

OUR SKIN TELLS A STORY



Investora
September 2020

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Cassiopea Overview

- Publicly traded on SIX - Cosmo Pharma holds 46.6%
- Innovative late stage pipeline of 4 dermatology NCE products
- Winlevi (clascoterone cream) 1% - First in Class¹ Topical Androgen Receptor (AR) Inhibitor Targeting Acne - Approved by the FDA as a novel drug¹- August 26, 2020

NCE: new chemical entity

Source: 1. US FDA. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020>

Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

Agenda

- Winlevi (clascoterone cream) 1%
- Commercial Update
- Product Development Update

Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.




Winlevi[®]
(clascoterone)
cream 1%

Acne is the most prevalent skin condition in the U.S...yet the last new mechanism of action approved by the FDA was almost **40** years ago

50

Million
sufferers in
US

\$5

Billion US
market

24

Million
prescriptions

70%

Total Prescriptions
written in the
Dermatology Office



Source: 1. Thielitz A, Gollnick H. *Am J Clin Dermatol*. 2008;9(6):369–81; 2. Costa CS et al. *Cochrane Database Syst Rev* 2018;11:CD009435. 3. Skin Conditions by the numbers. American Academy of Dermatology. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. 4. IQVIA National Prescription Audit Sept. 2019.

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Approval of Winlevi[®] (clascoterone) cream 1% Fills a Long-Standing Gap in Topical Acne Therapy^{1,2}

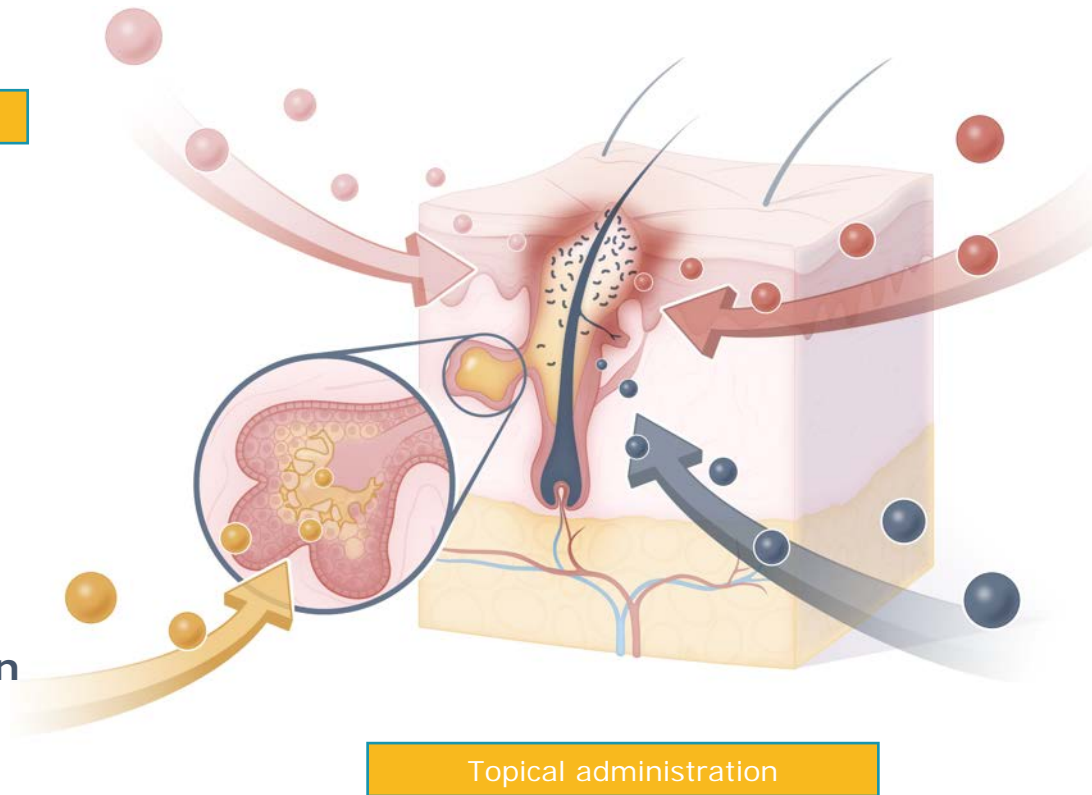
Multi-factorial disease results in a complementary approach to treat acne

Drugs that normalize follicular keratinization

Retinoids

Drugs that inhibit sebaceous gland function

Topical Androgen Receptor Inhibitor



Drugs with anti-inflammatory effects

Retinoids

Antibiotics

Benzoyl peroxide

Drugs with antibacterial effects

Benzoyl peroxide

Antibiotics

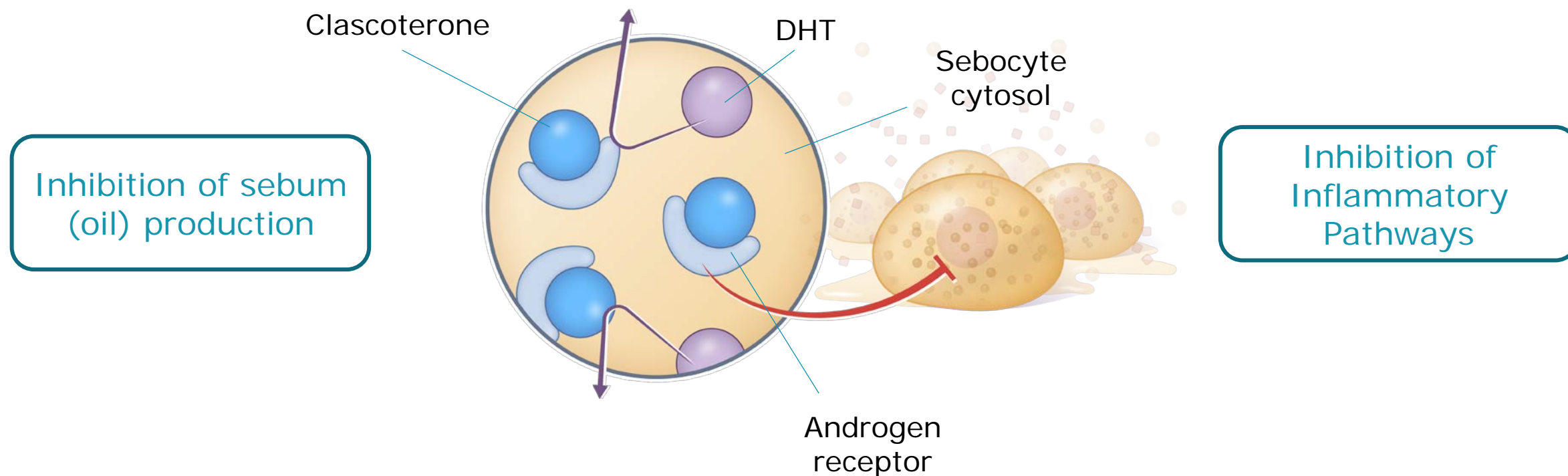
Topical administration

Source: 1. Zaenglein AL et al. J Am Acad Dermatol 2016;5:945–73. 2. Del Rosso JQ et al. J Drugs Dermatol. 2020;19(3 Suppl 1):s30-35

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Clascoterone is an androgen receptor inhibitor: In Vitro Activity

Clascoterone competes with DHT for binding to the androgen receptor^{1,2*}



Source: 1. Ferraboschi P et al. Med Chem Commun 2014;5:904–14; 2. Rosette C, et al. J Drugs Dermatol. 2019; 18(5):412-418. <https://www.ncbi.nlm.nih.gov/pubmed/31141847>

Winlevi Publications

Trending as top article

The screenshot displays the JAMA Dermatology website interface. At the top, the JAAD logo is visible alongside navigation links for Log in, Register, Subscribe, and Claim. The main header area features the article title 'Open-label, long-term extension study to evaluate the safety of clascoterone (CB-03-01) cream, 1% twice daily, in patients with acne vulgaris' by Lawrence Eichenfield, MD, et al. Below the title, there are links for 'Download PDF', 'Figures', 'Save', 'Share', 'Reprints', and 'Request'. The article is categorized as an 'ORIGINAL ARTICLE' and is available 'for Free'. The page also shows a search bar, a sidebar with 'Key words', 'Methods', 'Results', 'Discussion', and 'Conclusions', and a 'Top of Article' section with links to 'Key Points', 'Abstract', 'Introduction', 'Methods', 'Results', 'Discussion', and 'Conclusions'. The article's publication date is April 22, 2020, and it has 14,073 views, 0 citations, 106 altmetrics, and 1 comment.

Nearly 20,000 views /downloads from JAMA Derm website alone

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A Phase 2b, Randomized, Double-Blind Vehicle Controlled, Dose Escalation Study Evaluating Clascoterone 0.1%, 0.5%, and 1% Topical Cream in Subjects With Facial Acne

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^bCassiopea Inc., San Diego, CA

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Pharmacokinetic Profile, Safety, and Tolerability of Clascoterone (Cortexolone 17-alpha propionate, CB-03-01) Topical Cream, 1% in Subjects With Acne Vulgaris: An Open-Label Phase 2a Study

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^aCassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy

^bCassiopea Inc., San Diego, CA

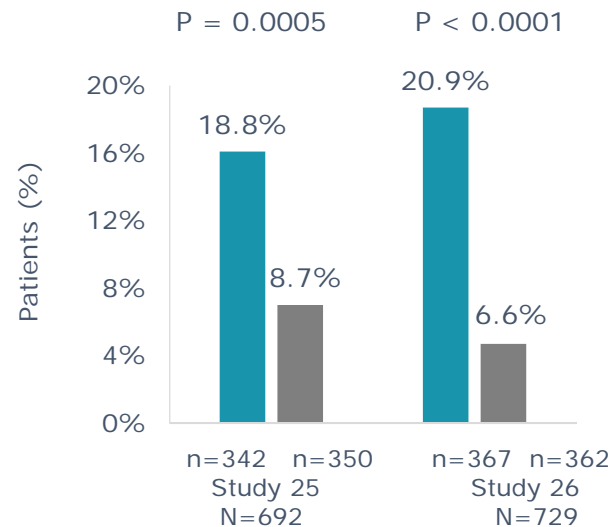
Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.



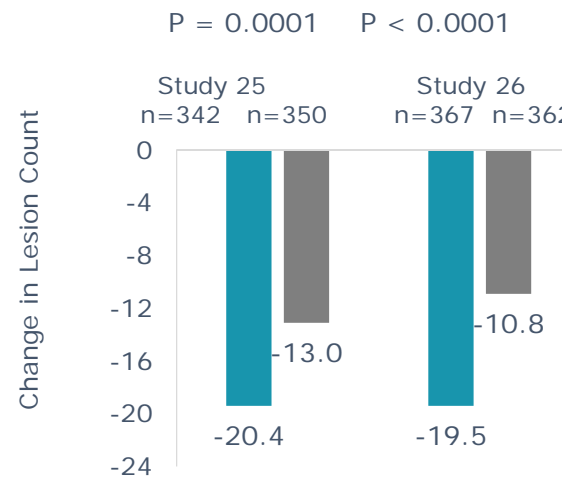
Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle—IGA Success and Absolute Reduction in Lesion Count^{1,2}

EFFICACY (CO-PRIMARY ENDPOINTS) ITT (WEEK 12)

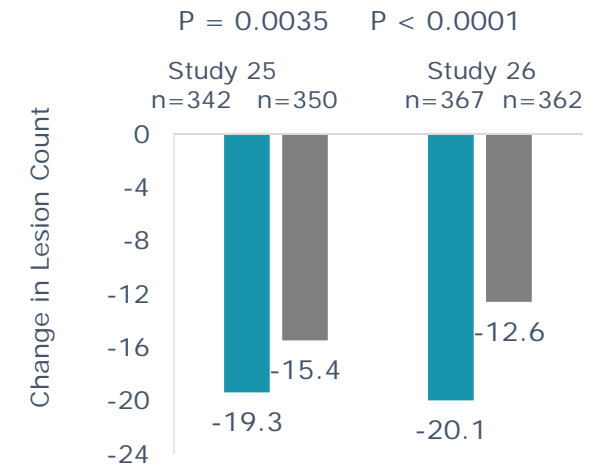
2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)



Absolute change from baseline in non-inflammatory lesion count



Absolute change from baseline in inflammatory lesion count



Winlevi
N=709

Vehicle
N=712

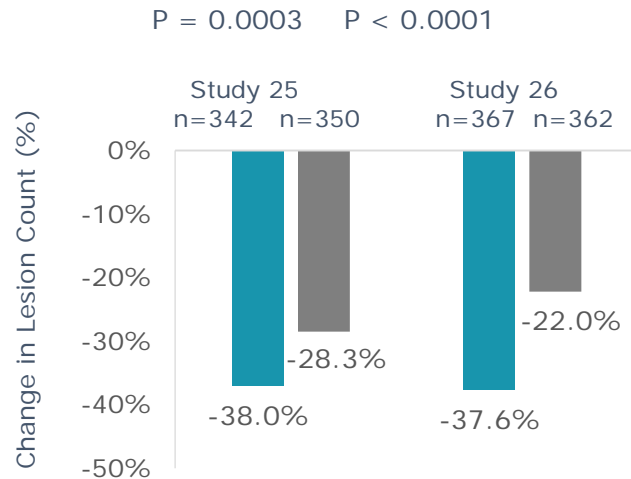
1. Hebert A, et al. JAMA Dermatol. JAMA Dermatol. 2020; 156(6):621-630 . doi:10.1001/jamadermatol.2020.0465. 2. Winlevi ® [Package Insert]. Cassiopea 2020. Statistical significance if P < 0.05 significance level $\alpha=0.05$

Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

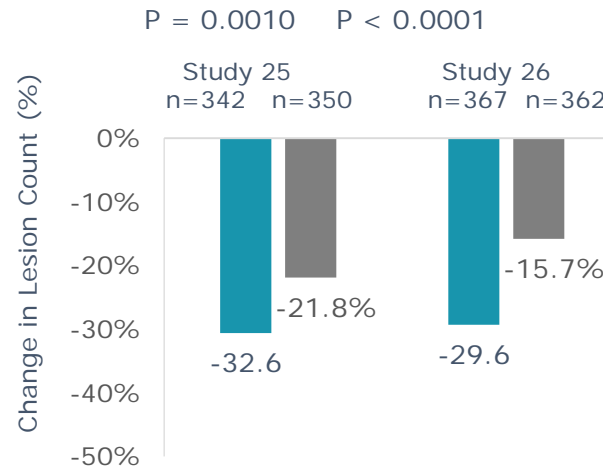
In Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle - Percent Reduction in Lesions^{1,2}

EFFICACY (SECONDARY ENDPOINTS) ITT (WEEK 12)

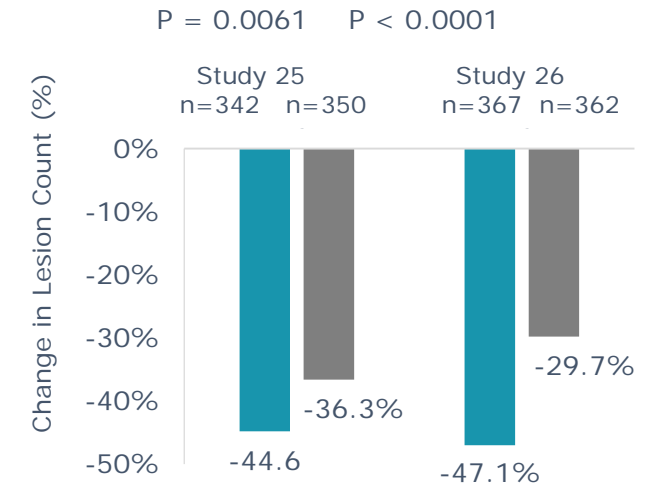
Percent reduction from baseline in total lesion count



Percent reduction from baseline in non-inflammatory lesion count



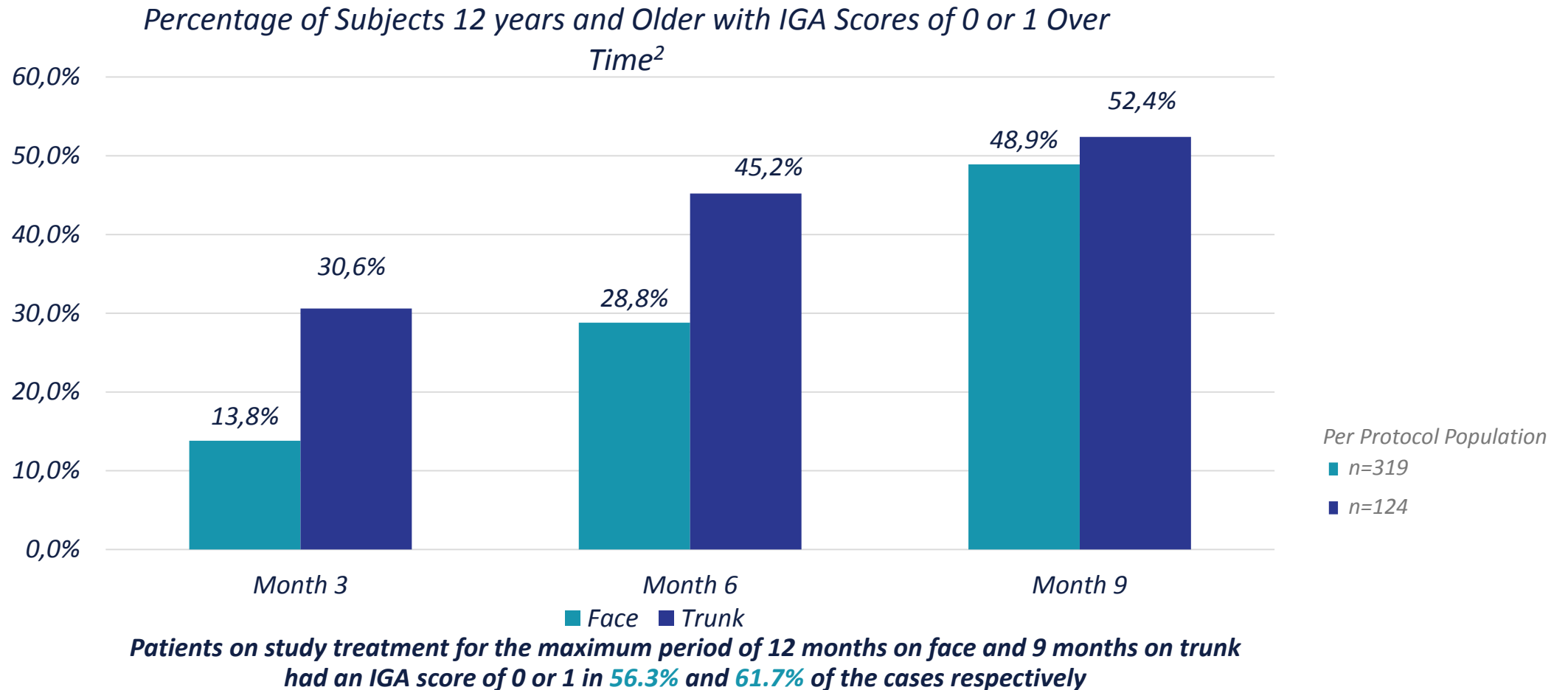
Percent reduction from baseline in inflammatory lesion count



■ Winlevi ■ Vehicle
N=709 N=712

1. Hebert A, et al. JAMA Dermatol. Published online April 22, 2020. doi: 10.1001/jamadermatol.2020.0465. 2. Winlevi ® [Package Insert]. Cassiopea 2020. Statistical significance if P < 0.05 significance level $\alpha=0.05$

Clascoterone Cream 1% Phase III Open Label Extension Study: Secondary Endpoint: Efficacy Summary^{1,2}

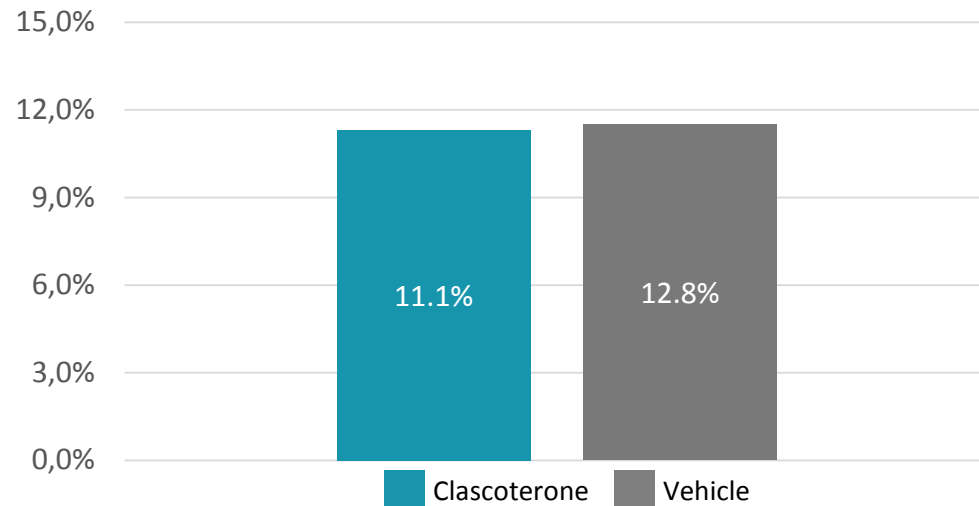


Source: 1. Eichenfield L et al. In press. JAAD 2020 2. Data on File. Cassiopea. 2020

Winlevi Safety Profile—Phase 3 Studies & Open Label Extension^{1,2}— Indicated Population³

Phase 3 trials across 1,421 patients demonstrated side effects similar to vehicle^{1,2}

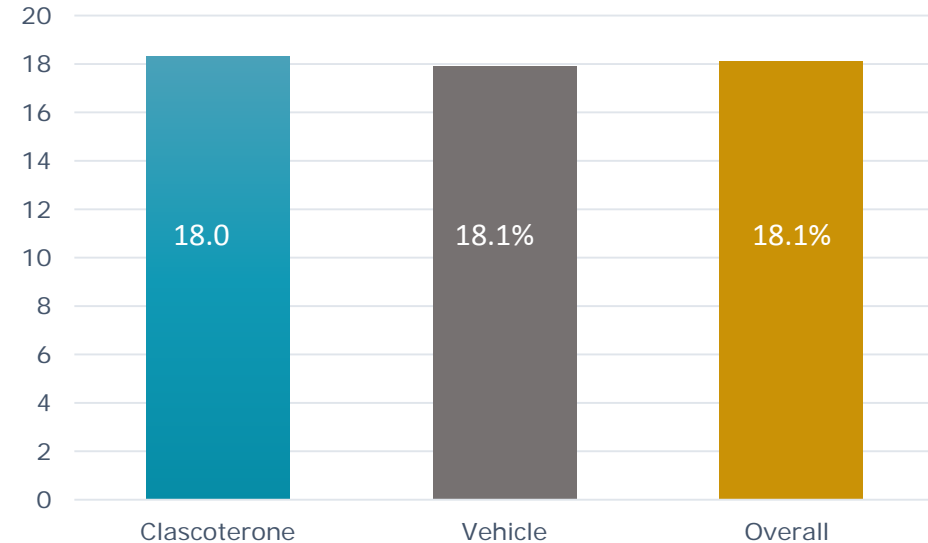
Pooled Safety Data – TEAE* Study 25, 26



*Treatment Emergent Adverse Events

The open label trial involving 600 patients from the parent Phase 3 studies showed similar TEAE levels^{2,3}

Study 27 Percent of Subjects with TEAEs—by parent study



Source: 1. Hebert A. et al. *JAMA Dermatol.* 2020;156(6):621-630. 2. Eichenfield L et al. In press. *JAAD.* 2020. 4. Data on File. Cassiopea.2020. 3.Winlevi [Package Insert]. Cassiopea. 2020

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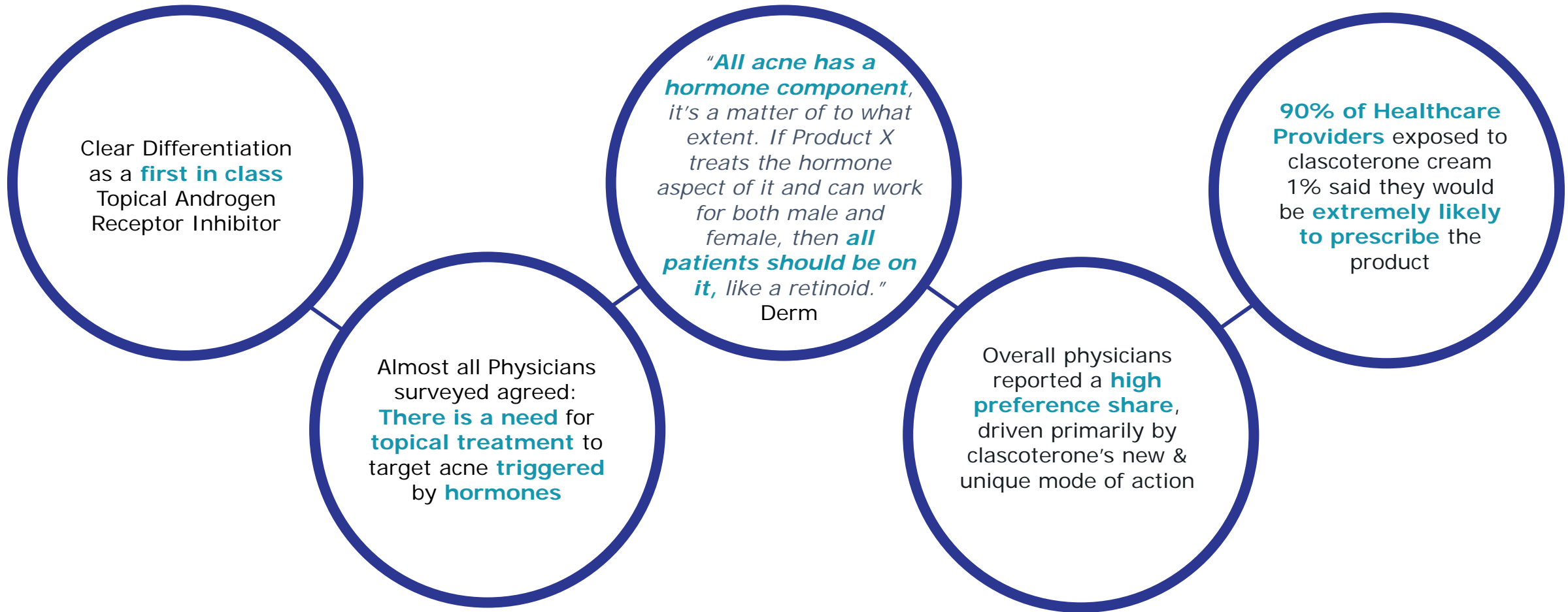
Commercial Update

Key US Acne Market Insights and Positioning

- Acne market continues to be an important market in Dermatology
 - High volume, concentrated target market with 8,200 providers accounting for almost 60% of prescriptions
- Unmet need among providers for a novel approach, especially targeting the hormonal aspect for all acne patients
 - Spironolactone (oral anti-androgen) used off label for acne is the third highest prescribed drug in Dermatology for any indication, limited use to females only
- Acne is treated with polypharmacy, using multiple, complementary drugs to address varying parts of the disease
- Market research demonstrates clear positioning for WINEVI around the unique mechanism of action and significant market share uptake predicted among segmented high value providers

Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.

Market Research confirms WINLEVI can be positioned as a foundation for acne treatment

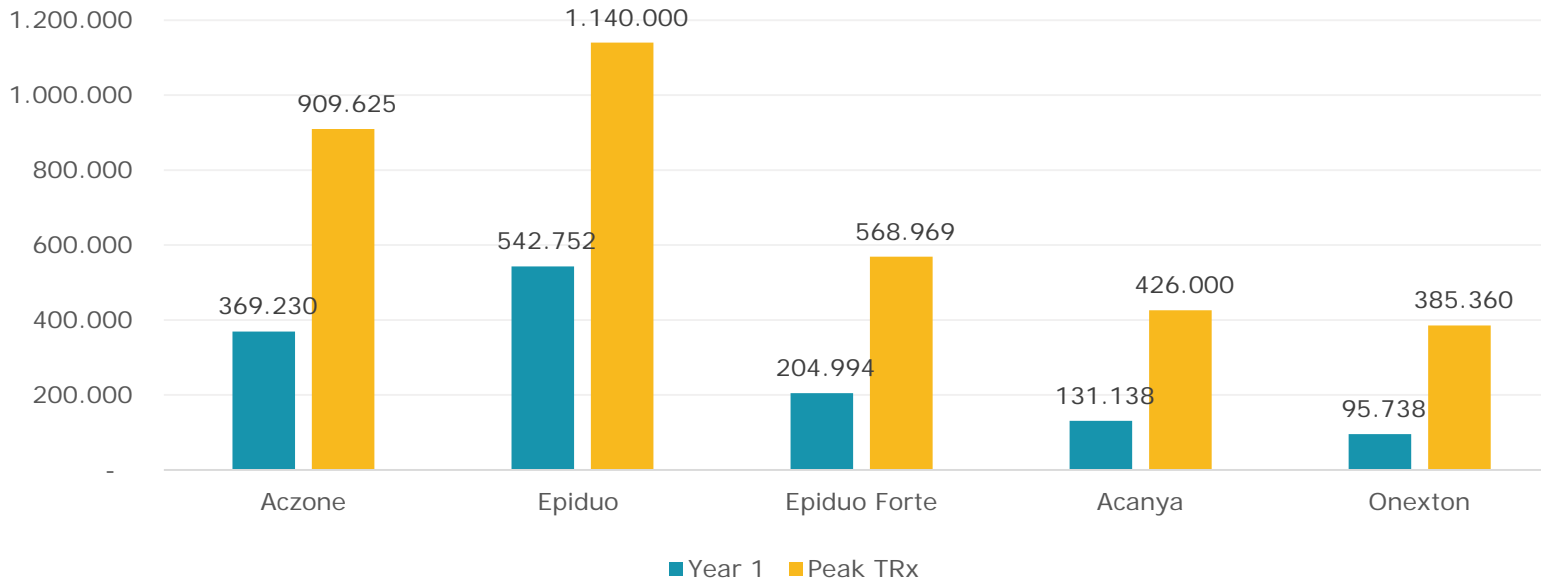


Source: IQVIA Primary Market Segmentation Research July- Sept 2019. Qualitative research n=50. Q. How likely are you to prescribe Product X for your acne patients? Number of HCPs; Rating 1-7: 1 = Not Likely; 4 = Somewhat Likely 7 = Extremely Likely

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Market research confirms interest in WINLEVI is similar to Epiduo and Aczone.

Acne Launch Surrogates: Year 1 & Peak TRx Volume



"This is not only a new product, but also novel product. It's a good option for both men and women struggling with hormonal acne. I would definitely use it!"

—High Priority Segment Derm

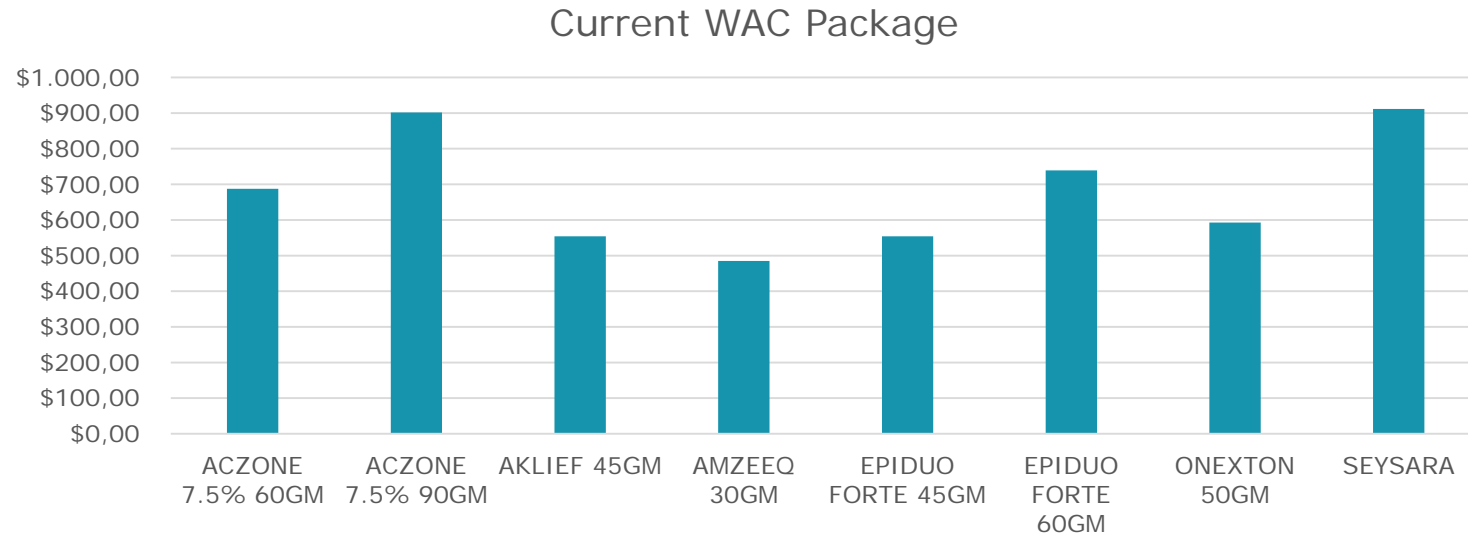
Provider Response to clascoterone cream 1%

- Average **clascoterone efficacy ratings** were similar to products like **Adapalene**, and **Aczone Gel 7.5%®**, given that it provided decent reduction in inflammatory lesions and sufficient long term efficacy (especially in truncal acne)
- **Clascoterone had the highest tolerability rating** of all the products that were rated, given its very positive tolerability profile and its small rate of discontinuation
- HCPs saw most value of Winlevi in **moderate patients** so they can target **both the inflammation and the hormonal** component of acne in these patients

Source: IQVIA NPA Sept. 2019 Data, Aczone & Epiduo Peak Volume in 2015, Acanya 2013, Onexton 2016

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Acne Brand WAC Prices range from \$500-\$900 and vary in pack sizes from 30gm -90gm



- The average wholesale acquisition cost (WAC) of approximately 1 month's supply for a topical acne product is \$613
- New topical brands launched are Akliel® (45gm-\$554.25) and Amzeeq™ (30gm-\$485.00)
- New systemic brand is Seysara® (\$911.60)

*There is a significant deduction from WAC to net price based on the percent discounted to wholesaler for distribution and to payers and patients for market access. This will vary over the life of the product.

Source: Analysource, First DataBank Pricing March 2020

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Market Access Insights and Expected Coverage

- Acne is a fairly stable and predictable payer market
 - They manage the products consistently, without major category evaluations
- Our market research confirms that payers will continue to treat acne as a medical disease and will provide coverage for patient acne visits and products
- Although price in acne is a key driver of the decision for the level of coverage, innovation and new mechanism of action does matter
 - Drugs over \$600 monthly cost may have higher restrictions
 - Clascoterone targeting to be in a unique category as a first in class androgen receptor inhibitor
- Coverage expected in at least 70% of commercial lives without highly restrictive PAs or multiple step edits at an acceptable Net Price per month
- Early Payer reception/willingness to meet with Cassiopea for introductory calls is strong
 - Payers representing >75mm lives scheduled meetings within the first week of contact

Source: In depth interviews conducted June and August 2019 by Precisions Xtract Inc. Perception and coverage expectation data based on primary research conducted June 2019; N=12 Payers (~92M Commercial Lives). Price-Access projections are based on primary research conducted August 2019; N=10 Payers (~79M Commercial Lives)

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Winlevi launch approach

- Adopted a step wise approach to investment and launch preparation
- Exploring M&A options to optimize commercialization and profitability before building own organization
- Built a US management team with extensive dermatology experience in over 20 derm launches
- Built a solid foundation for launch
 - Extensive Medical Affairs program has rapidly increased awareness of clascoterone new MOA and clinical data in the dermatology community
 - Marketing research conducted on positioning, messaging and market segmentation
 - Market access research conducted on value proposition, downstream payer analysis and pricing, and introductory meetings with payers scheduled over next 8 weeks
- Identified areas of external or contract support, rather than build internally
 - Intend to launch with a contract sales organization - Size TBD post COVID
- 2 step launch approach: Market Access Launch at PDUFA (Sept. 2020), Commercial Sales Launch March 2021

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Commercial Launch Priorities



Educate on
the Benefits
of Androgen
Receptor
Inhibition



Establish
Market
Access at
Launch



Generate
Awareness
and Trial at
Launch

A close-up photograph of dark, textured skin, possibly a person's shoulder or back, with a teal-colored background visible in the upper left corner. The image is partially obscured by a white circular shape on the right side of the slide.

Product Development Update

Cassiopea Pipeline

PRODUCT

PROPOSED INDICATION

WINLEVI®
(clascoterone cream 1%)
Androgen receptor inhibitor

Acne Vulgaris



Clascoterone solution
Androgen receptor inhibitor

Androgenetic alopecia in males



Clascoterone solution
Androgen receptor inhibitor

Androgenetic alopecia in females



CB-06-01
Antibiotic

Acne



CB-06-02
Immune modulator

Genital warts



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A close-up photograph of a person's hand, which is covered in thick, dark, wavy hair. A finger is gently touching the hair on the back of the hand. The background is a soft, out-of-focus teal color.

OUR SCIENCE TELLS A STORY

Clascoterone Solution 7.5%
First in Class Androgen Receptor Inhibitor
Targeting Androgenetic Alopecia

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Clascoterone solution is not FDA approved. It is poised as a first in class therapy for androgenetic alopecia

Clascoterone Solution Status and Next Steps

Status:

- Phase 2 dose ranging study in males successful and most effective dose identified
- End of Phase 2 Meeting with FDA held
- Special Protocol Assessment for Phase 3 Program submitted to FDA
- Extensive Medical Affairs program has increased visibility in the Dermatology community
 - 9 Published Papers, Abstracts and Posters, 17 KOL podium presentations
- Phase 2 study in females initiated, enrollment ongoing

Next Steps:

- Finalize Special Protocol Assessment for Phase 3 Program in males with FDA
- Initiate Activities for Phase 3 trials in males – after agreement with FDA on SPA
- Complete enrollment of Phase 2 study in females

Clascoterone Solution for AGA in Females

Phase 2 Study Ongoing:

- Multicenter, prospective, randomized, double blind
- Minoxidil solution 2% BID, vehicle BID, Clascoterone solution 5% BID and Clascoterone solution 7.5% BID
- Females 18-55
- 6 months treatment
- 280 subjects split in 4 groups of 70 subjects


Status/Next Steps:

- Enrollment temporarily stopped for 3 months due to COVID19 and re-started in June
- 272 subjects randomized, plus 22 in screening
- Complete enrollment September 30
- Topline Results anticipated 2Q21

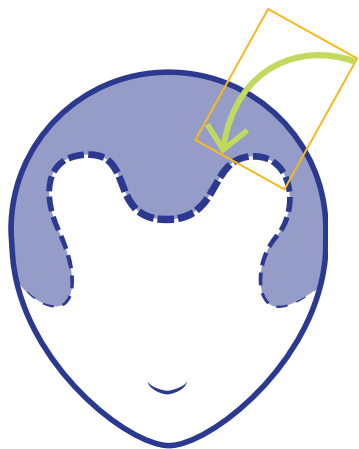
Androgenetic Alopecia and Existing Treatments



DHT = Dihydrotestosterone

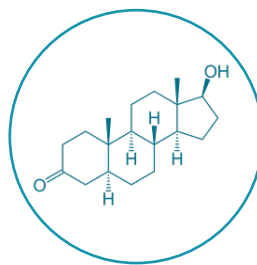
Existing Treatments		Clascoterone Solution
		A Novel Androgen Receptor Inhibitor
<div><p>Propecia (finasteride)</p><ul style="list-style-type: none">Shows anti-androgenic activity on follicleHowever, serious side effects due to hormonal imbalanceNot indicated for women</div>	<div><p>Minoxidil</p><ul style="list-style-type: none">Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla</div>	<ul style="list-style-type: none">Antagonizes DHT’s negative effects on dermal papillaReduces hair miniaturizationReduces dermal inflammation

US Androgenetic Alopecia Market



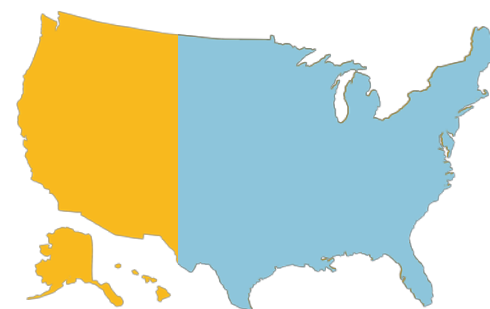
Androgenetic alopecia, also known as **pattern baldness**, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern

It is caused by high concentrations of **dihydrotestosterone (DHT)** at the hair-follicle, which shortens the hair growth cycle.



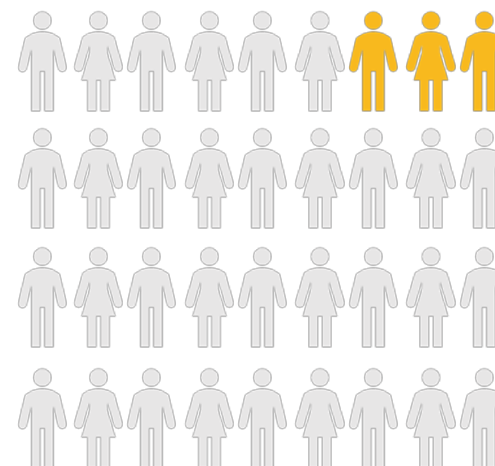
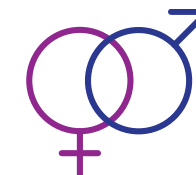
Known psychosocial complications of androgenetic alopecia include **depression, low self-esteem, and less frequent and enjoyable social engagement**

Studies have indicated that **women are more likely to suffer from psychological complications than men**



80-95 million Americans suffer from Androgenetic alopecia

Both men and women are impacted



Only 4-9 million patients are estimated to get treatment

Treatment options are limited to old therapies developed **20 -30 years ago**

Clascoterone solution is not FDA approved. It is poised as a first in class therapy for androgenetic alopecia

Providers and Patients are excited about Clascoterone Solution for AGA

- HCPs were highly receptive to the product profile, emphasizing the novel mechanism and impressive clinical photographs
 - All provider specialties suggest high utilization with a reported adoption of over 60% of male patients and 50% of female patients
 - Physicians reported high adoption rates and would take replace finasteride and minoxidil equally
- Nearly half of Rogaine® patients indicated that they would be at least highly likely to request Clascoterone Solution from their physician
- Clascoterone Solution could be priced like other cash pay lifestyle drugs ie \$100-200 per month



"I'm so excited [about Breezula]. We haven't had anything innovative in a long time."

- Dermatologist



"I have never been able to give my female patients something that could really fix their issue. This product could give a bit of hope to female alopecia patients."

- Primary Care Physician

Upcoming Company Milestones

- Clascoterone Cream 1% launch
 - Market Access 4Q2020, Sales launch March 2021
- Finalize SPA with FDA on Phase 3 program for Clascoterone Solution in males
- Complete enrollment (Sept) and announce topline results for Phase 2 program for Clascoterone Solution in Females 2Q21

PDUFA: The Prescription Drug User Fee Act

Clascoterone solution is not FDA approved. It is poised as a first in class therapy for androgenetic alopecia

Cassiopea SpA

Information

Number of shares: 10,750,000

Listing: SIX Swiss exchange, Main board

ISIN: IT0005108359

Ticker: SKIN

Contacts

Diana Harbort, CEO

dkharbort@cassiopea.com

Chris Tanner, CFO

ctanner@cassiopea.com

WINLEVI® (clascoterone) cream, 1%

Indication & Important Safety Information

INDICATIONS AND USAGE

WINLEVI® (clascoterone) cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION

- Apply a thin layer (approximately 1 gram) to affected area twice daily (morning and evening). Avoid contact with eyes, mouth, and mucous membranes.
- Not for ophthalmic, oral or vaginal use.

DOSAGE FORM AND STRENGTHS

Cream 1%.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Local Irritation: Pruritus, burning, skin redness or peeling may be experienced with WINLEVI cream. If these effects occur, discontinue or reduce the frequency of application of WINLEVI cream.

- Hypothalamic-pituitary-adrenal (HPA) axis suppression may occur during or after treatment with clascoterone.
- Attempt to withdraw use if HPA axis suppression develops.
- Pediatric patients may be more susceptible to systemic toxicity.
- Hyperkalemia: Elevated potassium levels were observed in some subjects during the clinical trials.

ADVERSE REACTIONS

Most common adverse reactions occurring in 7 to 12% of patients are erythema/reddening, pruritus and scaling/dryness. Additionally, edema, stinging, and burning occurred in >3% of patients and were reported in a similar percentage of subjects treated with vehicle.

See

<https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf> for full prescribing information