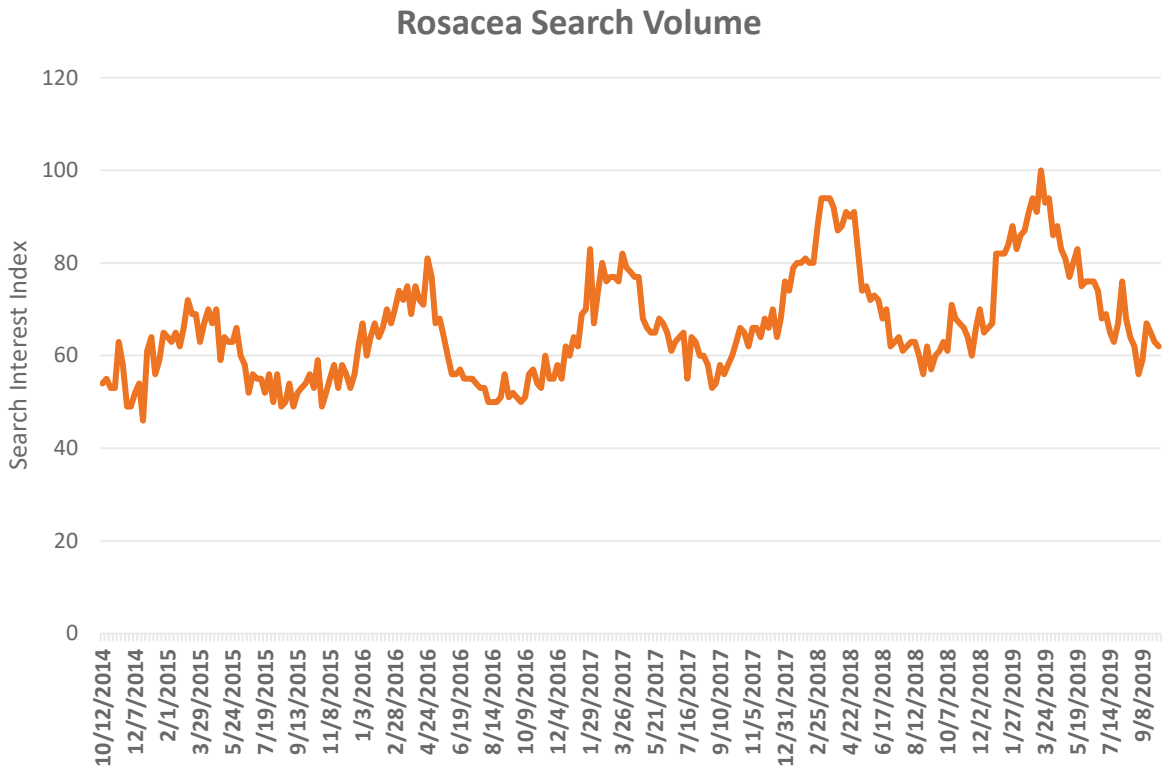
What Worsens or Triggers Rosacea

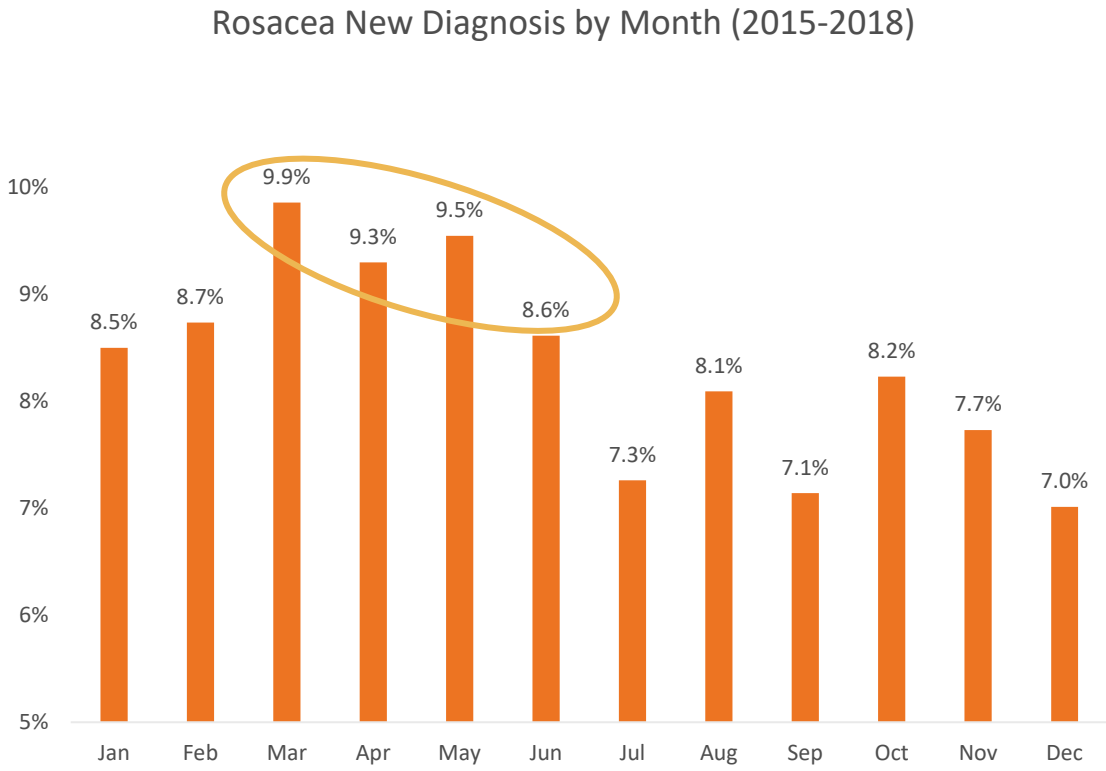


Source -FMX103 Demand Study, Consumer Arm June 2019
Q.11 - Which of the following things, if any, do you feel makes your rosacea worse or triggers it? Select all that apply.
N=100

Rosacea Seasonality

Transition to warmer months (March/April) trigger consumer online search and new diagnoses

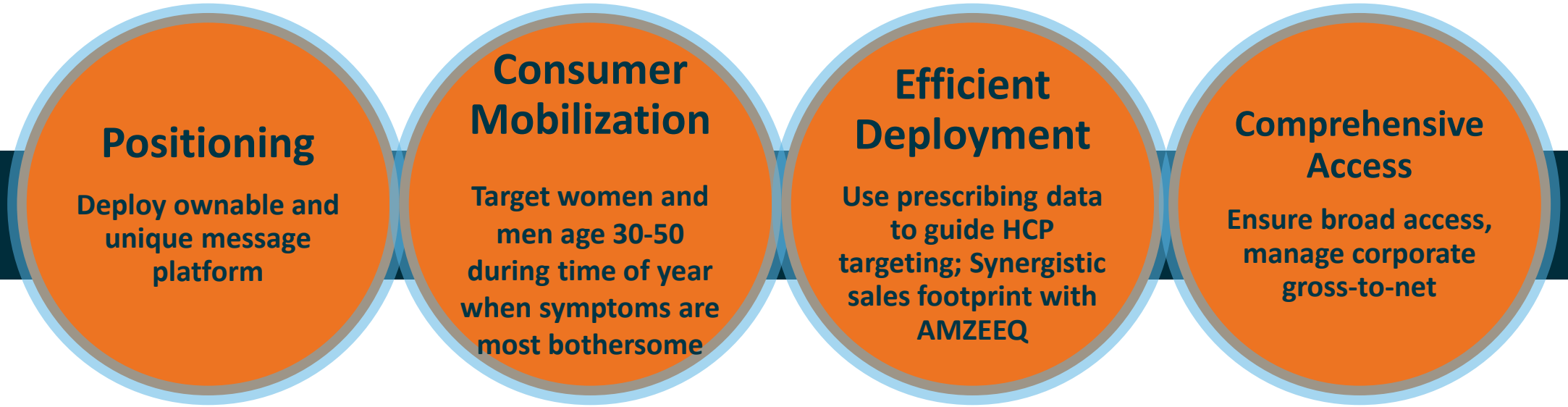




Source: Symphony Health

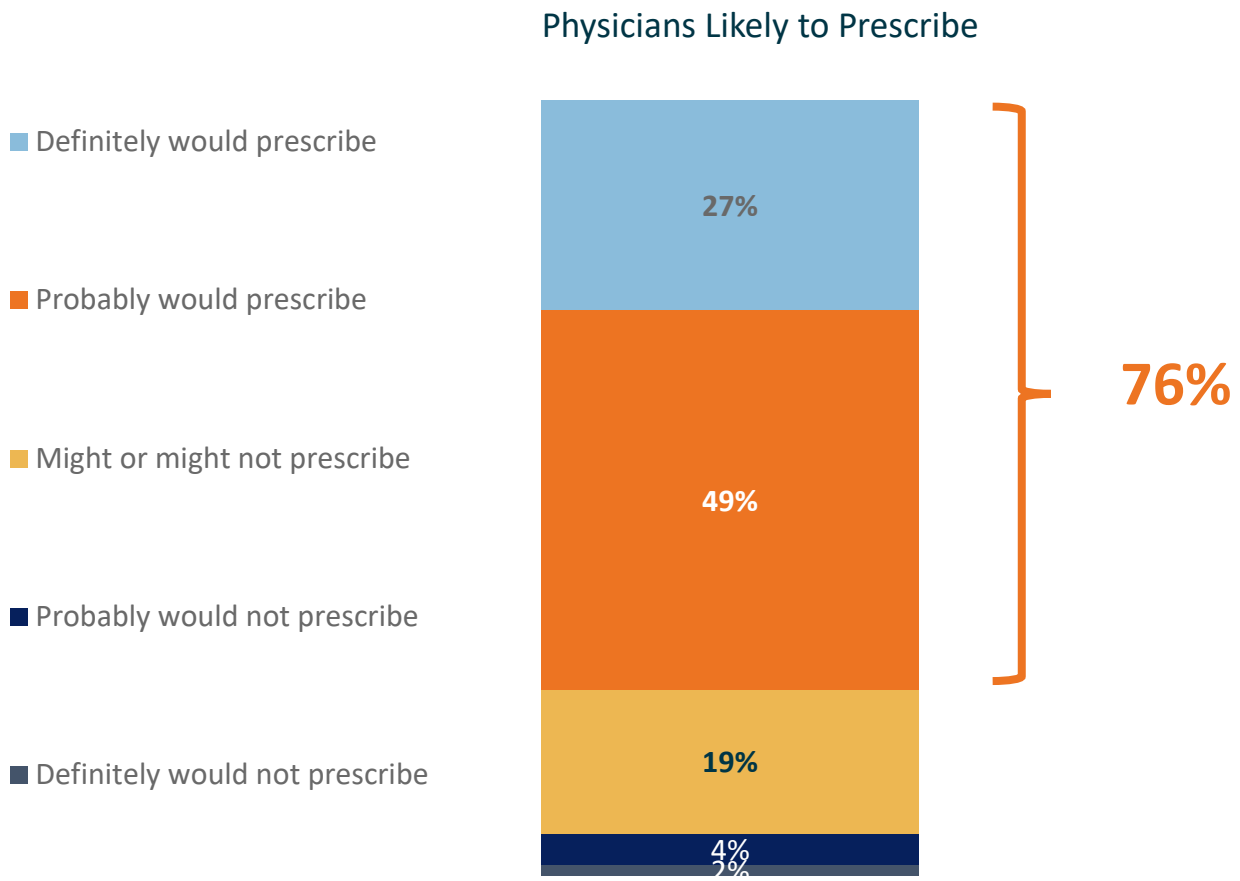
Source: Google Trends & Key Planner's Historical Metrics 10/12/14 to 10/6/19
Note: "search interest index" is the relative popularity of a keyword and is the ratio of a query's search volume to the sum of the search volumes of all possible queries, scaled on a range of 0 to 100 based on a topics proportion to all searches.

ZILXI Launch Strategy



Intent to Treat

76% of physicians are likely to prescribe ZILXI based on blinded product profile

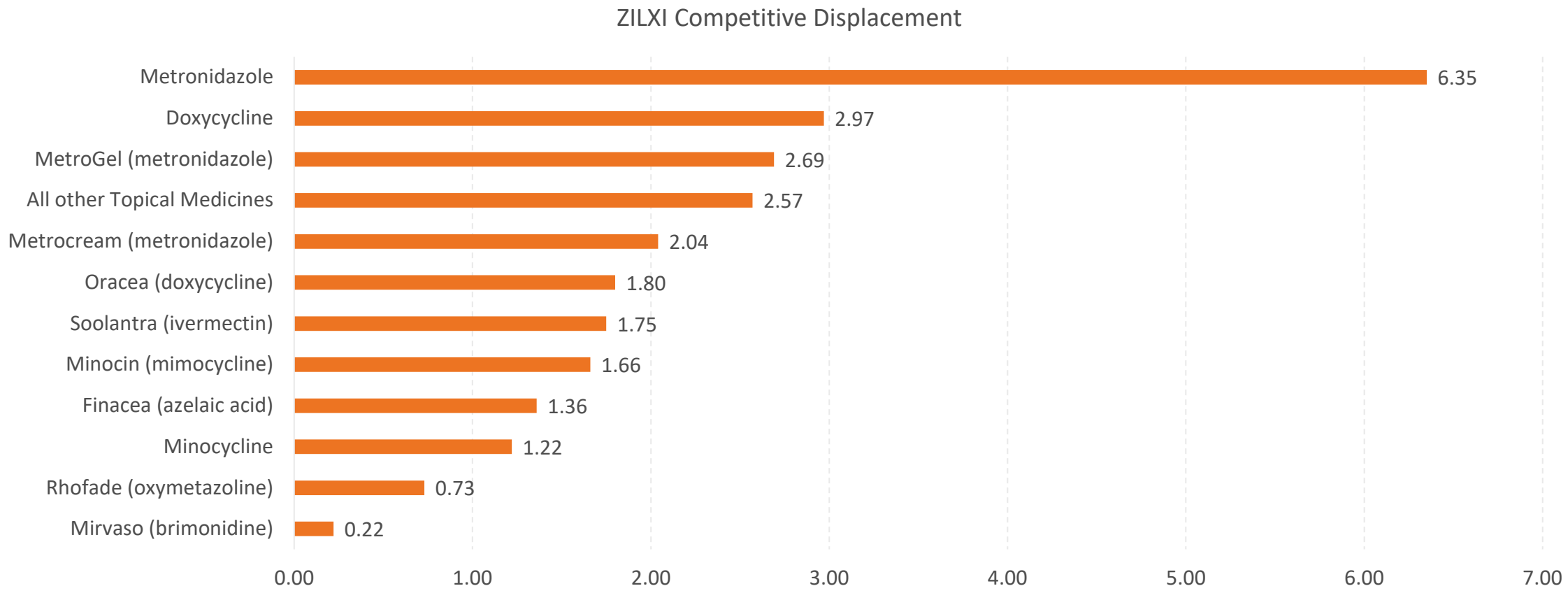


Source: Ipsos HCP ATU September 2020 Topline Report
Q630. How likely would you be to prescribe Product X for patients with moderate-to-severe papulopustular rosacea?

N=200

ZILXI Sources of Share

ZILXI taking share primarily from metronidazole and doxycycline, disrupting the market overall



Source: FMX103 Demand Study, HCP Arm June 2019 N=306

ZILXI Campaign

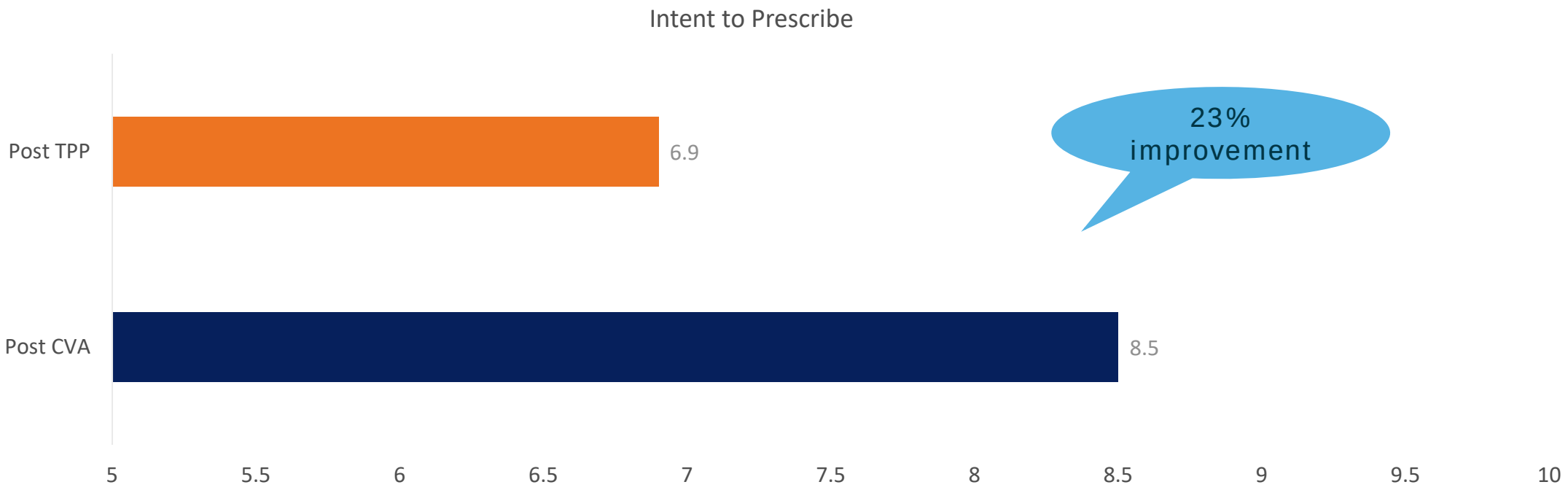
Core Visual Aid (CVA)

The Core Visual Aid (CVA): Primary Promotional Asset Presents ZILXI Through A Simple, Motivating Story

- Minocycline, trusted molecule
- Molecule stabilizing technology (MST™)
- ZILXI: Redefining topical therapy for rosacea
- Efficacy of ZILXI
- Demonstrated safety for long-term use
- Well-tolerated on already-sensitive skin
- Convenient, once-daily formulation
- Affordable for patients

Market Research: ZILXI Intent to Prescribe

- 8.5 out of 10 are likely to use after hearing the complete ZILXI promotional story (23% improvement from rating for blinded profile)



Source: ZILXI Core Visual Aid Testing, July 2020

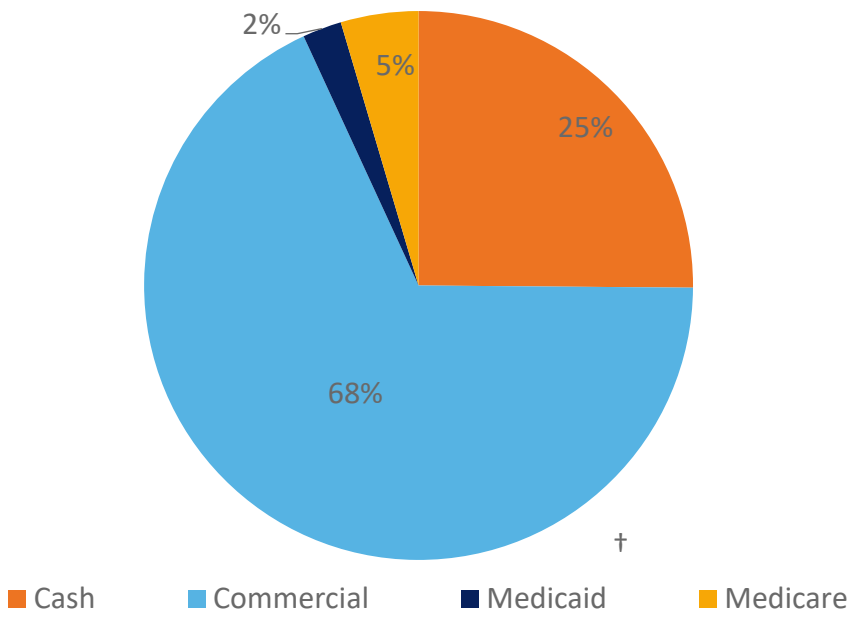
TPP=Target Product Profile

CVA=Core Visual Aid

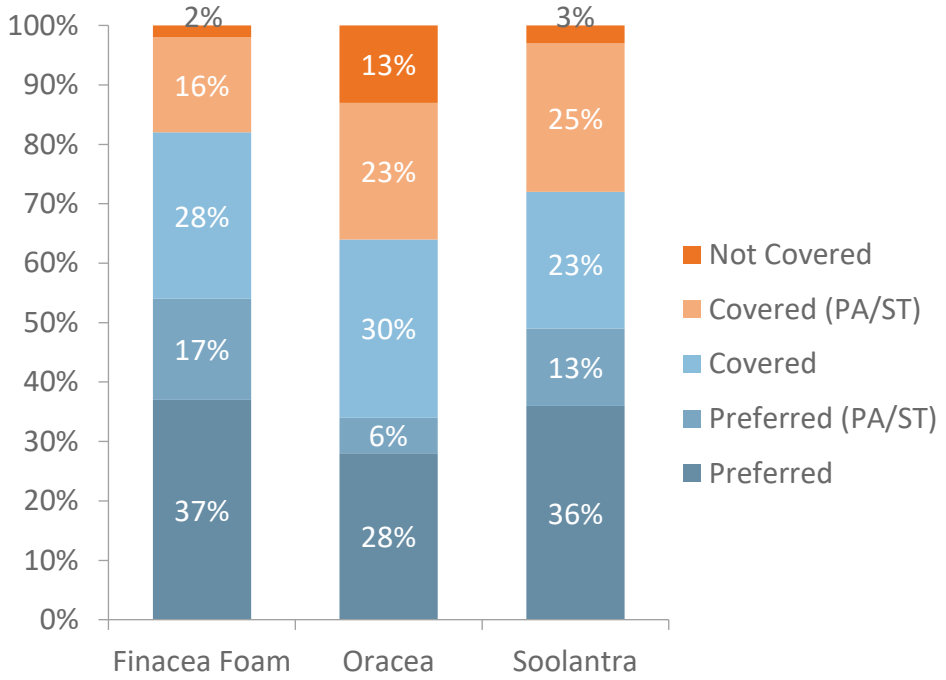
Rosacea Market Access Dynamics

The majority of the branded market is covered via commercial insurance or cash, with competitive access predominantly covered 90% or better.

% Branded Rosacea Market TRxs by Payment Type[1]



Representative Brand Access Coverage Status



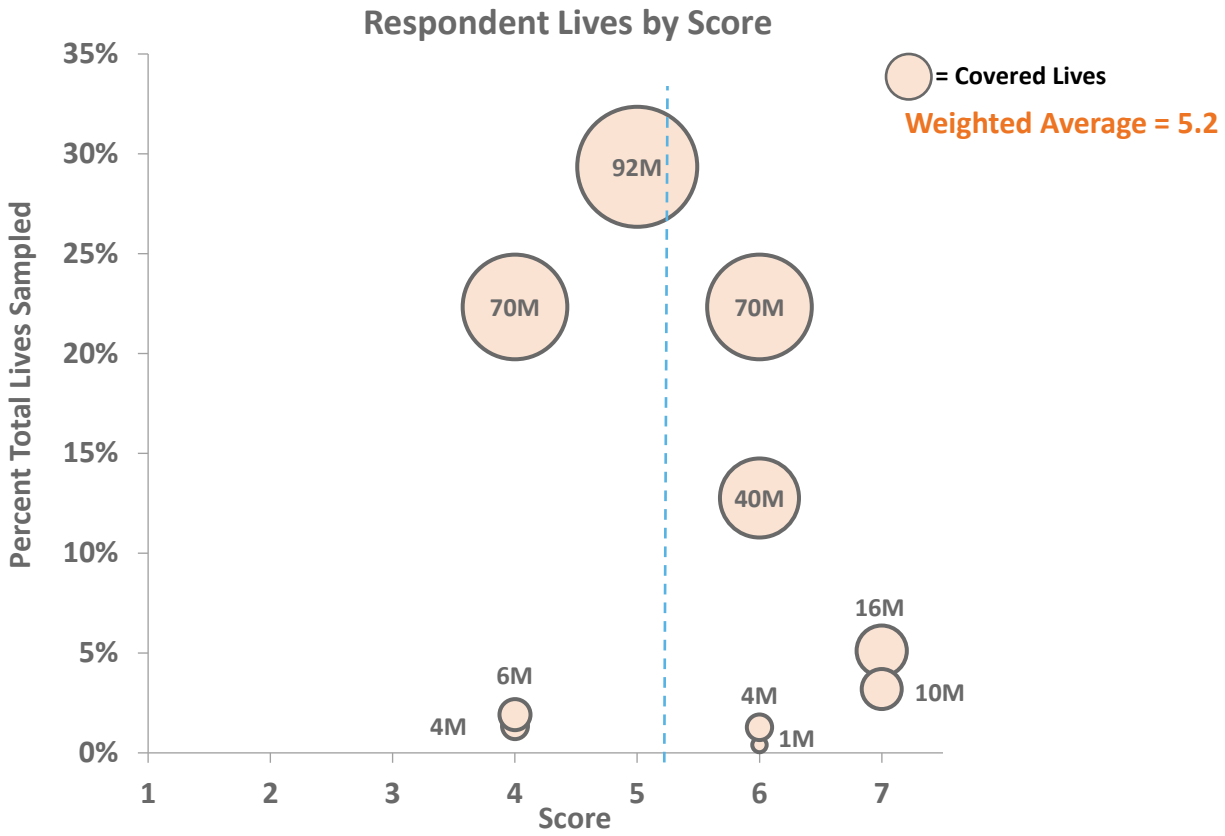
*Cash: Cash + Assistance Programs (Combines Cash Assistance Programs, Cash Coupon Programs, and Cash Discount Cards)

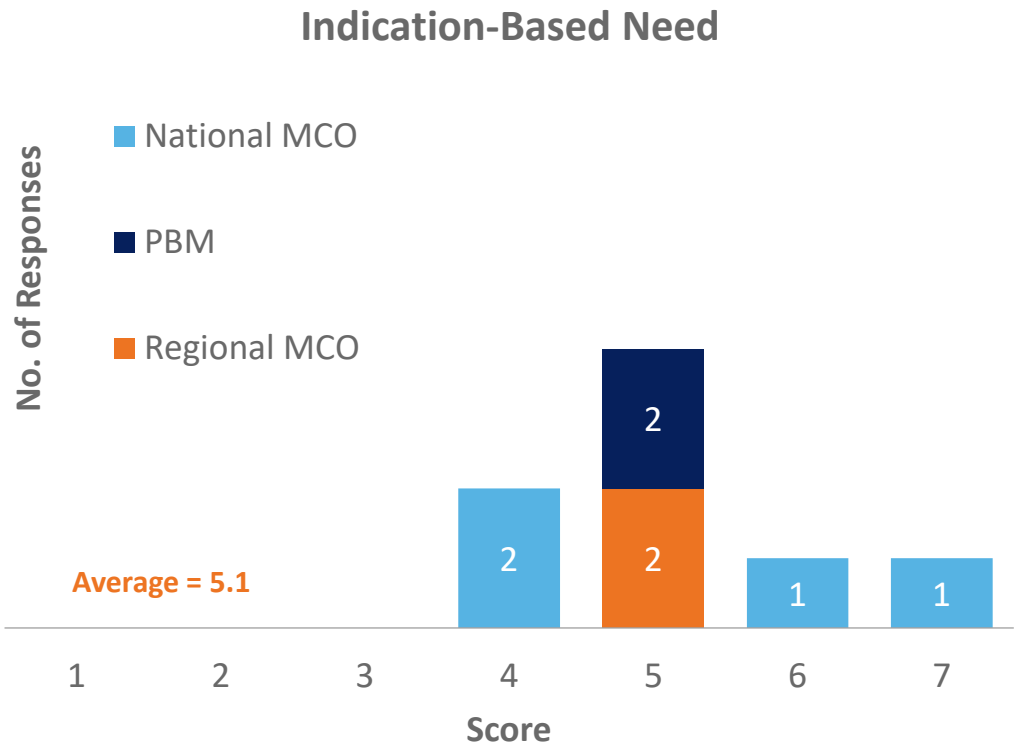
†Medicaid: Managed Medicaid + FFS Medicaid

Sources: 1. Symphony PHAST TRx by channel: weighted values ; Date: May 2020

ZILXI Payor Market Research: Favorability

Payors representing ~313m lives* favorably view the ZILXI product profile and indicate that it will fill a market need. Feedback that at the $200-400 net-to-plan range it would have access with limited utilization management.

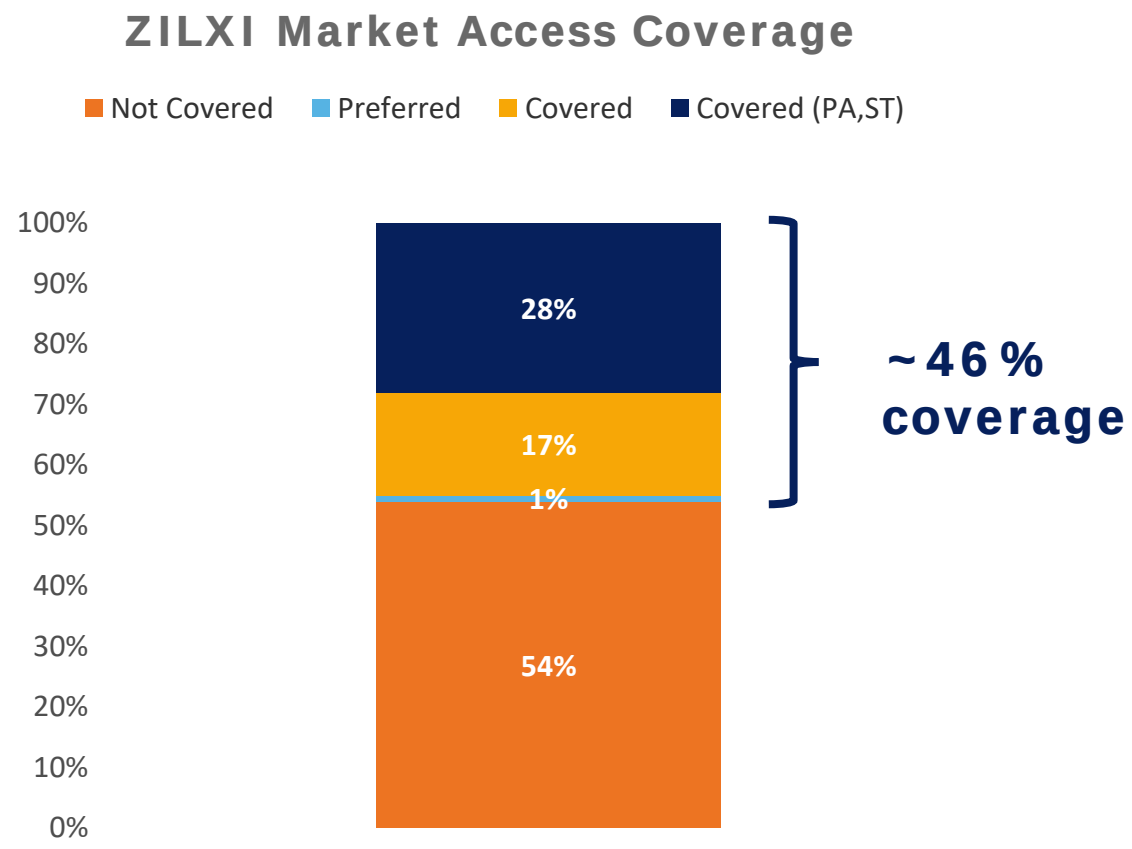




Source: N=10 and N=8 stakeholder interviews conducted by Syneos Health in August 2019. *Payers self-reported membership and number of plan subscribers.

ZILXI Market Access

ZILXI has secured ~46% of the covered lives prior to launch, with other contract negotiations actively underway.

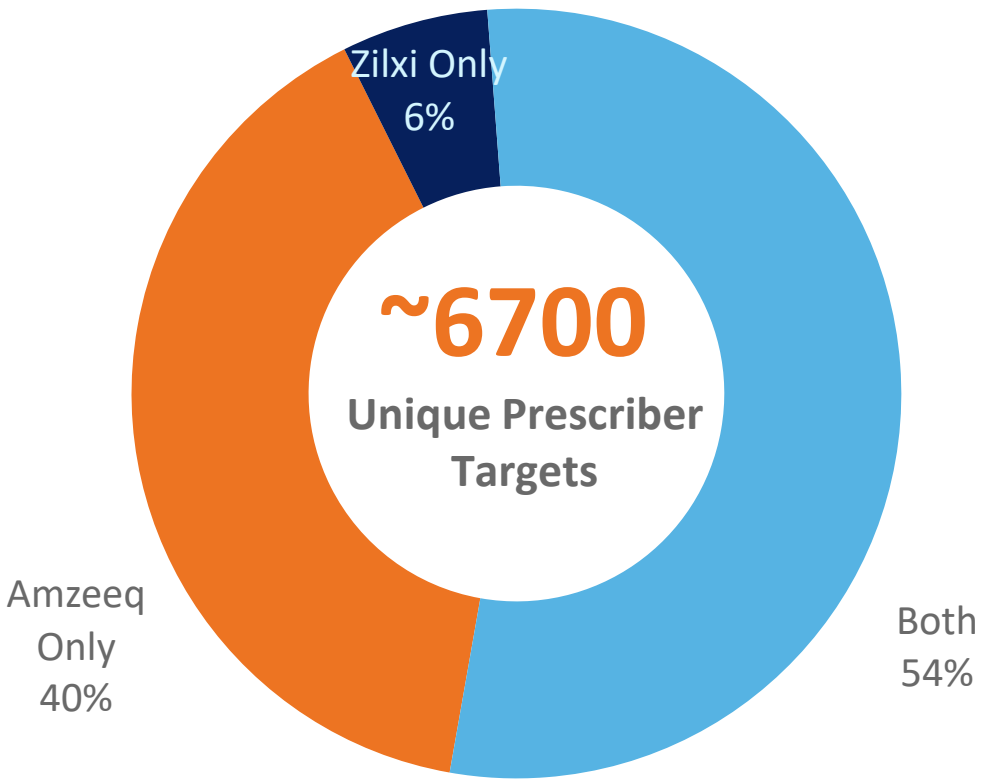


Key Strategic Imperatives:

- Leverage AMZEEQ contracts to quickly engage payers
- Launch ZILXI at parity pricing to AMZEEQ
- Recent Express Scripts win brings 26m lives to coverage.
- Two other major PBM contracts are in negotiations.

Source: MMIT Data on file, 2020 Data as of 9/24/20
Note: Coverage may fluctuate initially until full reviews are completed, Tricare covered until offer is evaluated

Layering ZILXI™ Prescriber Targeting with AMZEEQ® Sales Efforts



87% Zilxi™ targets in current called on universe

75% of diagnosed patient volume captured within target universe

Source: VYNE data on file

Summary

- Significant unmet need in rosacea for HCPs and patients
- Strong promotional story and expected demand for ZILXI
- Large market with launch surrogates suggesting strong adoption for new products

Disclaimer: Not an actual patient

ROSACEA: WHAT'S NEW AND WHAT'S COMING

Linda Stein Gold, MD

Director of Clinical Research

Department of Dermatology

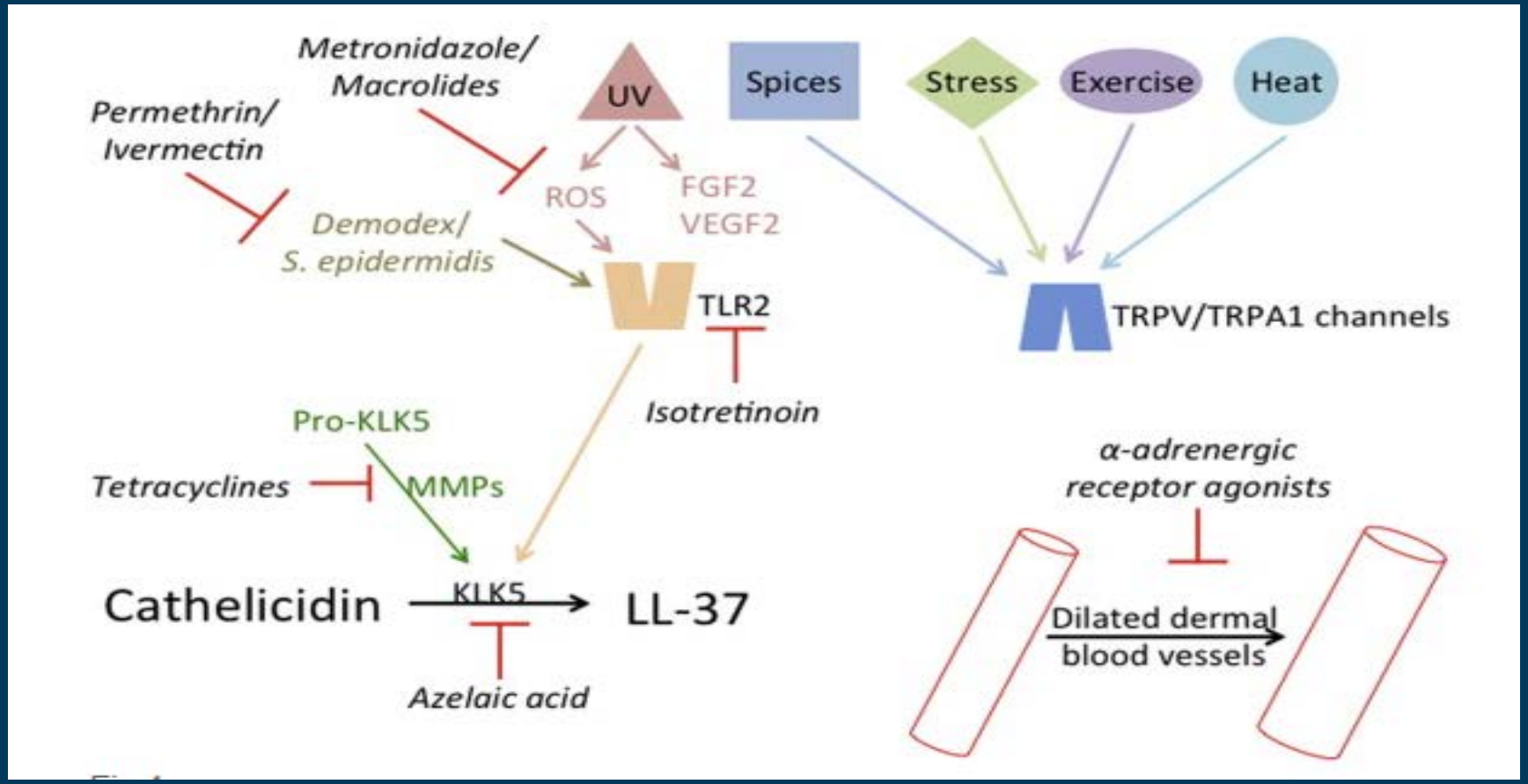
Henry Ford Hospital

Detroit, MI

DISCLOSURES

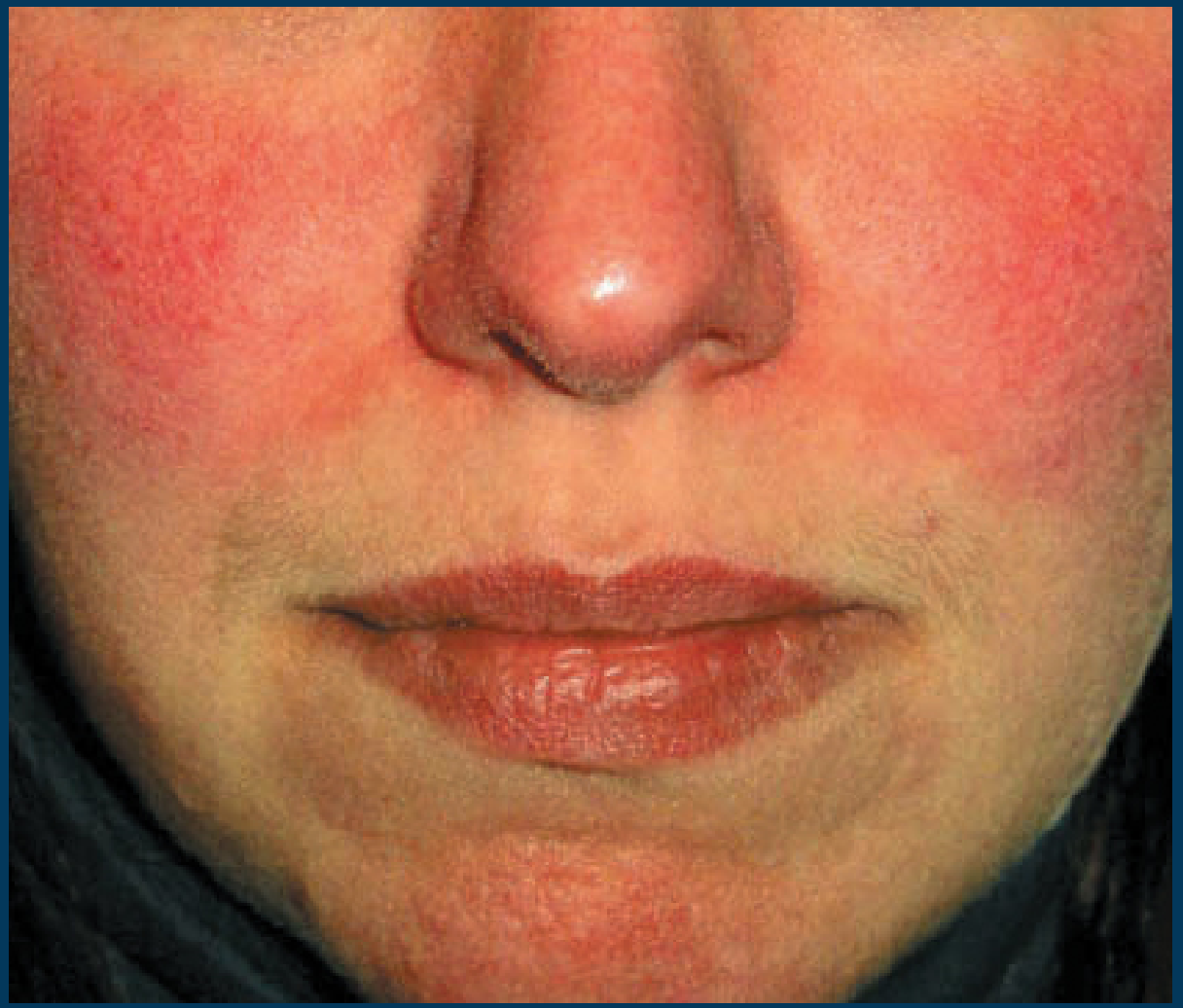
- This is an event hosted by VYNE Therapeutics. It is not a CME-accredited program.
- Linda Stein Gold is a consultant/speaker of Vyne and is receiving compensation for her presentation at today's event.
- Dr. Stein Gold also is consultant, speaker, advisor, and/or investigator for Galderma, Almirall, Sol-Gel, Ortho Derm, Sun, Novartis

MECHANISM OF ACTION OF ROSACEA TREATMENTS*



*The mechanism of action of minocycline in treating inflammatory lesions of rosacea is unknown.
Two, et.al. Journal of the American Academy of Dermatology, 2015-05-01

TREATING ROSACEA



EVALUATING ROSACEA TREATMENT OPTIONS

- Evaluate which signs are present
  - Papules and pustules
    - Metronidazole
    - Azelaic Acid
    - Ivermectin
    - Oral antibiotics
- Background erythema
  - Topical alpha-adrenergic agonist e.g. brimonidine, oxymetazoline
- Telangiectasias
  - Device
- Phyma
  - Surgery

CHALLENGES IN TREATING ROSACEA

01.

Tolerability

- High incidence of local irritation

02.

Compliance

- Once daily preferred
- Simplify the regimen

TOPICAL MINOCYCLINE

- Minocycline is a member of the tetracycline family of bacteriostatic/anti-inflammatory agents that are very challenging to deliver topically
- Also very challenging to keep it stable in a topical formulation
- Challenging to create a cosmetically acceptable vehicle

Minocycline 1.5% foam for the topical treatment of moderate to severe papulopustular rosacea: Results of 2 phase 3, randomized, clinical trials

Linda Stein Gold, MD,[a] James Q. Del Rosso, DO,[b] Leon Kircik, MD,[c] Neal D. Bhatia, MD,[d] Deirdre Hooper, MD,[e] Walter K. Nahm, MD, PhD,[f] and Iain Stuart, PhD[g]

Detroit, Michigan; Las Vegas, Nevada; New York, New York; San Diego, California; New Orleans, Louisiana; and Bridgewater, New Jersey

Background: Efficacious topical medications for rosacea are needed. FMX103 1.5% is a novel topical minocycline foam that may have therapeutic benefits in treating rosacea while minimizing systemic adverse effects due to its topical route of delivery.

Objective: To determine the efficacy, safety, and tolerability of 12 weeks of treatment with FMX103 1.5% topical minocycline foam for papulopustular rosacea.

Methods: Two 12-week, phase 3, randomized, multicenter, double-blind, vehicle-controlled, 2-arm studies were performed in patients with moderate to severe papulopustular rosacea.

Results: Participants who received FMX103 1.5%, versus control individuals treated with vehicle, exhibited a significantly greater reduction in the number of inflammatory lesions (FX2016-11: -17.57 vs -15.65; $P = .0031$; FX2016-12: -18.54 vs -14.88; $P < .0001$) and higher rates of Investigator Global Assessment treatment success (FX2016-11: 52.1% vs 43.0%; $P = .0273$; FX2016-12: 49.1% vs 39.0%; $P = .0077$). No serious treatment-related treatment-emergent adverse events occurred.

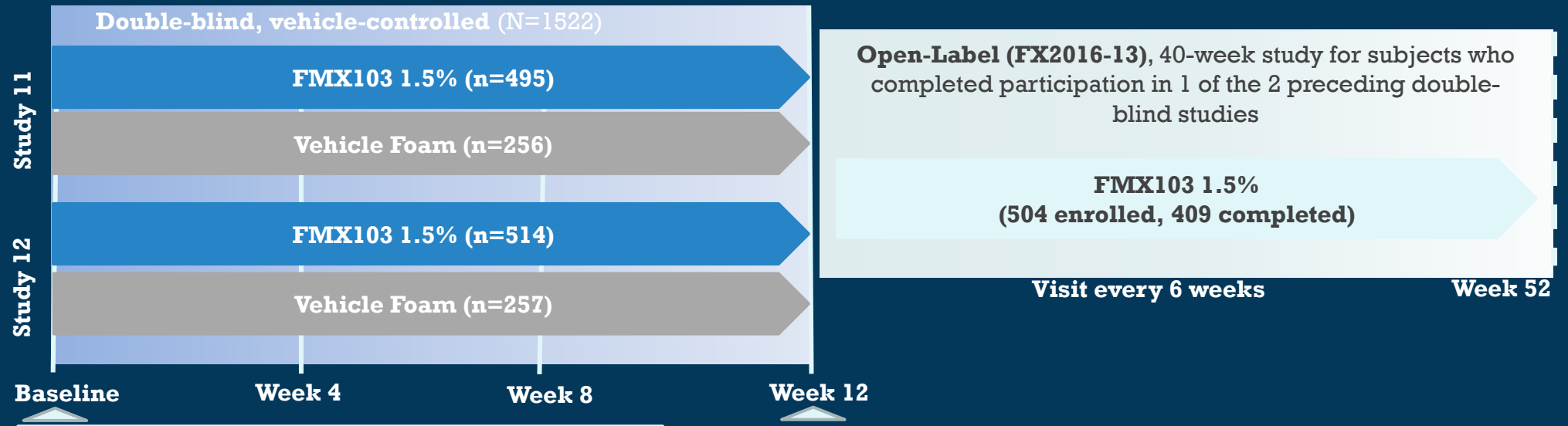
Limitations: The generalizability of these data from a controlled clinical trial should be examined in a real-world setting.

Conclusions: FMX103 1.5% was efficacious for moderate to severe papulopustular rosacea and maintained a favorable safety profile. (J Am Acad Dermatol 2020;82:1166-73.)

Key words: double-blind clinical trial; facial; minocycline; papulopustular rosacea; phase 3; topical foam.

FMX103 1.5%: METHODS

Phase 3 Program Design



Inclusion Criteria

- Males and nonpregnant females ≥18 years
- Moderate-to-severe facial papulopustular rosacea (IGA score of 3 or 4)
- >15 to ≤75 facial papules and pustules, excluding lesions involving eyes and scalp; ≤2 nodules on the face
- Presence or history of facial erythema or flushing

Co-Primary Endpoints

- Absolute change from baseline in inflammatory lesion count at week 12
- IGA treatment success at week 12, score of 0 (“clear”) or 1 (“almost clear”), and ≥2-grade decrease from baseline

Safety Evaluations

- Adverse events, physical exams, vital signs, clinical laboratory tests, local tolerability assessment
- Subject global assessment & satisfaction questionnaire

IGA=Investigator’s Global Assessment.

Stein Gold LS, et al. *Skin.* 2019; Abstract - 102 Poster PDF - 23

BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS

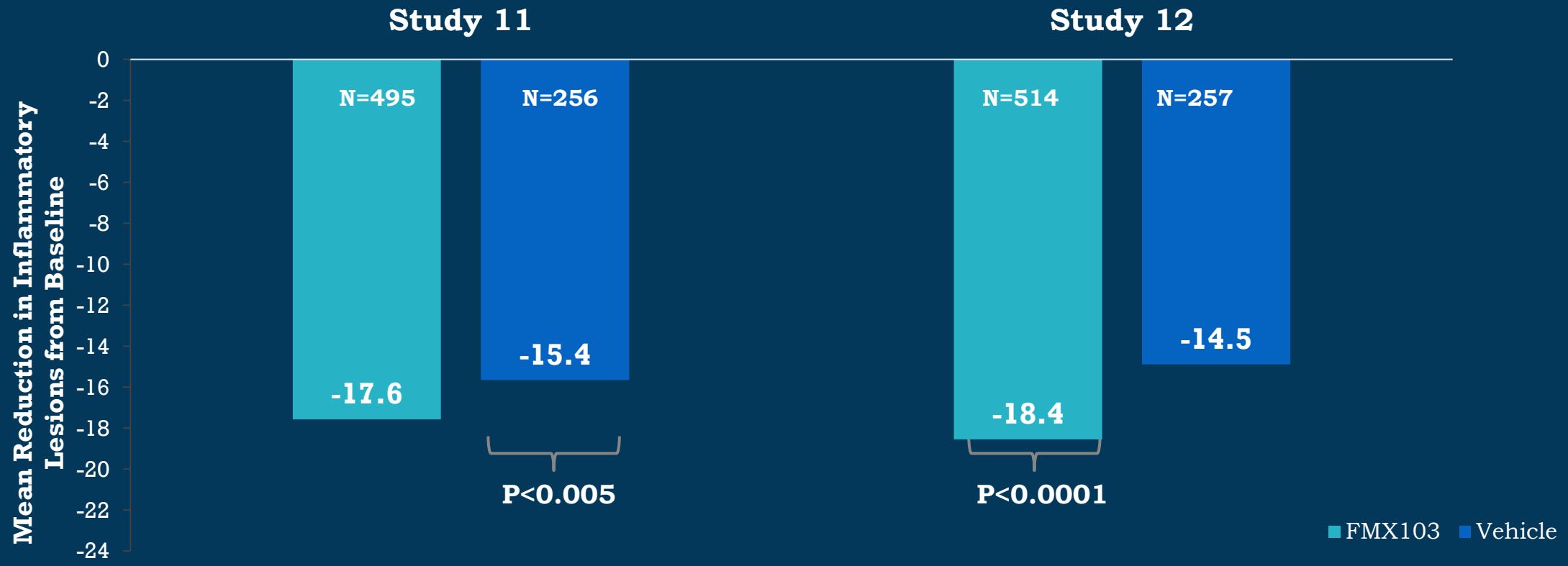
1522 subjects were enrolled in the two double-blinded, pivotal Phase 3 studies

	Study 11		Study 12	
	FMX103 1.5% (n=495)	**Vehicle Foam (n=256)**	**FMX103 1.5% (n=514)**	**Vehicle Foam (n=257)**
Mean age, years (range)	48.9 (18-82)	49.7 (22-86)	50.9 (18-85)	50.9 (18-82)
Male, n (%) **Female, n (%)**	140 (28.3) 355 (71.7)	70 (27.3) 186 (72.7)	149 (29.0) 365 (71.0)	89 (34.6) 168 (65.4)
Ethnicity, n (%) White Other	 474 (95.8) 21 (4.2)	 241 (94.5) 15 (5.5)	 499 (97.3) 15 (2.7)	 250 (97.7) 7 (2.3)
Inflammatory lesion count, mean (SD)	28.5 (12.05)	29.0 (12.13)	30.0 (12.84)	30.2 (12.99)
IGA score, n (%) 3 – Moderate 4 – Severe	 444 (89.7) 51 (10.3)	 222 (86.7) 34 (13.3)	 443 (86.2) 71 (13.8)	 213 (82.9) 44 (17.1)

SD=standard deviation.

ROSACEA PHASE 3 RESULTS

EFFICACY CO-PRIMARY ENDPOINT: ABSOLUTE CHANGE OF INFLAMMATORY LESION COUNT AT WEEK 12

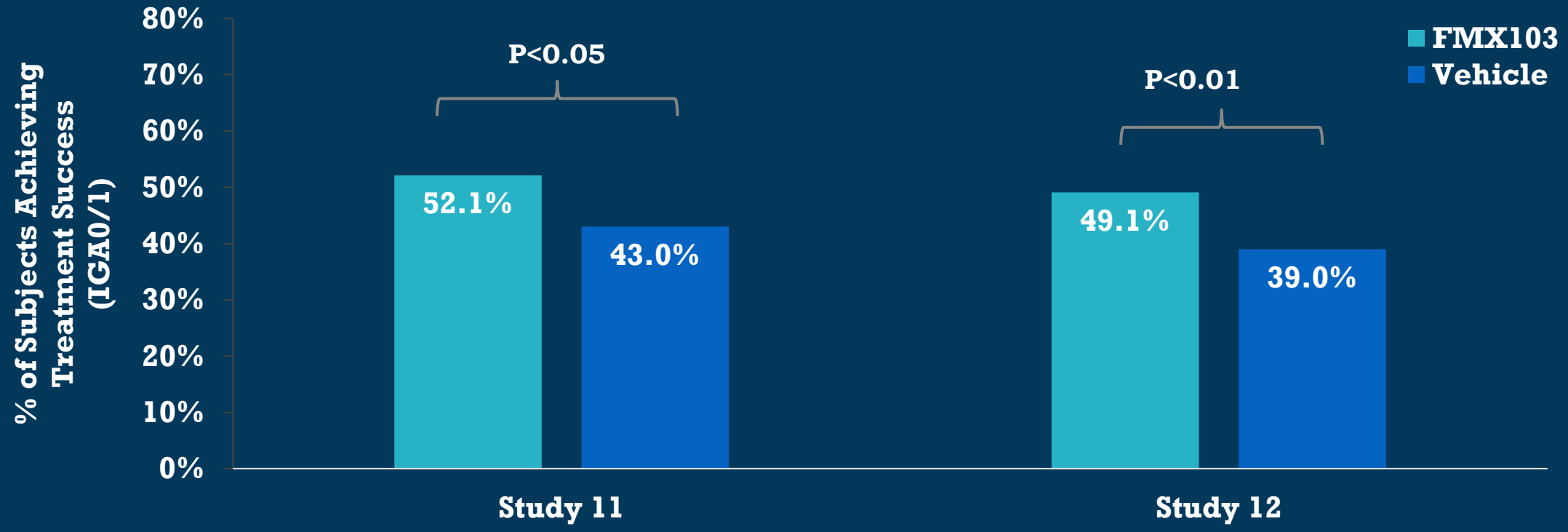


- In Study 11, absolute change in inflammatory lesion count for the FMX103, 1.5% treatment group was –17.6 versus –15.4 in vehicle treatment group (p=0.0031)
- In Study 12, absolute change in inflammatory lesion count for the FMX103, 1.5% treatment group was –18.4 versus –14.5 in vehicle treatment group (p<0.0001)

SD=standard deviation.

ROSACEA PHASE 3 RESULTS - EFFICACY

CO-PRIMARY ENDPOINT: IGA TREATMENT SUCCESS AT WEEK 12 [SCORE CLEAR (0) OR ALMOST CLEAR (1) AND AT LEAST A 2-POINT IMPROVEMENT FROM BASELINE]

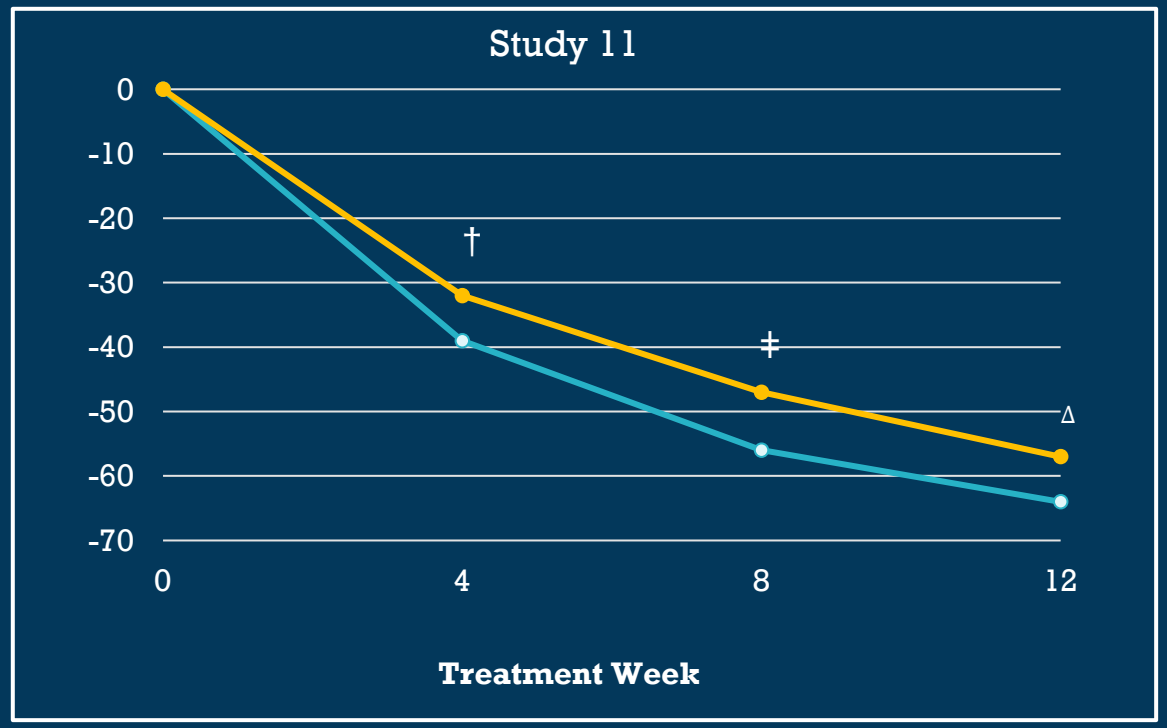


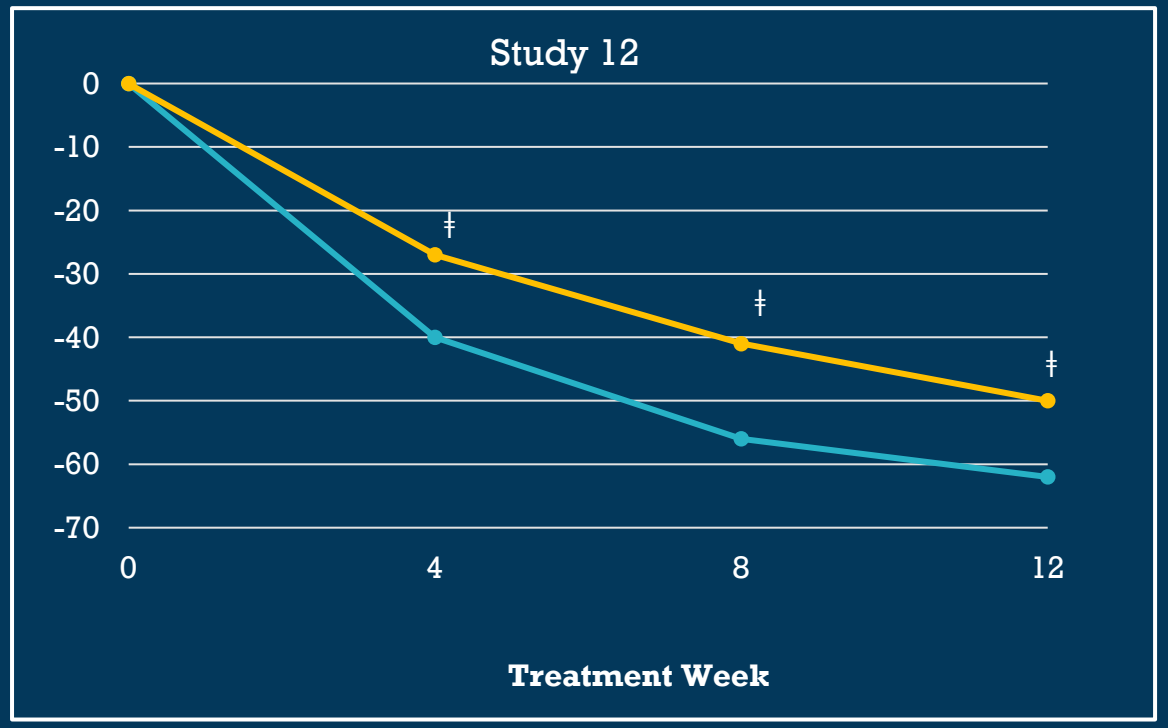
- In Study 11, IGA Treatment Success for FMX103, 1.5% treatment group was 52.1% versus 43.0% in vehicle treatment group (p=0.027)
- In Study 12, IGA Treatment Success for FMX103, 1.5% treatment group was 49.1% versus 39.0% in vehicle treatment group (p=0.0077)

SD=standard deviation.

PERCENTAGE CHANGE FROM BASELINE TO WEEK 12 IN INFLAMMATORY LESIONS BY VISIT

Percentage reduction in inflammatory lesions was statistically significant for FMX103 1.5% as compared with vehicle at all visits in both studies* – Weeks 4, 8, and 12





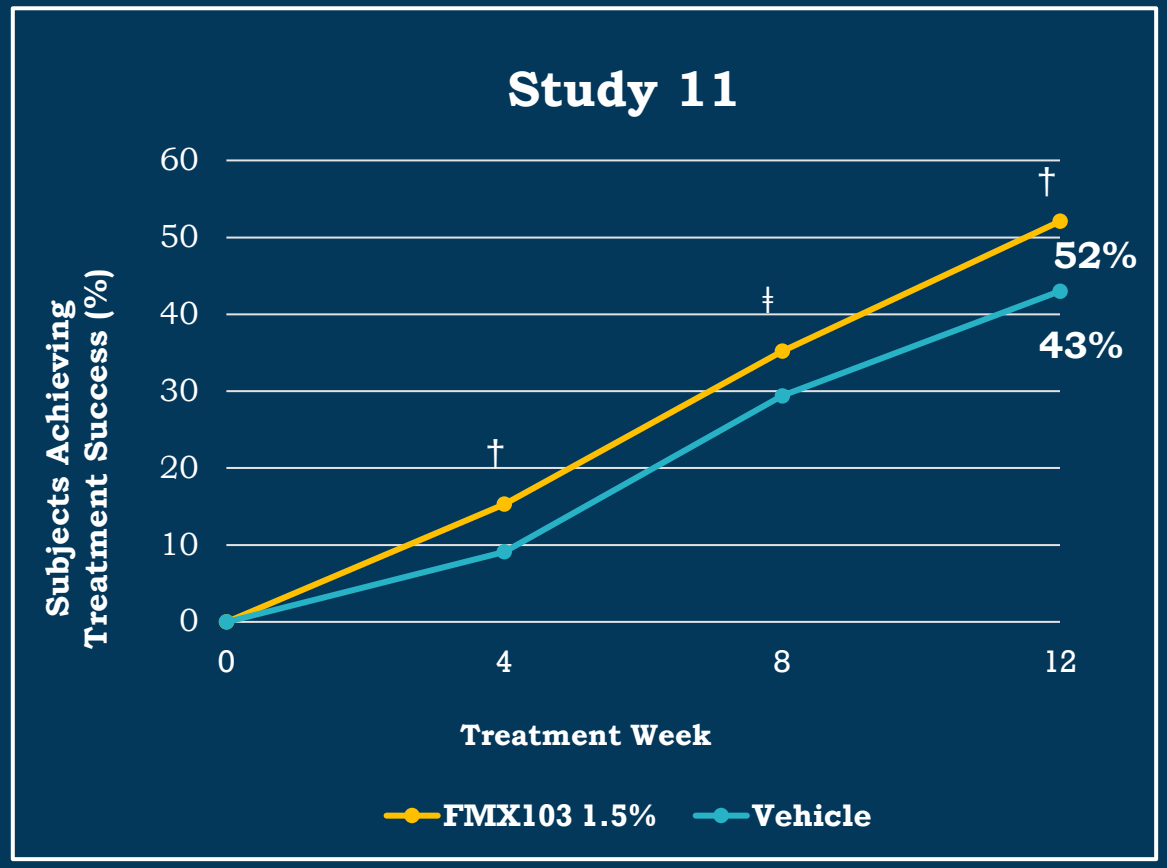
FMX103 1.5% Vehicle

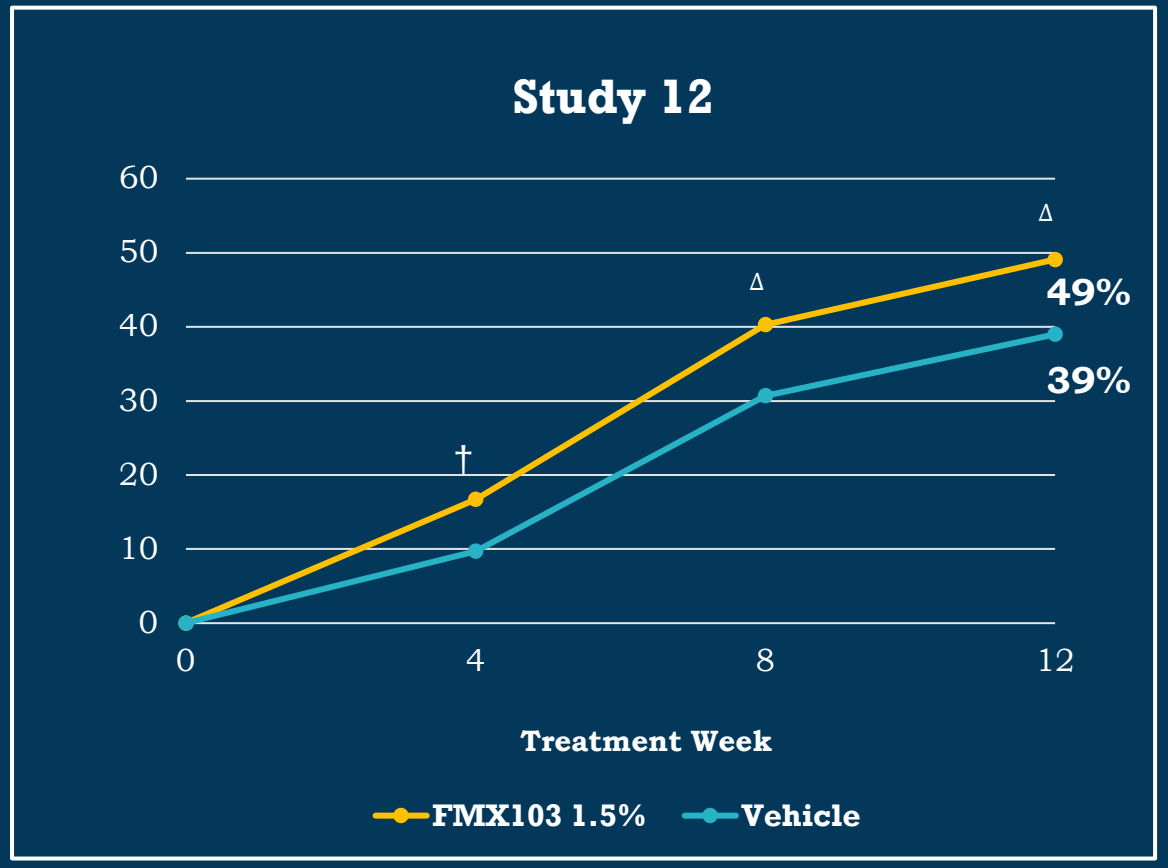
*ANCOVA, intent-to-treat, observed cases.

†*P*=.025; ‡*P*<.0001; Δ*P*=.002.

IGA TREATMENT SUCCESS

Proportion of subjects achieving IGA treatment success in both FMX103 1.5% treatment groups was statistically significant as compared with vehicle at weeks 4, 8 (Study 12 only), and 12*



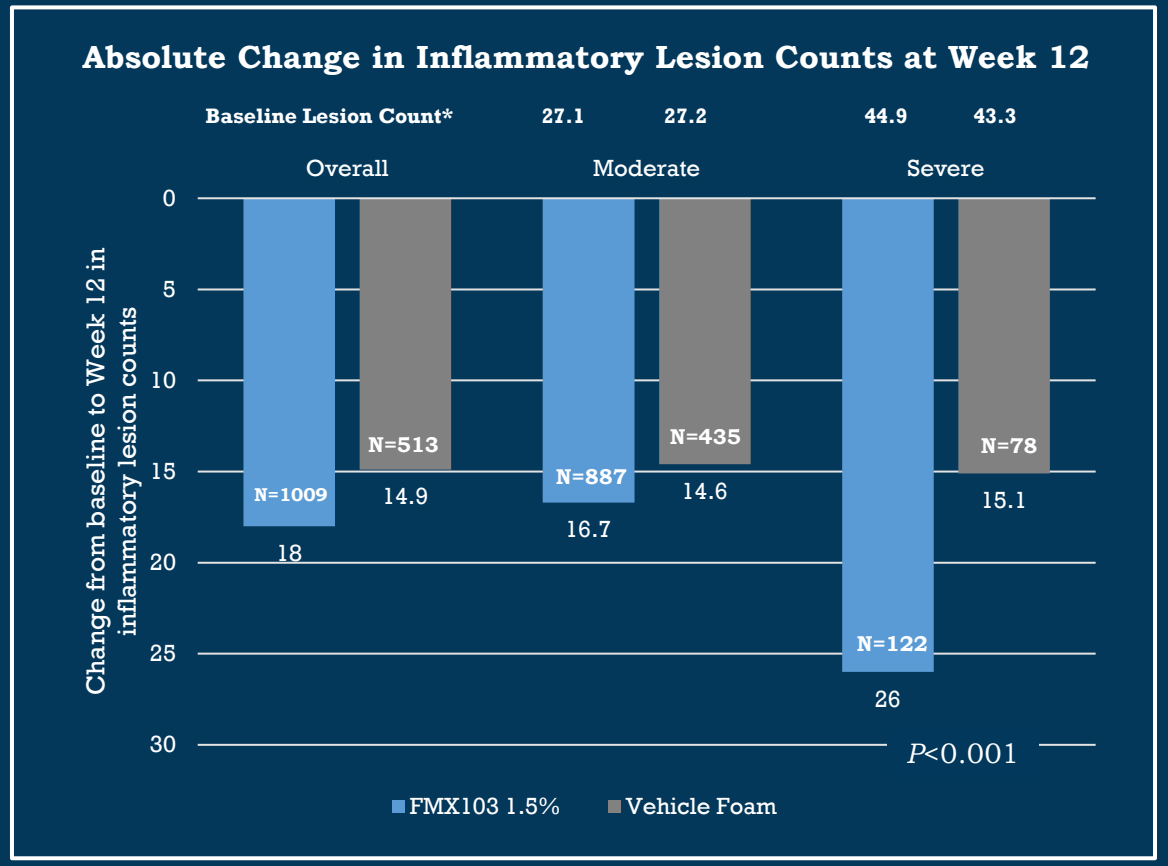


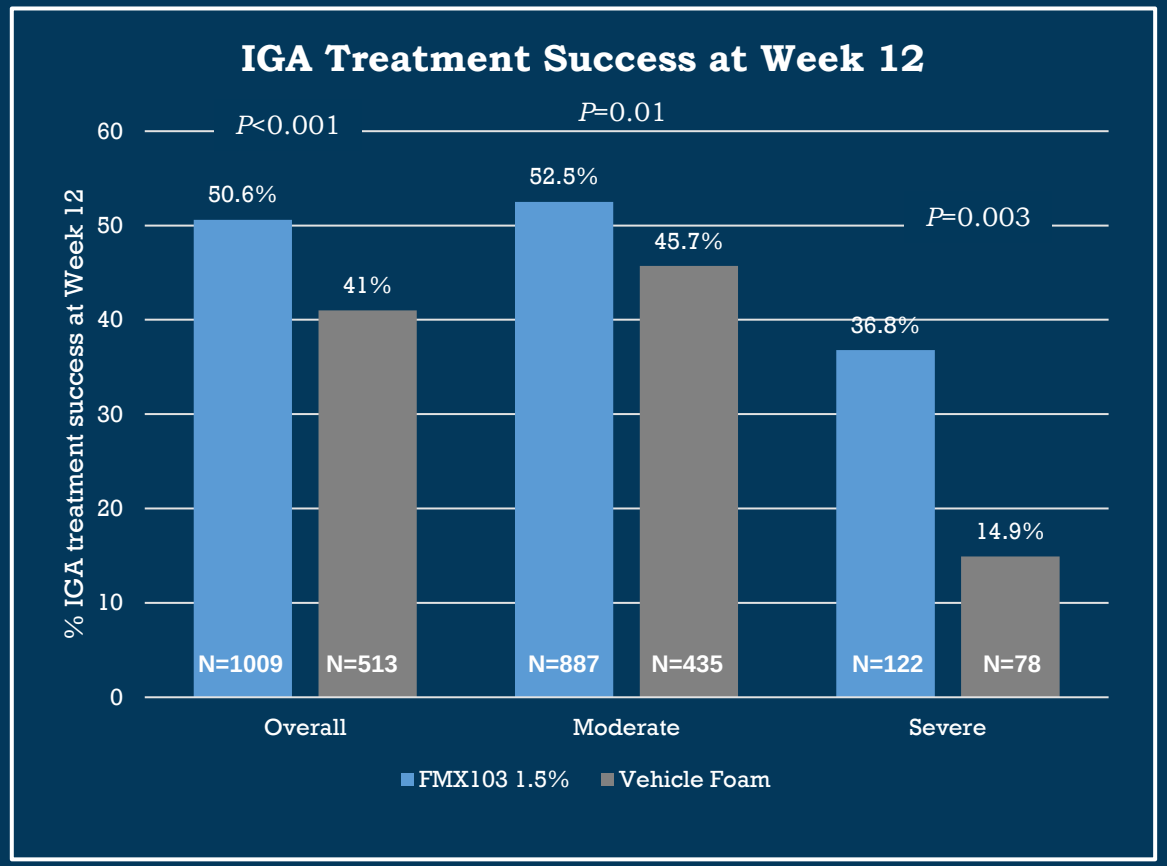
Data on file at VYNE

*Cochran-Mantel-Haenszel test, intent-to-treat, multiple imputation. † $P<.05$; ‡ $P=.13$; Δ $P<.01$.

POST-HOC, POOLED ANALYSIS OF PHASE 3 PRIMARY END POINTS BY BASELINE IGA

Consistent Decrease of Inflammatory Lesions and IGA Treatment Success Across Severities.
Over One Third of Patients with Severe Disease at Baseline were Clear or Almost Clear at Week 12.





IGA=Investigator's Global Assessment.
*observed cases
Integrated efficacy population; multiple imputation.
The change from baseline in inflammatory lesion count is (value at baseline)-(post-baseline value). Thus, a positive change will reflect a reduction in inflammatory lesion count.
Limitation: This is a post-hoc analysis, which is considered exploratory. Therefore, the results require cautious interpretation and could represent chance findings.

INTEGRATED SAFETY - OVERALL SUMMARY OF ADVERSE EVENTS

- All serious TEAEs were considered by the investigators as not related to study drug
- 9 subjects reported 10 TEAEs resulting in study discontinuation
  - 7 subjects in the FMX103 1.5% group and 2 subjects in the vehicle group
  - One TEAE (moderate pruritis) leading to drug withdrawal was considered related to study drug. The subject was randomized to FMX103 1.5% treatment

Summary of TEAEs and AEs in the integrated safety population	FMX103 1.5% (N=1008)	Foam Vehicle (N=513)	Overall (N=1521)
Subjects with any AE, n (%)	232 (23.0)	129 (25.1)	361 (23.7)
Number of AEs	380	200	580
Subjects with any TEAE, n (%)	219 (21.7)	122 (23.8)	341 (22.4)
Number of TEAEs	350	184	534
Subjects with any serious TEAE, n (%)	3 (0.3)	5 (1.0)	8 (0.5)
Number of serious TEAEs	8[a]	9[b]	17
Subjects with any treatment-related TEAE, n (%)	21 (2.1)	14 (2.7)	35 (2.3)
Number of treatment-related TEAEs	24[c]	17[d]	41
Subjects with any TEAE leading to discontinuation, n (%)	7 (0.7)	2 (0.4)	9 (0.6)
Number of TEAEs leading to study discontinuation	8[e]	2[f]	10

[a]Nausea, chest discomfort, fatigue, seasonal allergy, dehydration, syncope, dyspnea, hypertension
[b]Gastrointestinal hemorrhage, chest pain, pyrexia, dyspnea, asthma, hypertension, myocardial infarction, tachycardia
[c]Pruritis, rash, dermatitis, dermatitis contact, hair color changes, nail discoloration, skin hyperpigmentation, application site pain, application site erythema, facial pain, nodule, migraine, dizziness, dysgeusia, aphthous ulcer, cheilitis, eye irritation, ophthalmic herpes simplex, sunburn
[d]Nail discoloration, rosacea, skin exfoliation, application site pain, facial pain, application site pruritis, headache, cellulitis, skin cancer, urine odor abnormal
[e]Pruritis, dermal cyst, dermatitis, telangiectasia, influenza, urinary tract infection, bladder mass
[f]Rash pustular, myocardial infarction

INTEGRATED SAFETY NON CUTANEOUS TEAES

- The incidence rate of TEAEs by system organ class was similar between both treatment groups
- Overall, most subjects reported TEAEs that were not related to study drug (89.7%, 306/341)

TEAEs in ≥1% subjects in either group, n (%)	FMX103 1.5% (N=1008)	Foam Vehicle (N=513)
Viral upper respiratory tract infection	24 (2.4)	12 (2.3)
Upper respiratory tract infection	19 (1.9)	13 (2.5)
Headache	14 (1.4)	10 (1.9)[a]
Sinusitis	11 (1.1)	2 (0.4)
Diarrhea	10 (1.0)	2 (0.4)

[a]2 cases were considered to be treatment-related

INTEGRATED SAFETY CUTANEOUS TEAES

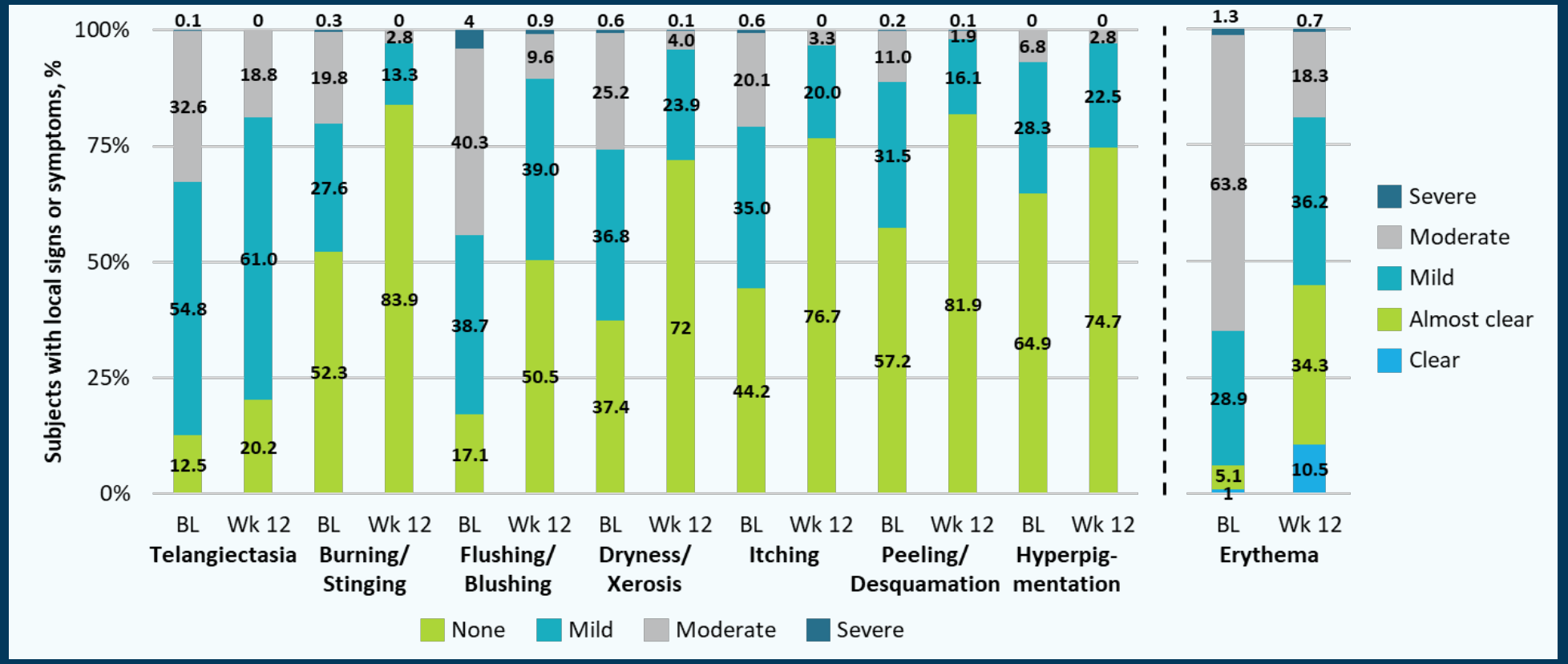
- Overall, the incidence of skin and subcutaneous disorders was similar between FMX103 1.5% (28, 2.8%) and vehicle (16, 3.1%) groups
- Skin and subcutaneous tissue disorders were most frequently considered as treatment-related TEAEs

Skin and subcutaneous tissue disorders, n (%)	FMX103 1.5%[a] (N=1008)	Foam Vehicle[b] (N=513)	Overall (N=1521)
Pruritis	7 (0.7)	1 (0.2)	8 (0.5)
Rash	5 (0.5)	2 (0.4)	7 (0.5)
Dermatitis	4 (0.4)	1 (0.2)	5 (0.3)
Dermatitis contact	2 (0.2)	0 (0.0)	2 (0.1)
Hair color changes	1 (0.1)	0 (0.0)	1 (0.1)
Nail discoloration	1 (0.1)	2 (0.4)	3 (0.2)
Skin hyperpigmentation	1 (0.1)	0 (0.0)	1 (0.1)
Rosacea	1 (0.1)	3 (0.6)	4 (0.3)
Skin exfoliation	0 (0.0)	1 (0.2)	1 (0.1)

[a]Treatment-related TEAEs included 3 cases of pruritis and 1 case each of rash, dermatitis, dermatitis contact, hair color changes, nail discolouration, and skin hyperpigmentation
[b]Treatment-related TEAEs included 2 cases of nail discoloration and 1 case each of rosacea and skin exfoliation

INTEGRATED SAFETY – FMX103, 1.5% DERMAL TOLERABILITY AT WEEK 12

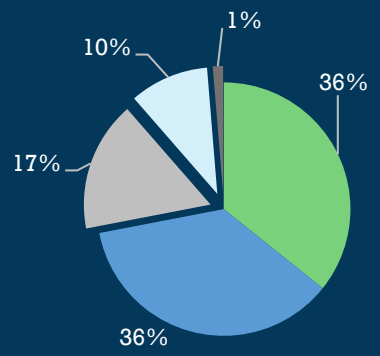
- The majority of subjects in the FMX103, 1.5% treatment groups had local tolerability assessments of “None” or “Mild” severities at Week 12
  - At Week 12, all facial local tolerability assessments showed improvement compared to baseline.
  - Subjects with clear or almost clear erythema increased from 4% at Baseline to 44.8% at Week 12.



Hyperpigmentation was most frequently assessed as characteristic of inflammatory and post-inflammatory changes associated with inflammatory lesions of rosacea.

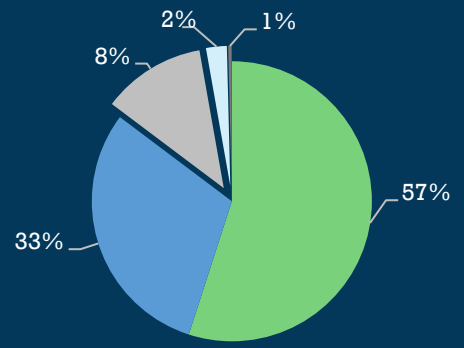
INTEGRATED SAFETY – FMX103, 1.5% DERMAL TOLERABILITY AT WEEK 12

Q1.
Overall, how satisfied are you with this product?
n=890



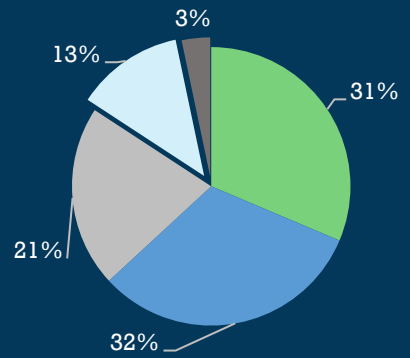
72% of patients satisfied or very satisfied with FMX103

Q2.
How satisfied are you with how easy this product is to use?
n=891



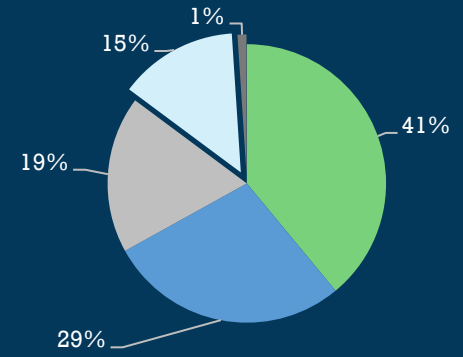
90% of patients satisfied or very satisfied with ease of use of FMX103

Q3.
How satisfied are you with how this product feels on your skin after treatment?
n=891



63% of patients satisfied or very satisfied with the product feel of FMX103

Q4.
How satisfied are you with how this product compares to other products you have previously used for rosacea?
n=891

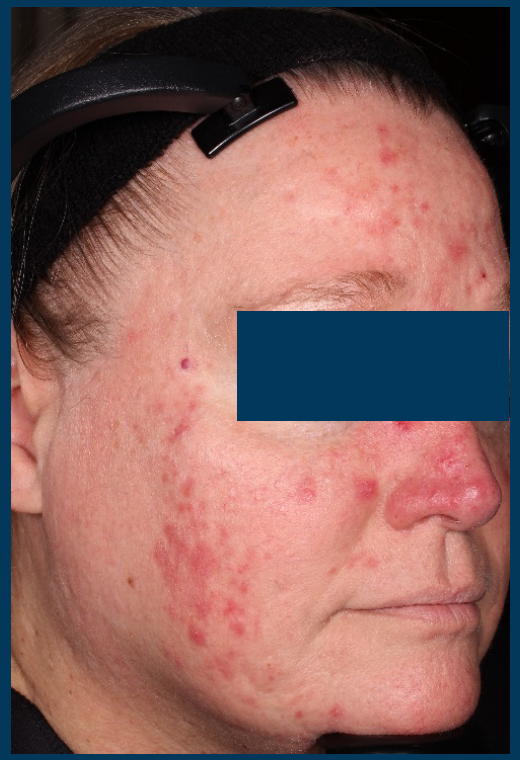


70% of patients satisfied or very satisfied with how FMX103 compares to other rosacea treatments

1- Very Satisfied
2- Satisfied
3- Somewhat Satisfied
4- Dissatisfied
5- Very Dissatisfied

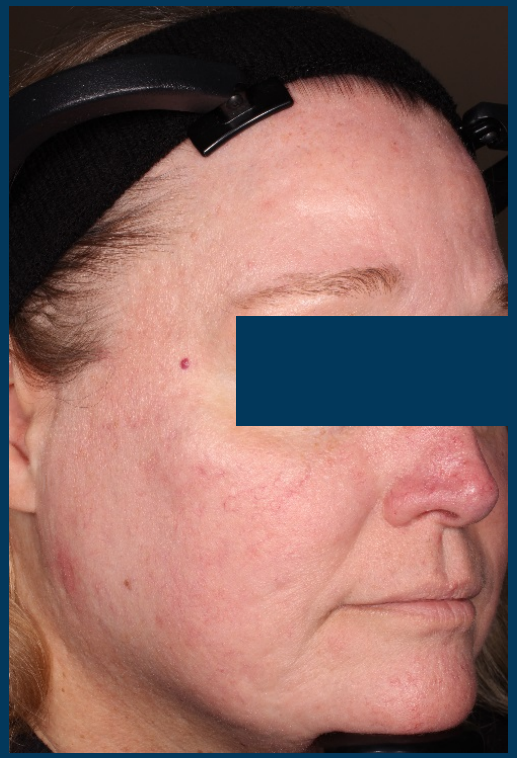
PHASE 3 RESULTS

Baseline



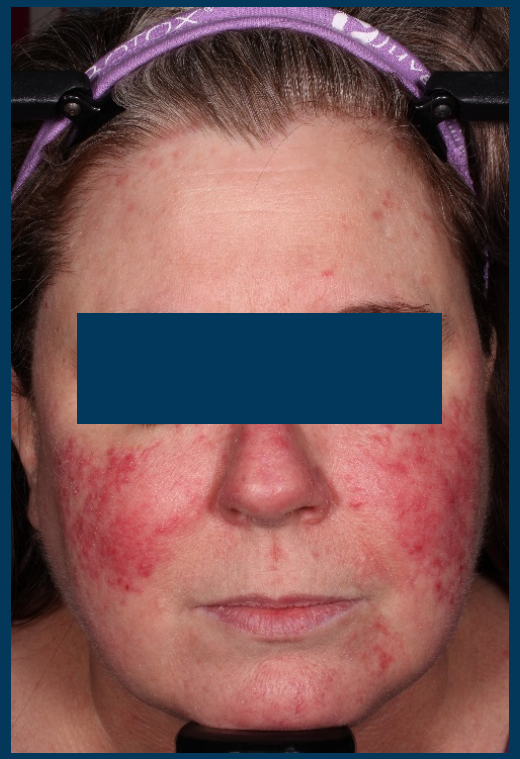
IGA=3

Week 12



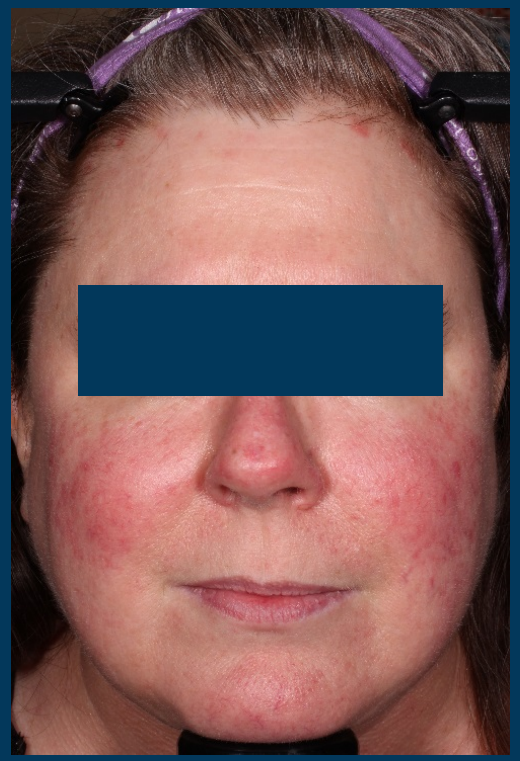
IGA=0

Baseline



IGA=3

Week 12

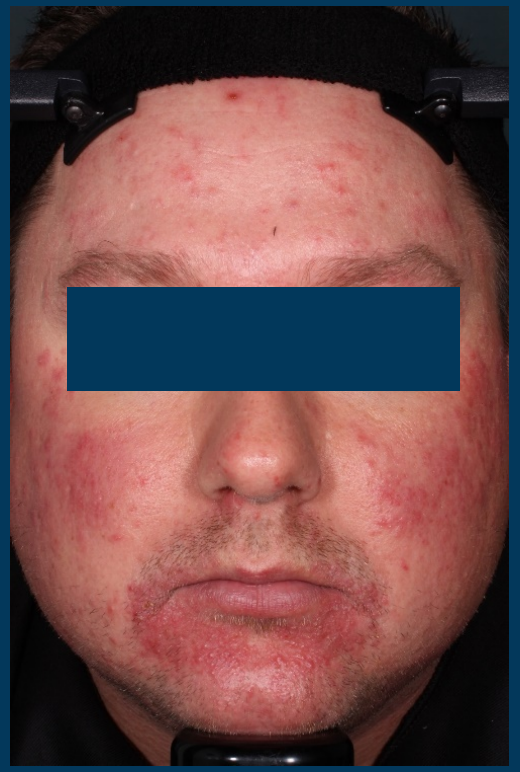


IGA=2

Images from clinical studies and used with permission. Photos of individual patients may not be typical and individual results may vary.

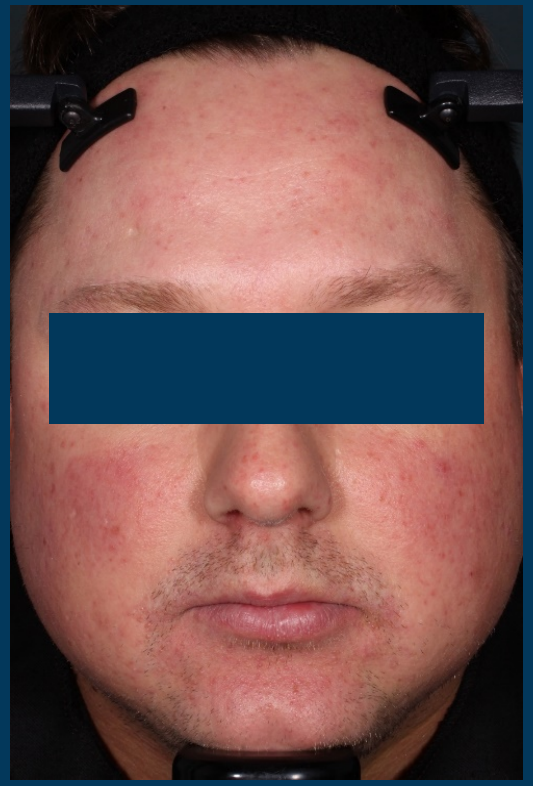
PHASE 3 RESULTS

Baseline



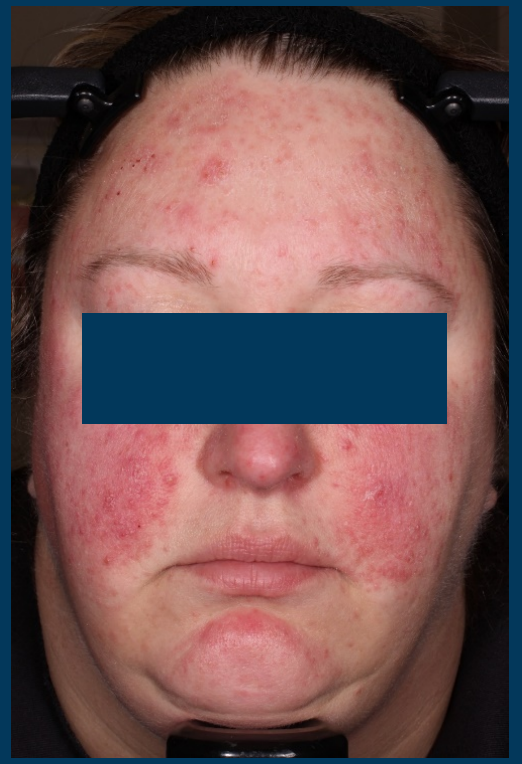
IGA=3

Week 12



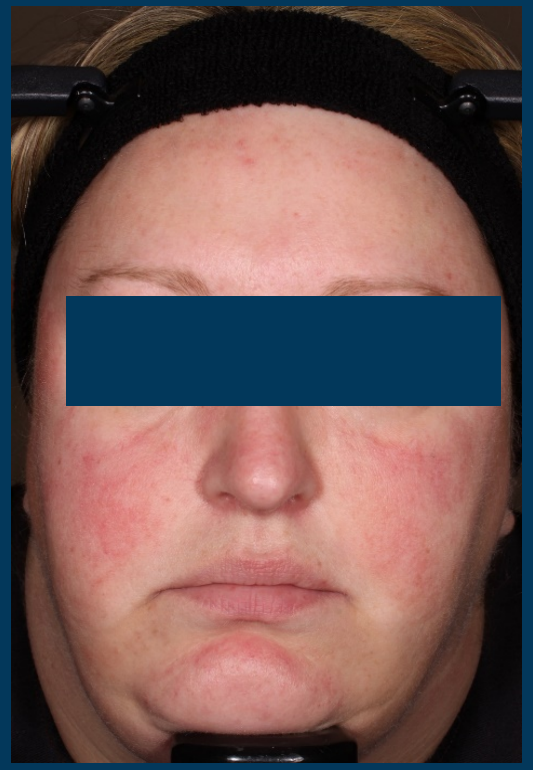
IGA=1

Baseline



IGA=4

Week 12



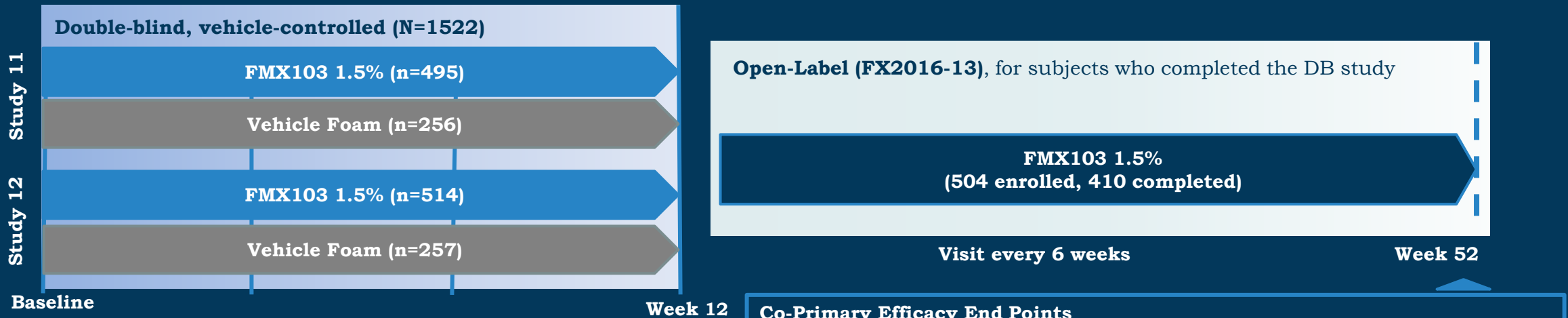
IGA=1

Stein Gold LS, et al. Skin. 2019; Abstract - 102 Poster PDF - 23

STUDY 13 - OPEN-LABEL, MULTICENTER, 40-WEEK EXTENSION STUDY

- Subjects were eligible to enter Study 13 upon successful completion of either 12-week double-blind study (Study 11 or Study 12)
- Concomitant use of prescription or OTC medications that the subjects were taking or any change in dosage was permitted and recorded
- IGAs were based upon a 5-point scale with 0=clear, 1=almost clear, 2=mild, 3=moderate, and 4=severe

Figure 1. Study Design



Inclusion Criteria for DB Study
- Males and nonpregnant females ≥18 years
- Moderate-to-severe facial papulopustular rosacea (IGA score of 3 or 4)
- >15 to ≤75 facial papules and pustules, excluding lesions involving eyes and scalp; ≤2 nodules on the face
- Presence or history of facial erythema or flushing

Co-Primary Efficacy End Points
- Absolute change in the inflammatory lesion count at Week 52 compared with DB baseline
- IGA Treatment Success Rate (dichotomized as yes/no) at Week 52, where success was defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from DB baseline

Secondary Efficacy End Points
- The absolute and percent change from DB baseline in inflammatory lesion count at Weeks 16, 22, 28, 34, 40, 46, and 52 of the OL study
- The dichotomized IGA Treatment Success Rate at Weeks 16, 22, 28, 34, 40, and 46
- The Subject Satisfaction Questionnaire (SSQ) at Week 52

IGA, Investigator's Global Assessment; DB, double-blind study; OL, open-label study

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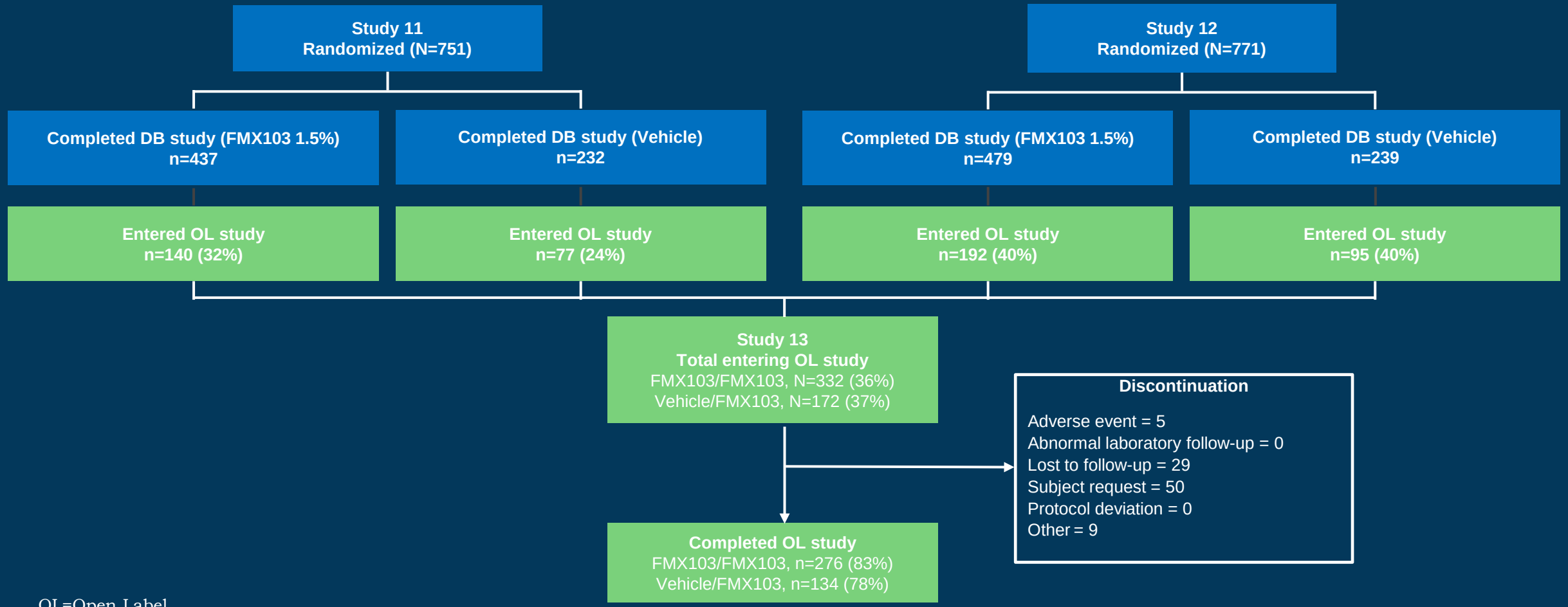
Limitation: These results must be interpreted with caution. The open-lavel extension study was not designed for efficacy. These results may be confounded by evaluator bias or represent chance findings. In total, 4.6% of patients reported using concomitant dermatological medication.

SUBJECT DISPOSITION AND DOUBLE-BLIND BASELINE DEMOGRAPHICS

504 subjects who completed the DB study (Study 11: N=217; Study 12: N=287) enrolled in the OL extension study (Study 13)



OL=Open Label

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SAFETY ANALYSIS - SUMMARY

- The majority of the TEAEs were considered mild or moderate in severity and no serious TEAEs were related to treatment

Variable	FMX103 1.5%/ FMX103 1.5% (N=332)	Vehicle Foam/ FMX103 1.5% (N=172)	Overall (N=504)
Subjects with any AE, n (%)	151 (45.5)	70 (40.7)	221 (43.8)
Subjects with any TEAE, n (%)	137 (41.3)	64 (37.2)	201 (39.9)
Subjects with any serious TEAE, n (%)	9 (2.7)[a]	4 (2.3)[b]	13 (2.6)
Subjects with treatment-related TEAEs, n (%)	5 (1.5)[c]	8 (4.7)[d]	13 (2.6)
Subjects with serious treatment-related TEAEs, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Subjects discontinued due to AE, n (%)	3 (0.9)[e]	2 (1.2)[f]	5 (1.0)
TEAEs resulting in death, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Subjects exposed to ≥6 months (>168 days), n (%)	319 (96.1)	146 (84.9)	465 (92.3)
Subjects exposed to ≥1 year (>350 days), n (%)	272 (81.9)	0 (0.0)	272 (54.0)

Number (%) of subjects with at least 1 AE per category; AE, adverse event; TEAE, treatment-emergent adverse event.
[a]Labyrinthitis, periorbital cellulitis, pneumonia, staphylococcal infection, cerebrospinal fluid leakage, cerebrovascular accident, syncope, subdural hematoma, death, hypokalemia, malignant melanoma.
[b]Appendicitis perforated, post procedural hemorrhage, large intestinal instruction, chronic obstructive pulmonary disease.
[c]Mydriasis, angular cheilitis, herpes simplex, dermatitis contact, hair color changes.
[d]Diarrhea, conjunctivitis, sunburn, acne, dermatitis contact, erythema, pruritus, rosacea, skin lesion.
[e]Dermatitis contact, mydriasis, enchondromatosis.
[f]Rosacea, anemia, leukocytosis, appendicitis perforated, sepsis, appendicectomy.

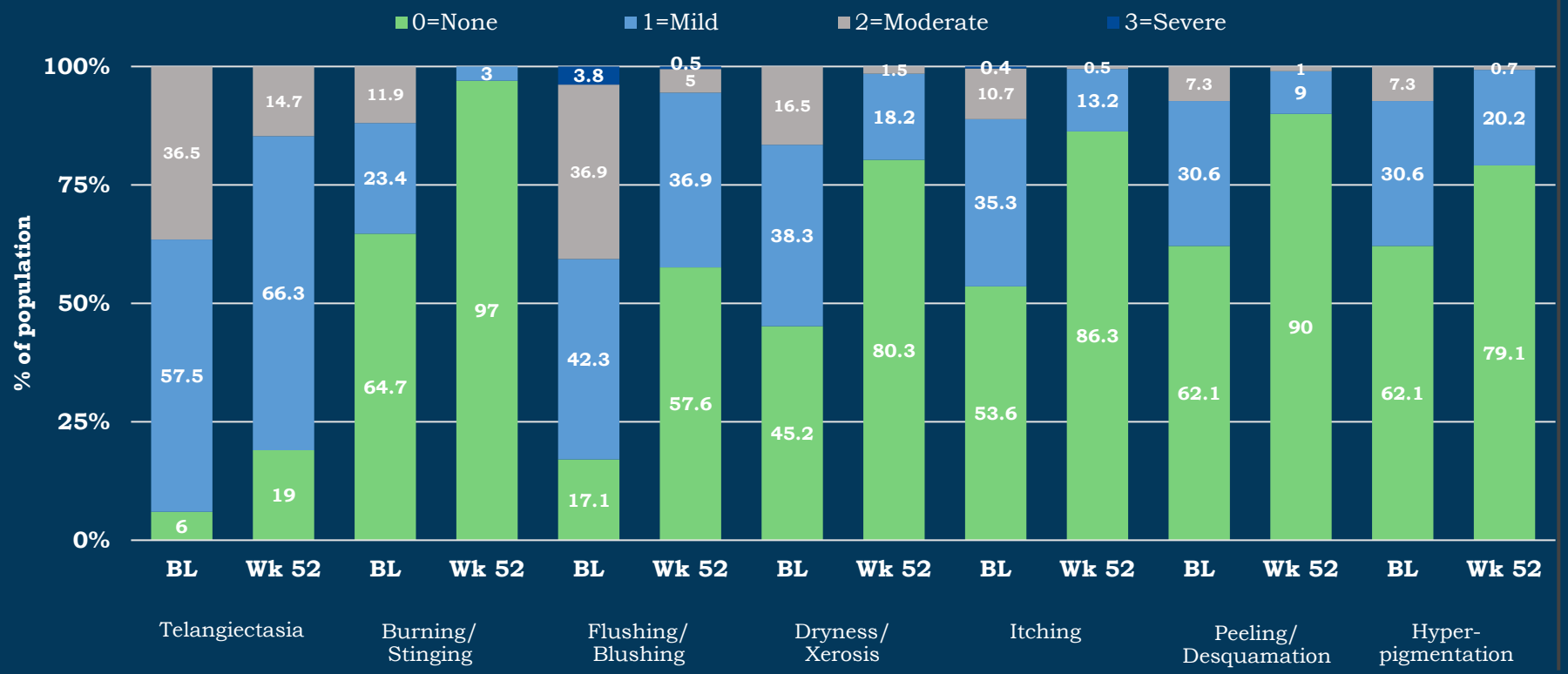
SAFETY ANALYSIS - TEAES OCCURRING IN AT LEAST 2% OF OPEN-LABEL SUBJECTS FROM EITHER ARM OF THE DOUBLE-BLIND PHASE

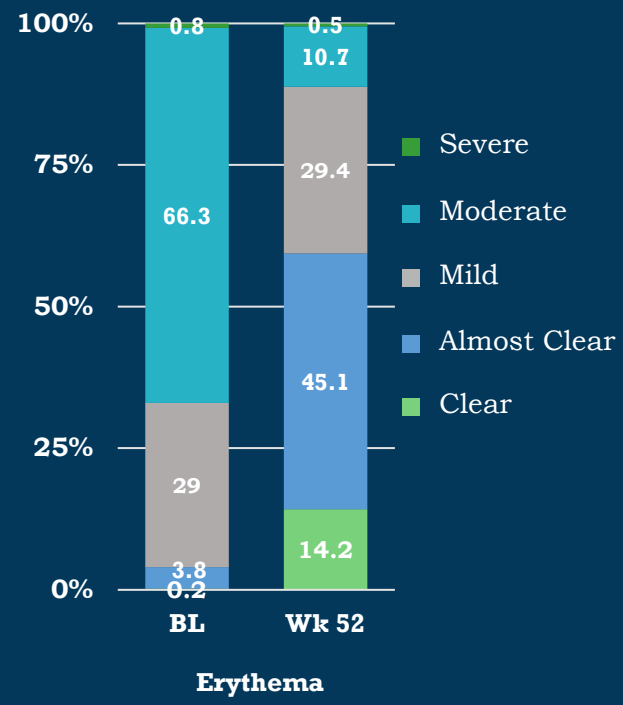
Variable	FMX103 1.5% / FMX103 1.5% (N=332)	Vehicle Foam / FMX103 1.5% (N=172)	Overall (N=504)
Subjects with 1 or more TEAE, n (%)	137 (41.3)	64 (37.2)	201 (39.9)
Infections and infestations			
Upper respiratory tract infection	14 (4.2)	5 (2.9)	19 (3.8)
Viral upper respiratory tract infection	14 (4.2)	5 (2.9)	19 (3.8)
Sinusitis	8 (2.4)	9 (5.2)	17 (3.4)
Influenza	9 (2.7)	5 (2.9)	14 (2.8)
Bronchitis	8 (2.4)	2 (1.2)	10 (2.0)
Urinary tract infection	8 (2.4)	1 (0.6)	9 (1.8)
Nervous system disorders			
Headache	8 (2.4)	2 (1.2)	10 (2.0)
Vascular disorders			
Hypertension	7 (2.1)	1 (0.6)	8 (1.6)

TEAE, treatment-emergent adverse event

TOLERABILITY ASSESSED AT WEEK 52

- Local facial assessments at Week 52 demonstrated that FMX103 1.5% was well tolerated during the open label extension study and local tolerability severities continued to improve beyond the initial 12 weeks of treatment.
- Patients with clear or almost clear erythema increased from 4% at Baseline to 59.3% at Week 52.



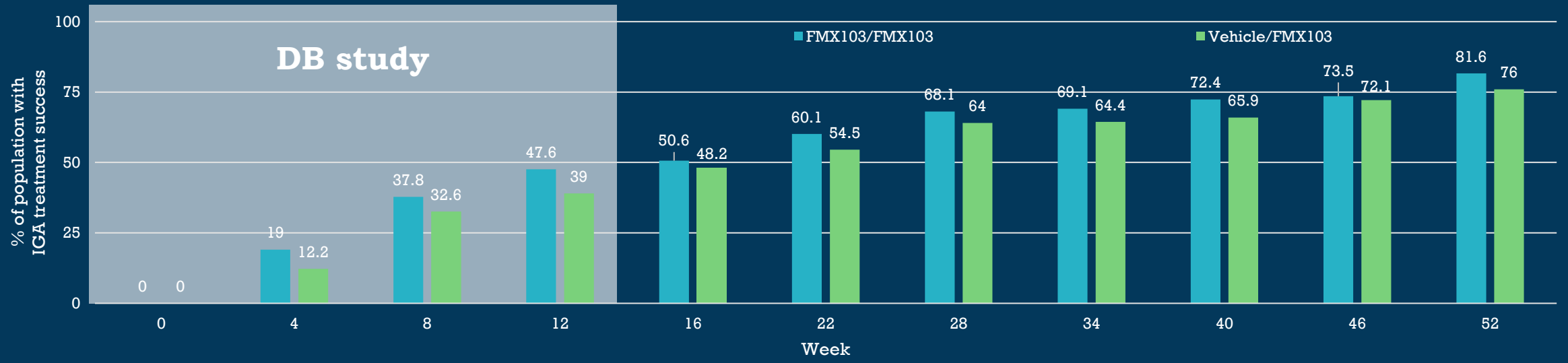


*Hyperpigmentation was most frequently assessed as characteristic of inflammatory and post-inflammatory changes associated with inflammatory lesions of rosacea.

Note: Percentages exclude missing responses as 60 responses were missing from the FMX103/FMX103 group (N=272) and 43 responses were missing from the Vehicle/FMX103 group (N=129).
BL refers to baseline of the double-blind study.

LONG-TERM EFFICACY - IGA TREATMENT SUCCESS

- Overall, >75% of the pooled population achieved IGA Treatment Success by the end of the OL extension study
  - At the end of the study, 81.6% of the FMX103/FMX103 patients and 76% of the Vehicle/FMX103 patients achieved IGA treatment success



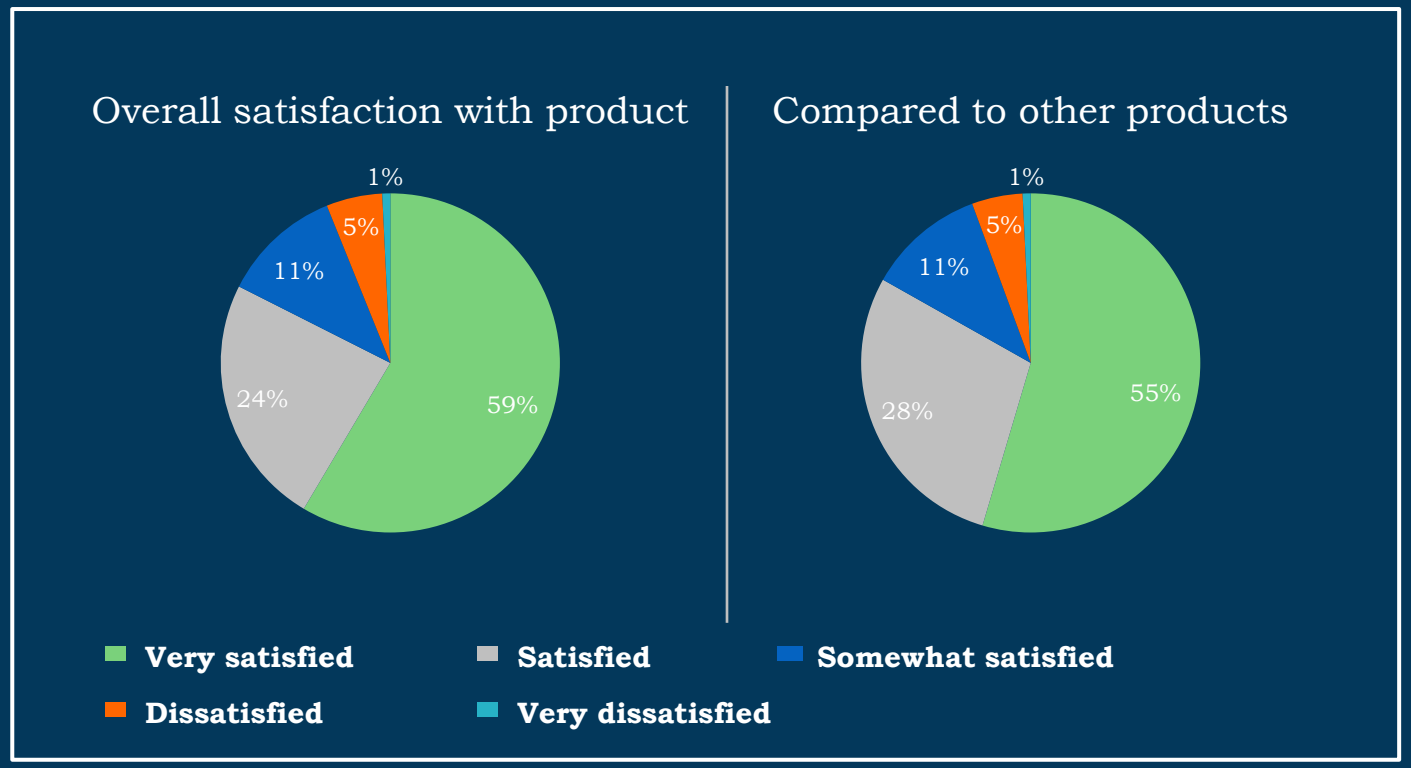
Number of subjects remaining in the study											
Week	**0**	**4**	**8**	**12**	**16**	**22**	**28**	**34**	**40**	**46**	**52**
FMX103/ FMX103	**332**	**332**	**331**	**332**	**326**	**321**	**310**	**298**	**286**	**279**	**272**
Vehicle/ FMX103	**172**	**172**	**172**	**172**	**168**	**156**	**150**	**146**	**138**	**136**	**129**

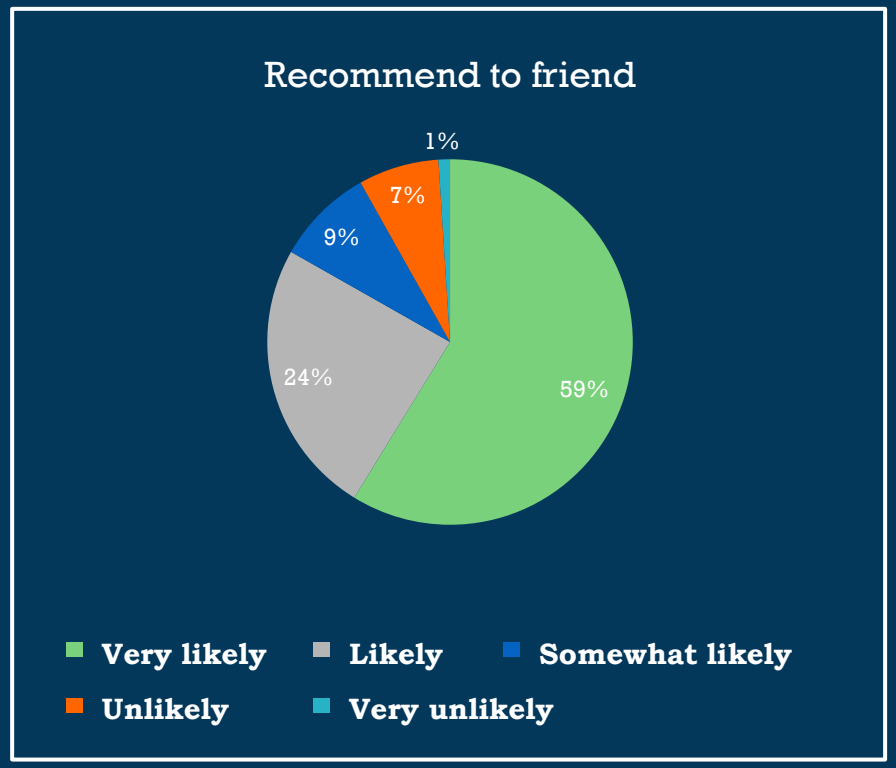
DB=double-blind study; OL=Open Label; IGA=Investigator's Global Assessment.
*The data for Week 12, which serves as the baseline for the open-label study, show the percent of subjects with an IGA score of 0 or 1. The data for Weeks 16-52 show the percent of subjects achieving IGA treatment success as prospectively defined (a score of 0 or 1 and at least a 2-grade improvement from double-blind baseline).

PATIENT SATISFACTION

- At the end of the open-label study, there was a high rate of subject satisfaction with FMX103 1.5% for the treatment of papulopustular rosacea

Subject satisfaction questionnaire results at Week 52
All Treated Population, N=504





Percentages exclude 110 missing responses.

IMPORTANT SAFETY INFORMATION

Indication

ZILXI™ (minocycline) topical foam, 1.5% is a topical form of the antibiotic minocycline for the treatment of adults with pimples and bumps caused by a condition called rosacea. ZILXI is available by prescription only.

ZILXI should not be used for the treatment of infections. It is not known if ZILXI is safe and effective in children. ZILXI is for use on skin only (topical use). ZILXI is not for use in the mouth, eyes or vagina.

Important Safety Information

- ZILXI should not be used in people who are allergic to ZILXI or any tetracycline medicine. Use of ZILXI should be stopped right away if a rash or other allergic symptom occurs.
- ZILXI should not be used in women who are pregnant, may become pregnant or are nursing. If a woman becomes pregnant while using ZILXI, she should talk to her doctor. Tetracycline medicine when taken by mouth during pregnancy, infancy and/or childhood up to the age of 8 years may permanently discolor teeth (yellow-gray-brown) and may slow the growth of bones.
- ZILXI is flammable and fire, flames, and smoking must be avoided when applying and right after applying ZILXI.
- People should protect their skin from the sun while using ZILXI and avoid sunlight or artificial sunlight such as sunlamps or tanning beds. Use of ZILXI should be stopped if skin is sunburned.
- When taken by mouth, minocycline may cause feelings of lightheadedness, dizziness or spinning. People should not drive or operate dangerous machinery if they have these symptoms.

ZILXI is a topical foam that contains minocycline, a tetracycline medicine. It is not taken by mouth. However, tetracyclines, when taken by mouth (capsules or tablets), may cause serious side effects, including: diarrhea, including watery or bloody stools; loss of appetite; tiredness; yellowing of the skin or eyes; bleeding more easily than normal; confusion; sleepiness; vision changes, including blurred vision, double vision, or permanent vision loss; unusual headaches; fever; rash; joint pain; body weakness; discoloration or darkening of the skin, scars, teeth, or gums. People should call their doctor right away if these side effects occur.

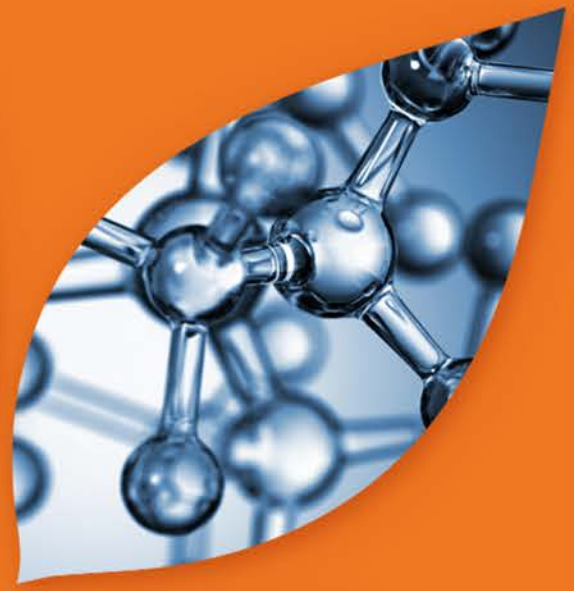
The most common side effect of ZILXI is diarrhea.

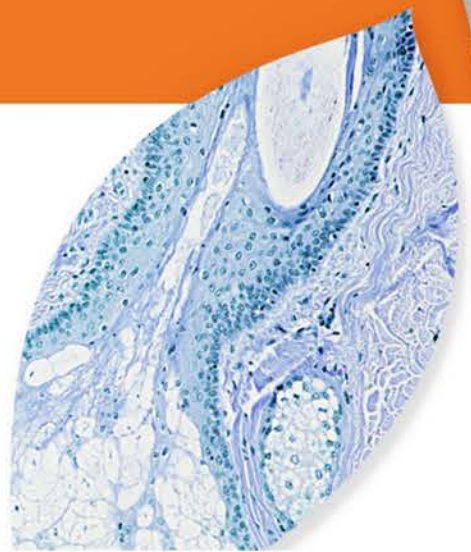
These are not all of the possible side effects with ZILXI. People should contact their doctor for medical advice about side effects and be sure to tell their doctor about all of their medical conditions and medicines they take before using ZILXI.

People are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information at www.ZILXI.com.

Thank You!





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