

# OUR SKIN TELLS A STORY



HC Wainwright Conference  
September 2020

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

# 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 Class<sup>1</sup> Topical Androgen Receptor (AR) Inhibitor Targeting Acne - Approved by the FDA as a novel drug<sup>1</sup>- 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>

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# 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**<sup>®</sup>  
(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<sup>®</sup> (clascoterone) cream 1% Fills a Long-Standing Gap in Topical Acne Therapy<sup>1,2</sup>

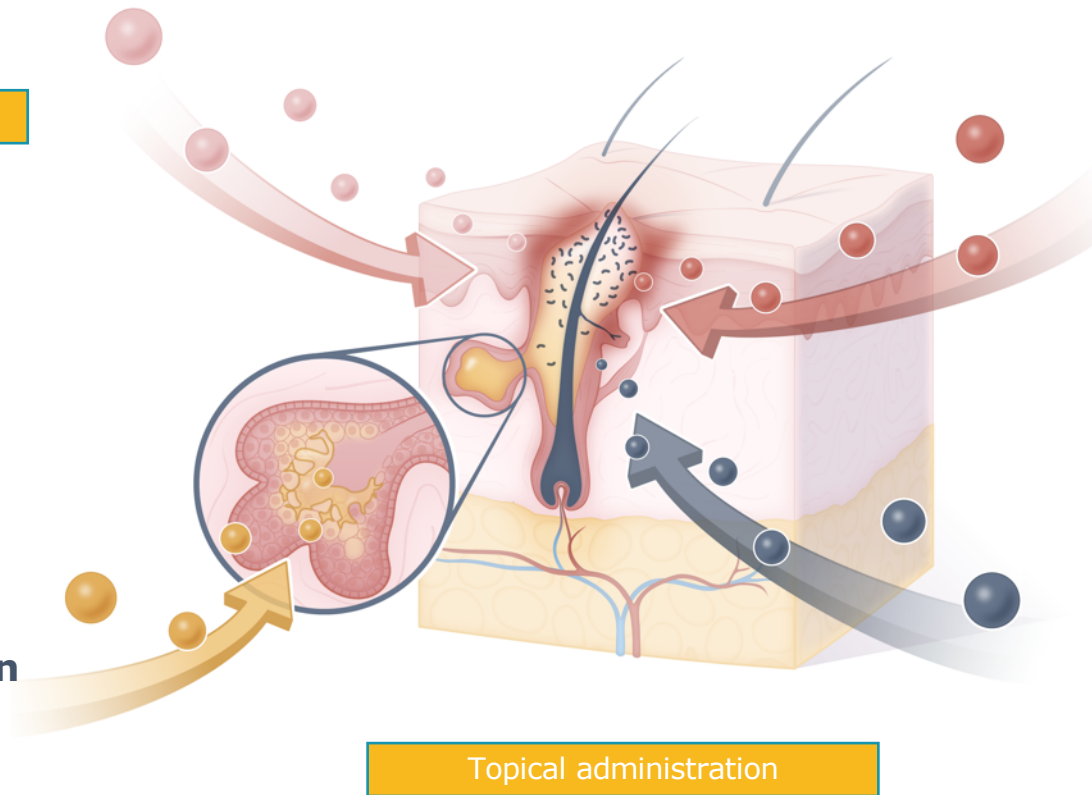
Multi-factorial disease results in a complementary approach to treat acne

**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

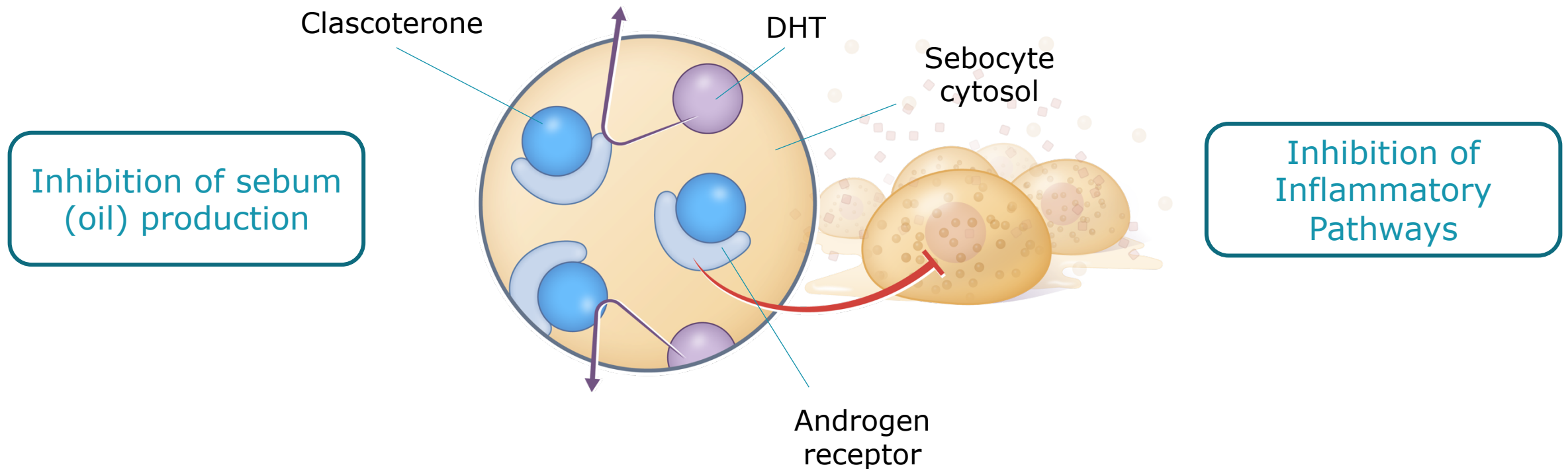
Antibiotics

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<sup>1,2\*</sup>



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, it shows the JAAD logo and navigation options like 'Log in', 'Register', 'Subscribe', and 'Claim'. The main article title is 'Open-label, long-term extension study to evaluate the safety of clascoterone (CB-03-01) cream, 1% twice daily, in patients with acne vulgaris'. Below the title, it lists authors: Lawrence Eichenfeld, MD; Adelaide Hebert, MD; Linda Stein Gold, MD; Enrico Fraggaso, MS; Luigi Moro, PhD; and Alessandro Mazzetti, MD. The article is categorized as an 'ORIGINAL ARTICLE' and is available for free. The page also shows a search bar, a 'This Issue' summary with 14,073 views, and a list of article contents including 'Key Points', 'Abstract', 'Introduction', 'Methods', 'Results', 'Discussion', and 'Conclusions'.

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

JUNE 2019

570

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ORIGINAL ARTICLE

JOURNAL OF DRUGS IN DERMATOLOGY

## 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

Alessandro Mazzetti MD,<sup>a</sup> Luigi Moro PhD,<sup>a</sup> Mara Gerloni PhD,<sup>a</sup> Martina Cartwright PhD<sup>b</sup>  
<sup>a</sup>Cassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy  
<sup>b</sup>Cassiopea Inc., San Diego, CA

JUNE 2019

217

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ORIGINAL ARTICLE

JOURNAL OF DRUGS IN DERMATOLOGY

## 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

Alessandro Mazzetti MD,<sup>a</sup> Luigi Moro PhD,<sup>a</sup> Mara Gerloni PhD,<sup>a</sup> Martina Cartwright PhD<sup>b</sup>  
<sup>a</sup>Cassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy  
<sup>b</sup>Cassiopea Inc., San Diego, CA

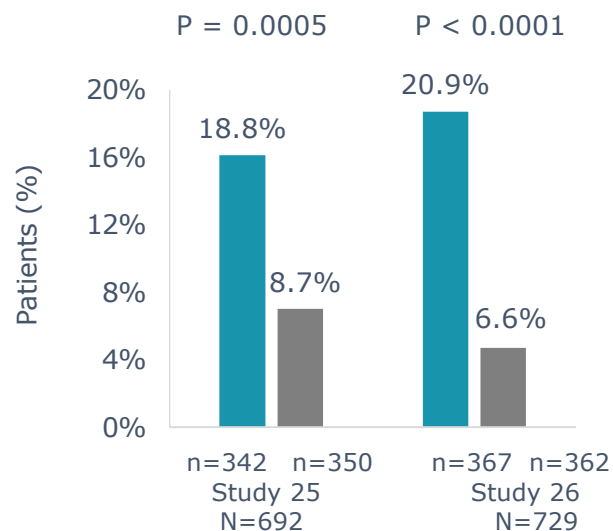
Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.



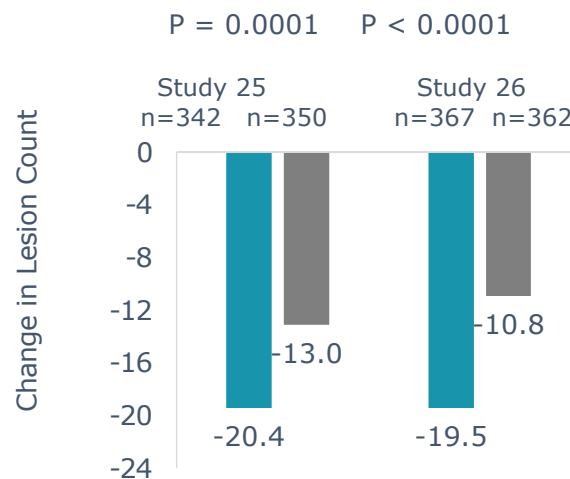
# Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle—IGA Success and Absolute Reduction in Lesion Count<sup>1,2</sup>

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

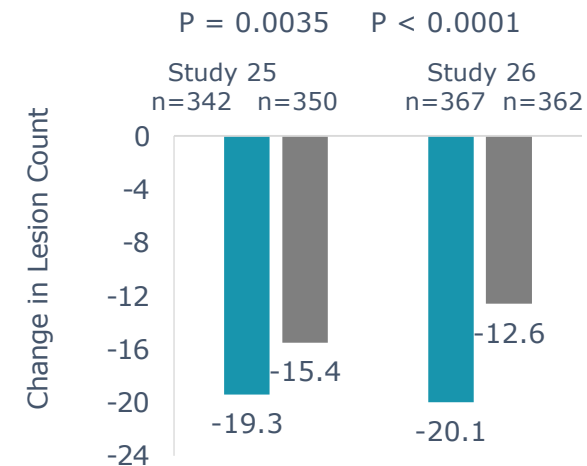
### 2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)



### Absolute change from baseline in non-inflammatory lesion count



### Absolute change from baseline in inflammatory lesion count



■ Winlevi N=709     ■ Vehicle N=712

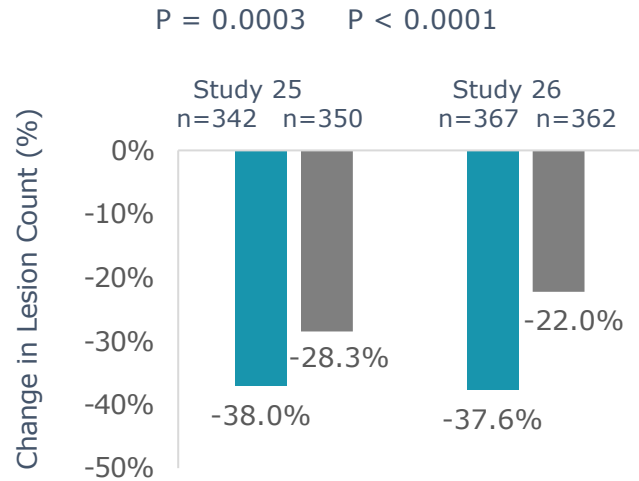
1. Hebert A, et al. JAMA Dermatol. JAMA Dermatol. 2020;156(6):621-630 . doi:10.1001/jamadermatol.2020.0465. 2. Winlevi ® [Package Insert]. Cassiopea 2020. Statistical significance if P < 0.05 significance level  $\alpha=0.05$

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

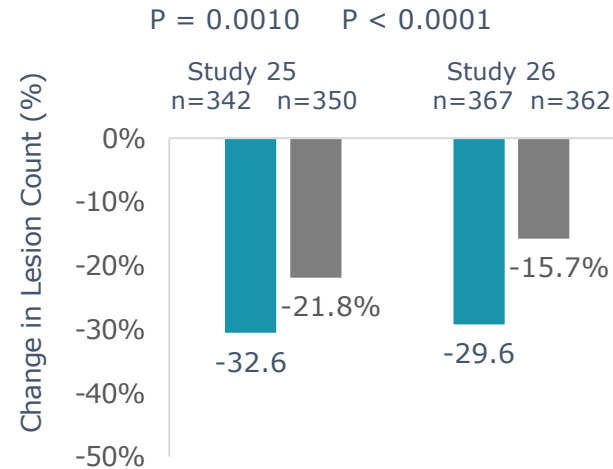
# In Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle - Percent Reduction in Lesions<sup>1,2</sup>

## EFFICACY (SECONDARY ENDPOINTS) ITT (WEEK 12)

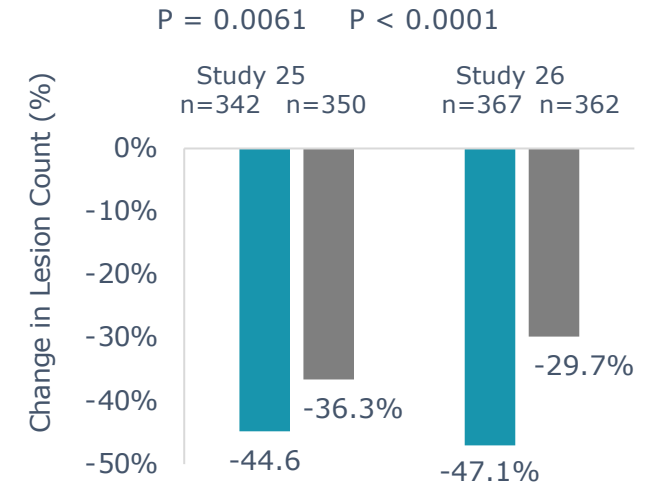
**Percent reduction from baseline in total lesion count**



**Percent reduction from baseline in non-inflammatory lesion count**



**Percent reduction from baseline in inflammatory lesion count**

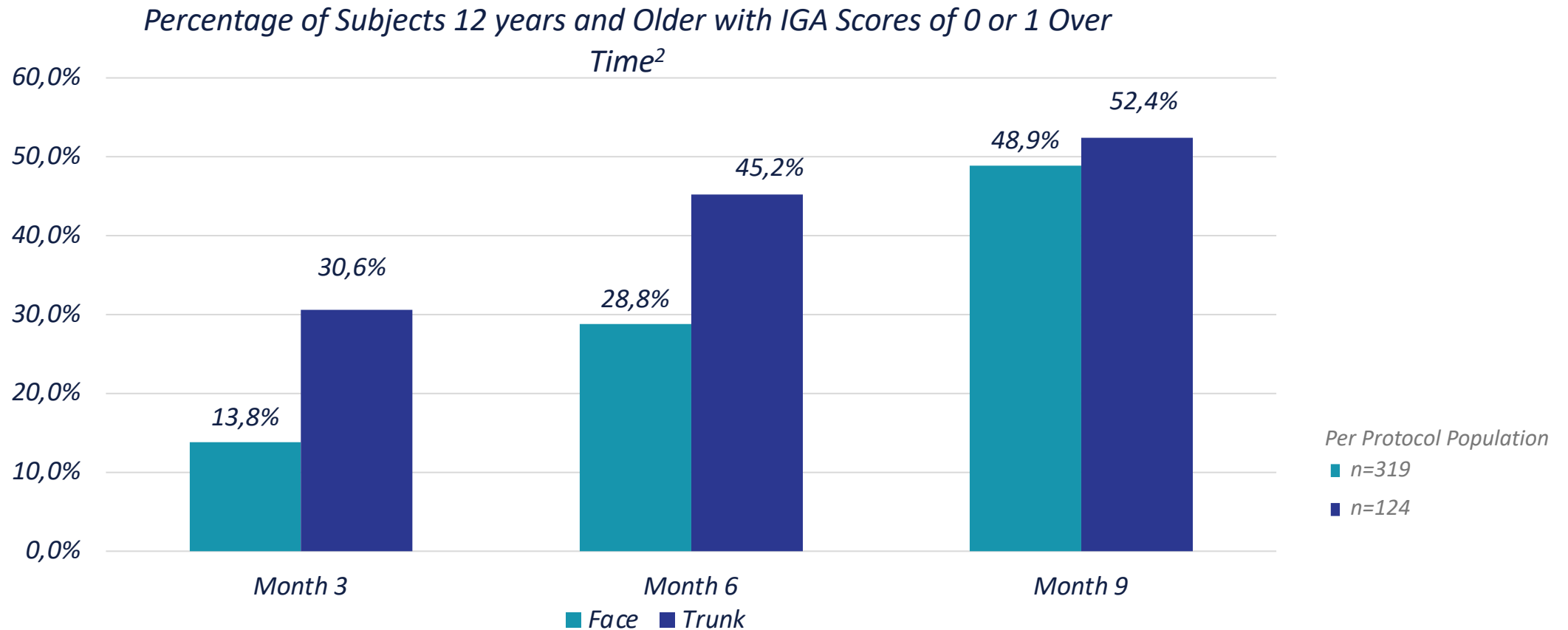


■ Winlevi    ■ Vehicle  
N=709    N=712

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  $\alpha=0.05$

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# Clascoterone Cream 1% Phase III Open Label Extension Study: Secondary Endpoint: Efficacy Summary<sup>1,2</sup>



**Patients on study treatment for the maximum period of 12 months on face and 9 months on trunk had an IGA score of 0 or 1 in 56.3% and 61.7% of the cases respectively**

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

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



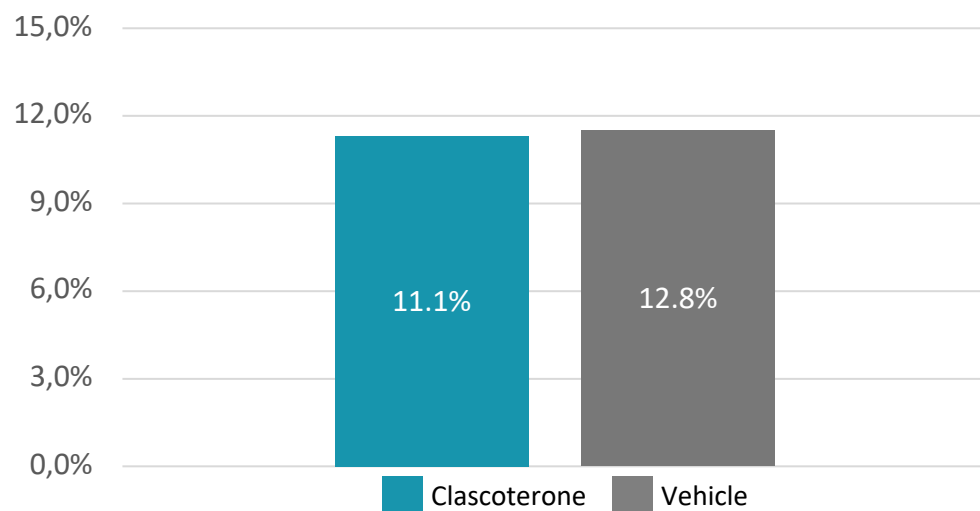


# Winlevi Safety Profile—Phase 3 Studies & Open Label Extension<sup>1,2</sup>— Indicated Population<sup>3</sup>

Phase 3 trials across 1,421 patients demonstrated side effects similar to vehicle<sup>1,2</sup>

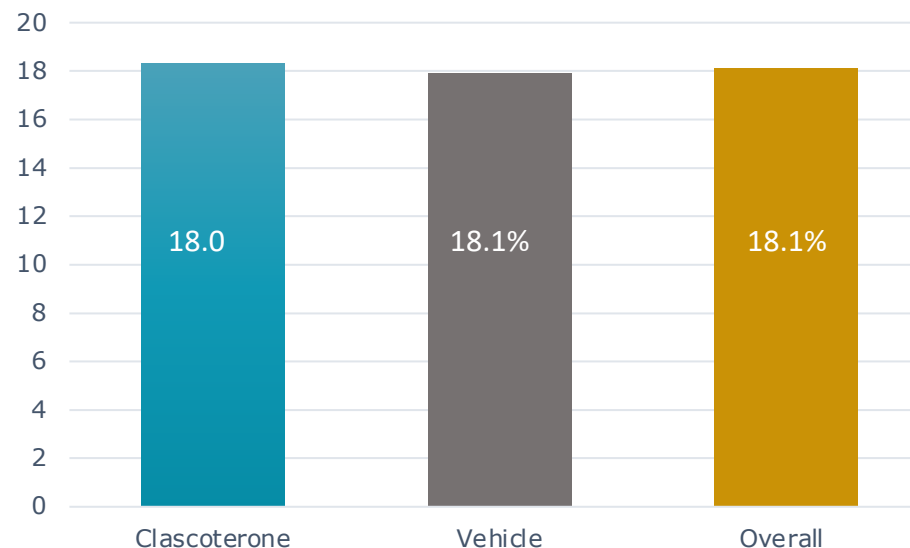
The open label trial involving 600 patients from the parent Phase 3 studies showed similar TEAE levels<sup>2,3</sup>

Pooled Safety Data – TEAE\* Study 25, 26



\*Treatment Emergent Adverse Events

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



**Winlevi**<sup>®</sup>  
(clascoterone)  
cream 1%

# 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

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

Clear Differentiation as a **first in class** Topical Androgen Receptor Inhibitor

*"All acne has a hormone component, it's a matter of to what extent. If Product X treats the hormone aspect of it and can work for both male and female, then **all patients should be on it, like a retinoid.**"*  
Derm

**90% of Healthcare Providers** exposed to clascoterone cream 1% said they would be **extremely likely to prescribe** the product

Almost all Physicians surveyed agreed: **There is a need for topical treatment** to target acne **triggered** by **hormones**

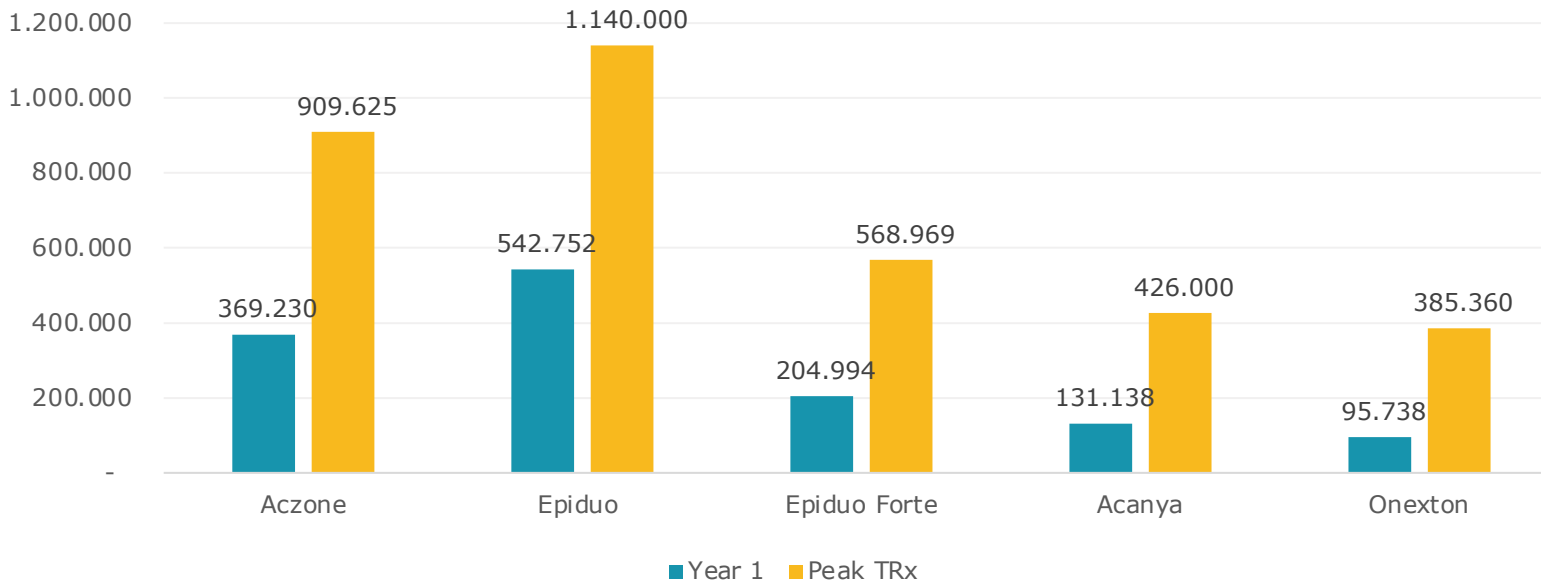
Overall physicians reported a **high preference share**, driven primarily by clascoterone's new & unique mode of action

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!"*

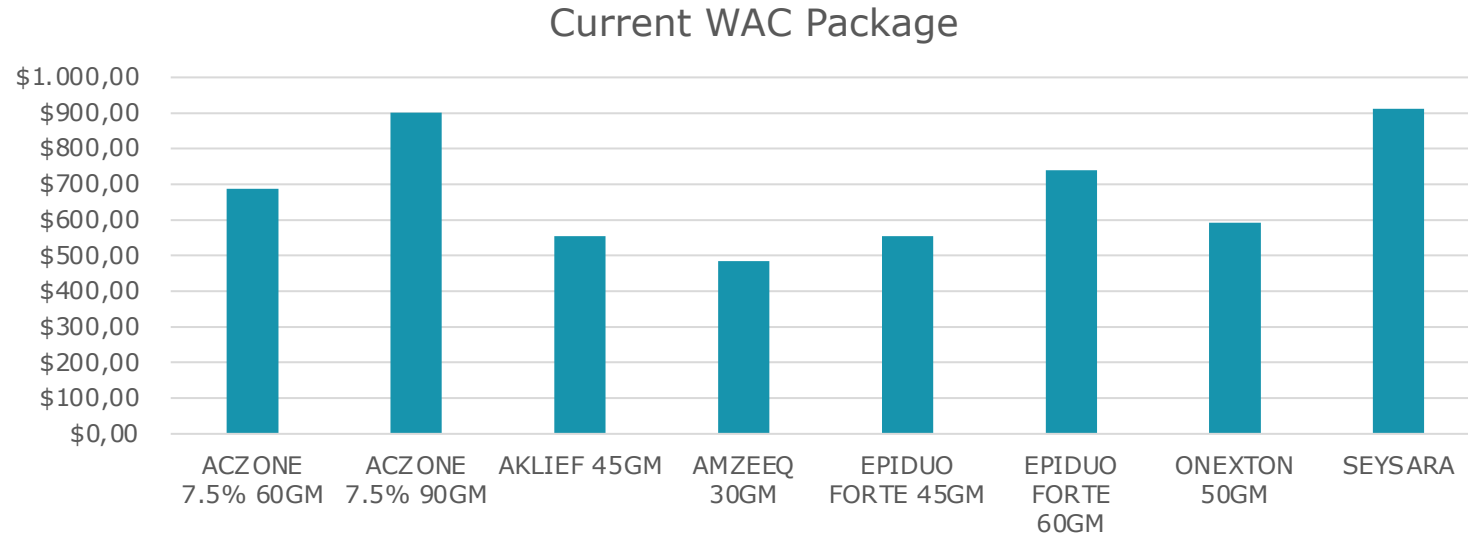
*–High Priority Segment Derm*

## 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

# 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



# 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 hair, likely a man, with a hand gently touching the side of the head. The hair is dark brown and appears to be thinning or receding at the temples. The background is a solid 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:

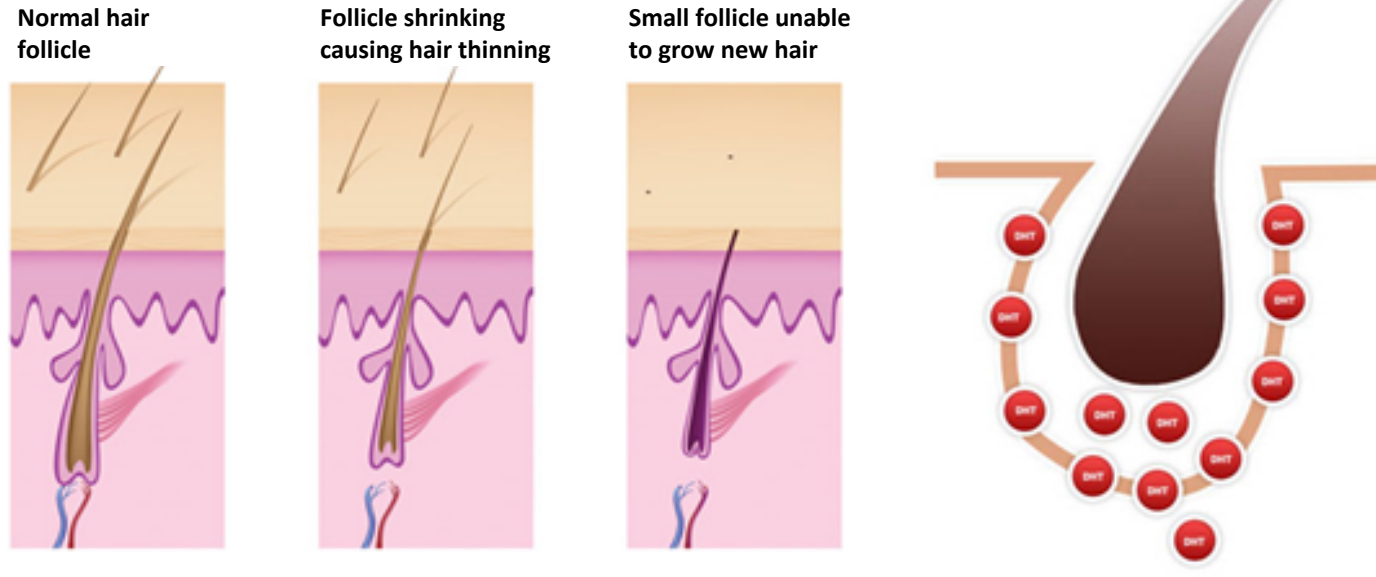
- Multicenter, prospective, randomized, double blind
- Minoxidil solution 2% BID, vehicle BID, Clascoterone solution 5% BID and Clascoterone solution 7.5% BID
- Females 18-55
- 6 months treatment
- 280 subjects split in 4 groups of 70 subjects

## 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

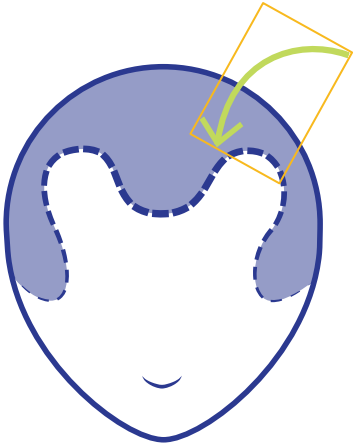


DHT = Dihydrotestosterone

Existing Treatments		Clascoterone Solution <small>A Novel Androgen Receptor Inhibitor</small>
<p><b>Propecia™</b> (finasteride)</p> <ul style="list-style-type: none"> <li>Shows anti-androgenic activity on follicle</li> <li>However, serious side effects due to hormonal imbalance</li> <li>Not indicated for women</li> </ul>	<p><b>Minoxidil®</b></p> <ul style="list-style-type: none"> <li>Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla</li> </ul>	<ul style="list-style-type: none"> <li>Antagonizes DHT's negative effects on dermal papilla</li> <li>Reduces hair miniaturization</li> <li>Reduces dermal inflammation</li> </ul>

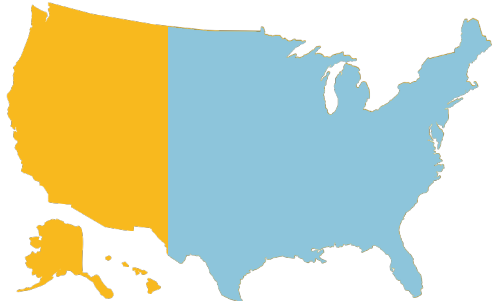
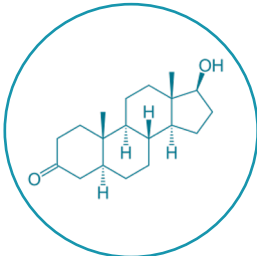
Clascoterone solution is not FDA approved. It is poised as a first in class therapy for androgenetic alopecia

# US Androgenetic Alopecia Market



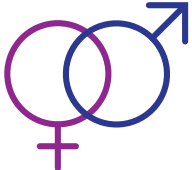
**Androgenetic alopecia**, also known as **pattern baldness**, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern

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



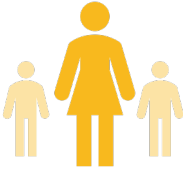
**80-95 million** Americans suffer from Androgenetic alopecia

**Both men and women** are impacted



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**



**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

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

# 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

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Chris Tanner, CFO

[ctanner@cassiopea.com](mailto: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