

OUR SKIN TELLS A STORY



HC Wainwright Virtual BioConnect Conference
January 2021

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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 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>

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Agenda

- Winlevi (clascoterone cream) 1%
- Commercial Update
- Clascoterone Solution Update

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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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Winlevi (clacoterone) cream 1% Approval Marks the Introduction of a **New Class of Topical Therapy to Dermatology**^{1,2}

First in Class Topical Androgen Receptor Inhibitor¹

Approved for the treatment of acne in Patients 12 years and older²

Tackles the androgen hormone component of acne in both males & females^{2,3}

The most frequent observed local skin reaction was mild erythema^{1,3}



1. US FDA. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020> 2. Winlevi Prescribing Information - <https://www.winlevi.com/assets/WINLEVI-clacoterone-cream-prescribing-info-08-2020.pdf> 3. US FDA Drug Trial Snapshot: WINLEVI. September 3, 2020. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-winlevi>

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

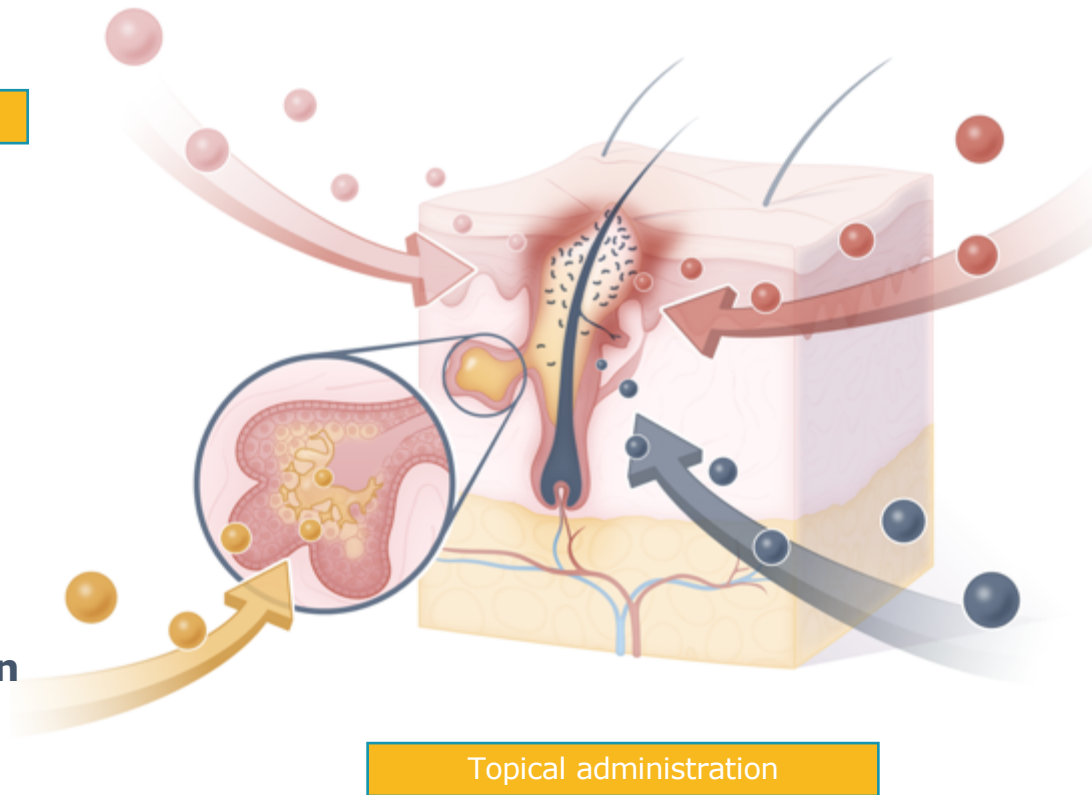
Multi-factorial disease results in a complementary approach to treat acne

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

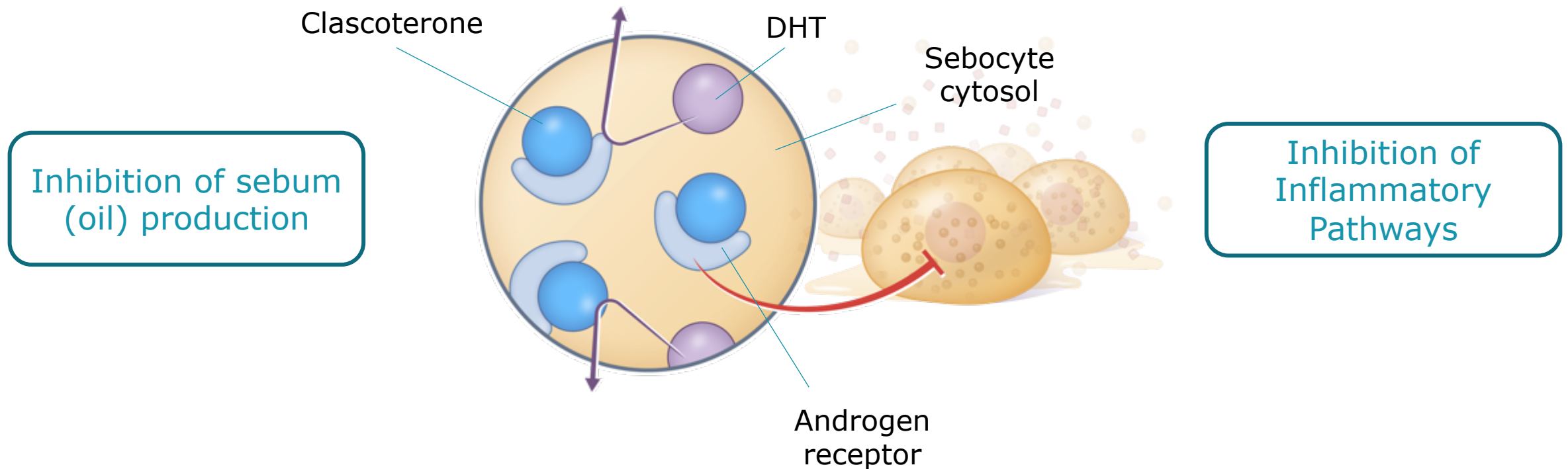
Antibiotics

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 shows the JAMA Dermatology website interface. At the top, there's a navigation bar with 'JAAD' and 'JAMA Dermatology' logos, and options for 'Log in', 'Register', 'Subscribe', and 'Claim'. Below this, a featured article is highlighted: 'Open-label, long-term extension study to evaluate the safety of clascoterone (CB-03-01) cream, 1% twice daily, in patients with acne vulgaris'. The article is by Lawrence Eichenfeld, MD, Adelaide Hebert, MD, Linda Stein Gold, MD, Enrico Frangaso, MD, Luigi Moro, PhD, and Alessandro Mazzetti, MD. It was published on April 26, 2020. The article is marked as 'Open Access' and 'For Free'. Below the article title, there are sections for 'Background', 'Objective', and 'Key words'. The 'Objective' section states: 'To assess the long-term safety of an androgen receptor inhibitor, clascoterone cream, 1%, in patients who participated in phase 3 studies.' The article is categorized as 'Original Investigation' and has 14,073 views, 0 citations, 106 Altmetric mentions, and 1 comment. The article title is 'Efficacy and Safety of Topical Clascoterone Cream, 1%, for Treatment in Patients With Facial Acne' and the subtitle is 'Two Phase 3 Randomized Clinical Trials'. The authors listed are Adelaide Hebert, MD¹; Diane Thiboutot, MD²; Linda Stein Gold, MD³; et al. The article information includes 'JAMA Dermatol. 2020;156(5):621-630. doi:10.1001/jamadermatol.2020.0465'.

Nearly 24,000 views /downloads from JAMA Derm website alone

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,^a Luigi Moro PhD,^a Mara Gerloni PhD,^a Martina Cartwright PhD^b
^aCassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy
^bCassiopea Inc., San Diego, CA

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,^a Luigi Moro PhD,^a Mara Gerloni PhD,^a Martina Cartwright PhD^b
^aCassiopea SpA, via Cristoforo Colombo 1, Lainate, Italy
^bCassiopea Inc., San Diego, CA

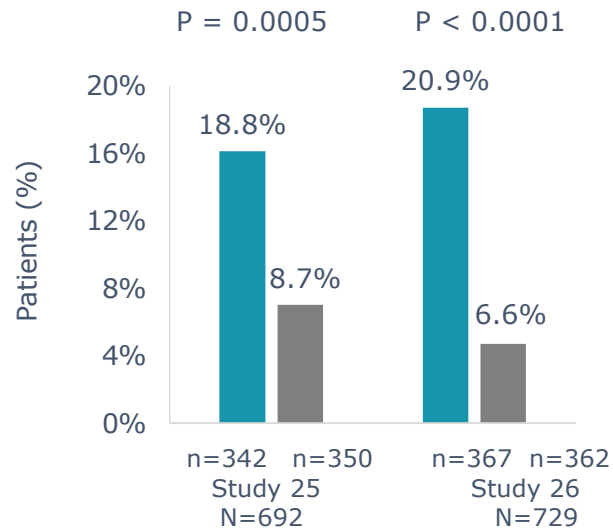
Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information.



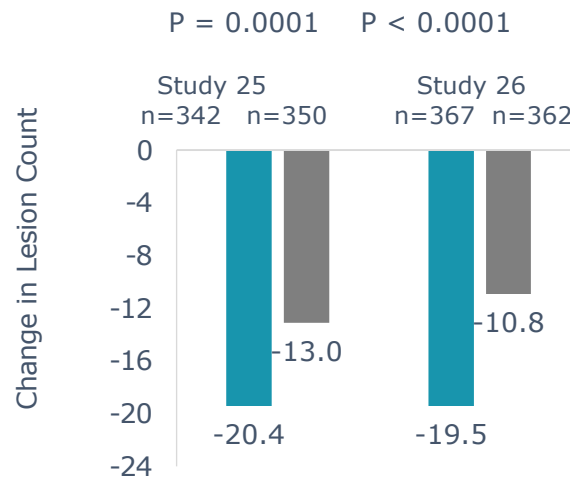
Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle—IGA Success and Absolute Reduction in Lesion Count^{1,2} Age 12 and older

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

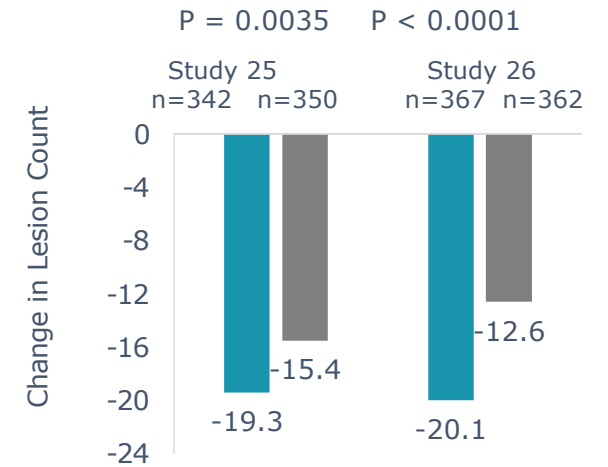
2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)



Absolute change from baseline in non-inflammatory lesion count



Absolute change from baseline in inflammatory lesion count



■ Winlevi N=709 ■ Vehicle N=712

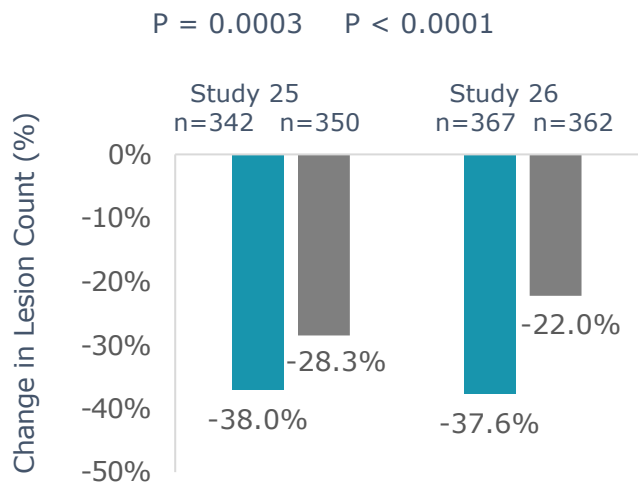
1. Hebert A, et al. JAMA Dermatol. 2020;156(6):621-630 . doi:10.1001/jamadermatol.2020.0465. 2. Winlevi ® [Package Insert]. Cassiopea 2020. Statistical significance if P < 0.05 significance level $\alpha=0.05$

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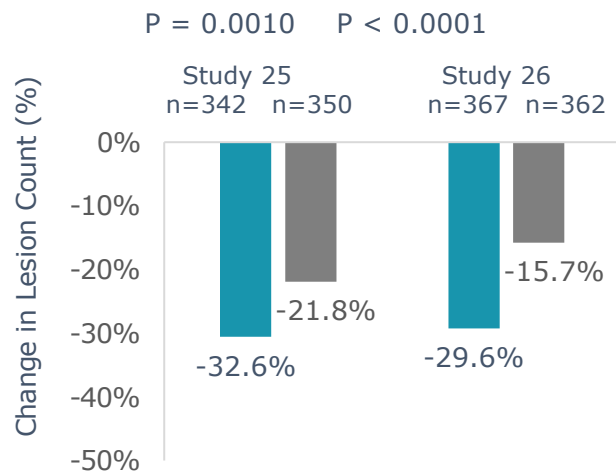
In Two Pivotal Phase III Trials, WINLEVI (clascoterone) Cream, 1% Demonstrated Statistically Significant Efficacy vs. Vehicle - Percent Reduction in Lesions^{1,2} Age 12 and older

EFFICACY (SECONDARY ENDPOINTS) ITT (WEEK 12)

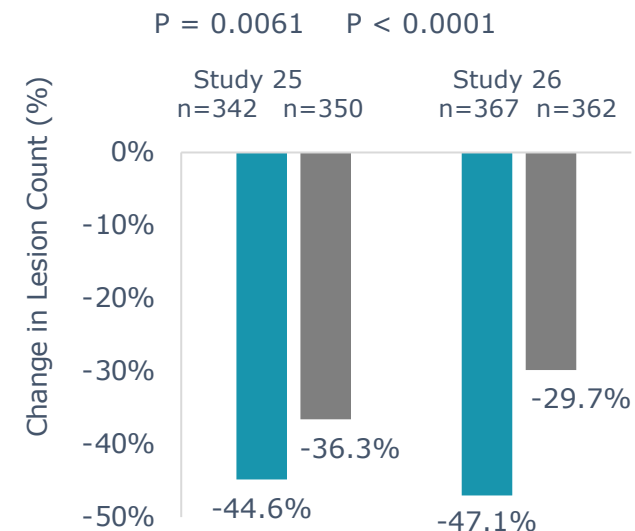
Percent reduction from baseline in total lesion count



Percent reduction from baseline in non-inflammatory lesion count



Percent reduction from baseline in inflammatory lesion count

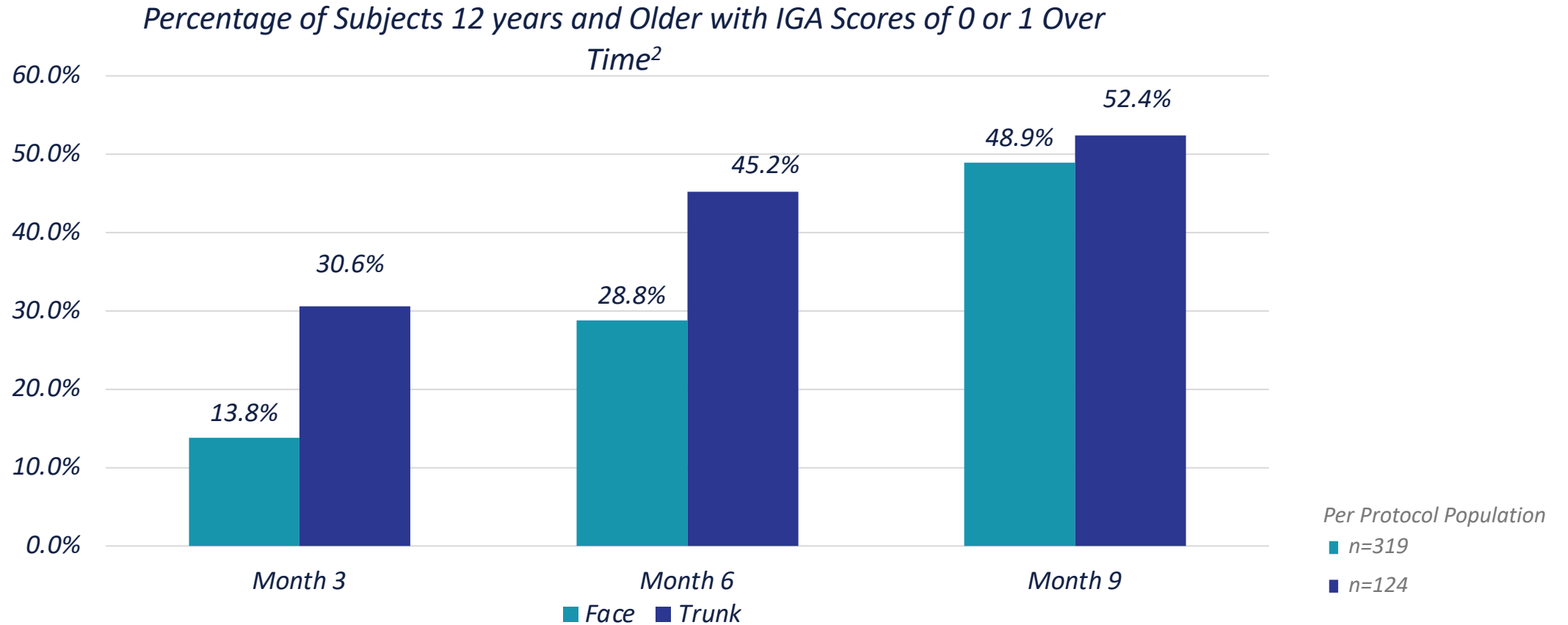


■ Winlevi ■ Vehicle
N=709 N=712

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^{1,2}



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

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

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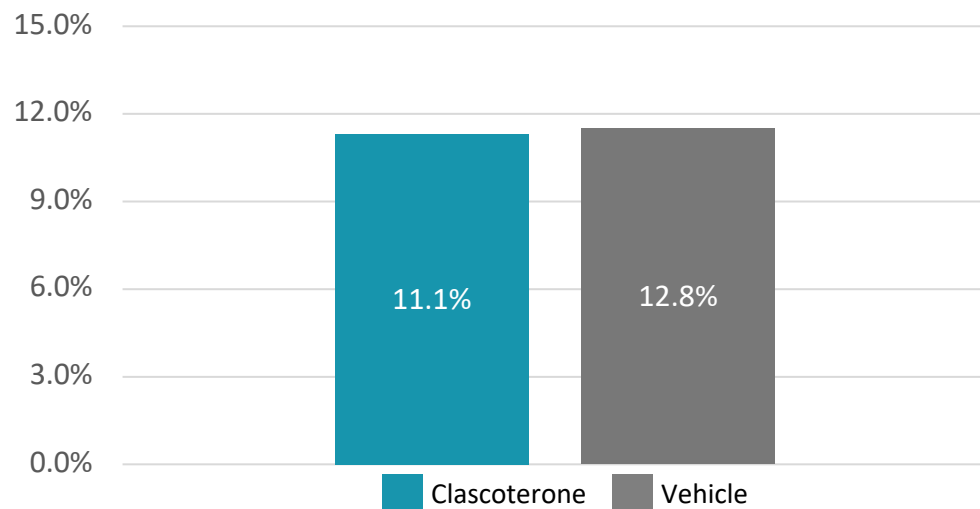


Winlevi Safety Profile—Phase 3 Studies & Open Label Extension^{1,2}— Indicated Population³

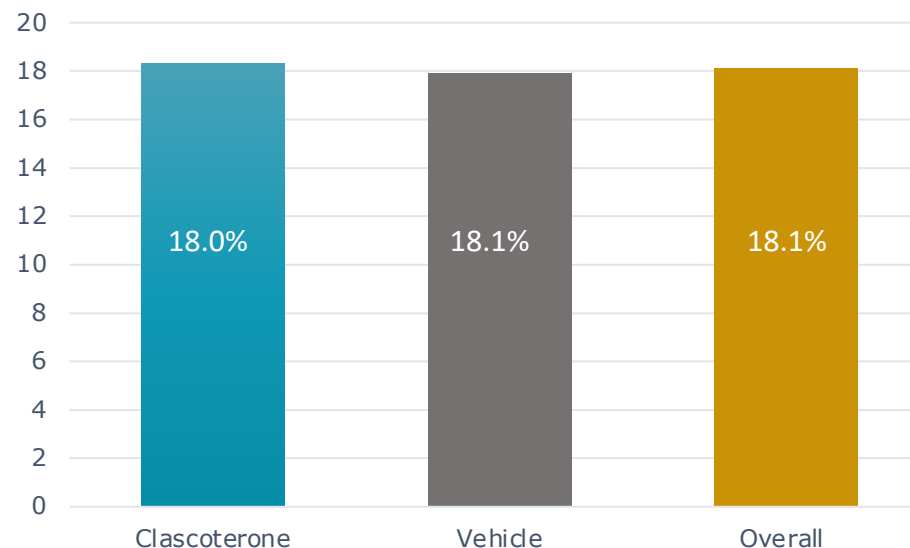
Phase 3 trials across 1,421 patients demonstrated side effects similar to vehicle^{1,2}

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

Pooled Safety Data – TEAE* Study 25, 26



Study 27 Percent of Subjects with TEAEs—by parent study



*Treatment Emergent Adverse Events

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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WINLEVI (clascoterone) Cream, 1% Incidence of New or Worsening Local Skin Reactions (LSRs) reported by $\geq 1\%$ of Patients ≥ 12 Years

Incidence of New or Worsening Local Skin Reactions Reported by $\geq 1\%$ of Patients Treated with Winlevi After Day 1 in 12-Week Controlled Clinical Trials

	Winlevi (N=687 ^a)	Vehicle Cream (N=662 ^a)
Edema	25 (3.6%)	23 (3.5%)
Erythema/reddening	84 (12.2%)	101 (15.3%)
Pruritus	52 (7.6%)	55 (8.3%)
Scaling/ dryness	72 (10.5%)	68 (10.3%)
Skin atrophy	11 (1.6%)	17 (2.6%)
Stinging/burning	28 (4.1%)	28 (4.2%)
Striae rubrae	17 (2.5%)	10 (1.5%)
Telangiectasia	8 (1.2%)	12 (1.8%)

a. The denominators for calculating the percentages were the 674 of 709 subjects treated with WINLEVI cream and 656 of 712 subjects treated with vehicle in these trials who had local skin reaction results reported after Day 1. LSR severity was recorded trace, minimal, mild, moderate or severe. Most were trace/minimal/mild.

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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

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**

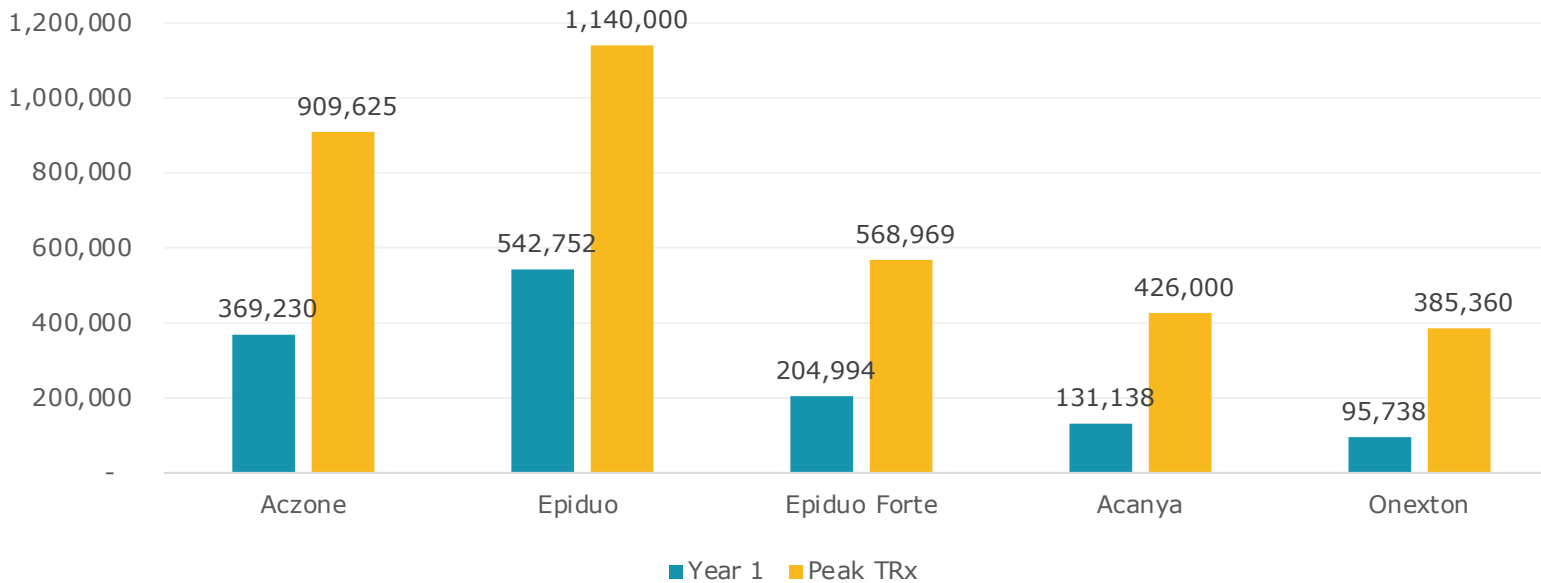
Overall physicians reported a **high preference share**, driven primarily by clascoterone's new & unique mode of action

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

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

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
- Reported market share of 18-24%

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Market Access

Summary Insights and Coverage Progress

- Research confirms that Payers will continue to provide coverage for acne patient visits and products
- While price is a key driver for coverage decisions, innovation and new MOA does matter
 - Drugs over \$600 WAC monthly cost may have higher restrictions
 - Clascoterone targeting to be in a unique category as a first in class androgen receptor inhibitor
 - Possibly decreasing steps through other drugs as there are no other drugs in the class
- Coverage expected in at least 70% of commercial lives without highly restrictive PAs or multiple step edits for an acceptable Net price per month to the payer
- Partnered with a syndicated National Account Team (NAM) of 8 with U.S. Payer engagements started July 2020
- \$550 WAC price set
- Positive feedback to product and clinical reviews with Payers covering ~94% of Commercial lives
- Q4 2020 Contracting Engagements have been initiated with Payers representing:
 - 83MM Commercial Lives
 - 55% of Annual Acne Prescriptions

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
 - Built a US management team with extensive dermatology experience in over 20 derm launches
 - 2 step launch approach: Market Access Launch at PDUFA (Sept. 2020), Commercial Sales Launch mid 2021
- 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/pricing and market access launch has begun
- In order to increase operating efficiency we are currently evaluating
 - Transactions that give access to additional products
 - Structures of external or contract support
 - Cooperations with a commercial sales partner with Cassiopea maintaining strategic control of the brand (marketing, medical affairs, market access)
 - M&A options to optimize commercialization and profitability before building own organization

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

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:

- FDA feedback on Special Protocol Assessment (SPA) for Phase 3 Program in males received in June with a request for a new validated PRO (Patient Reported Outcome)
- Type A FDA meeting held in November regarding development of the new PRO in parallel with Phase 3 studies, agreed
- Phase 2 study in 293 females fully enrolled, topline results expected 2Q21
- Extensive Medical Affairs program has increased visibility in the Dermatology community - 9 Published Papers, Abstracts and Posters, 17+ KOL podium presentations

Next Steps:

- Initiate Activities for PRO questionnaire
- Finalize SPA for Phase 3 Program in males with FDA, Type C meeting request sent Dec 2020
- Initiate Activities for Phase 3 trials in males – after agreement with FDA on SPA

Clascoterone Solution for AGA in Females

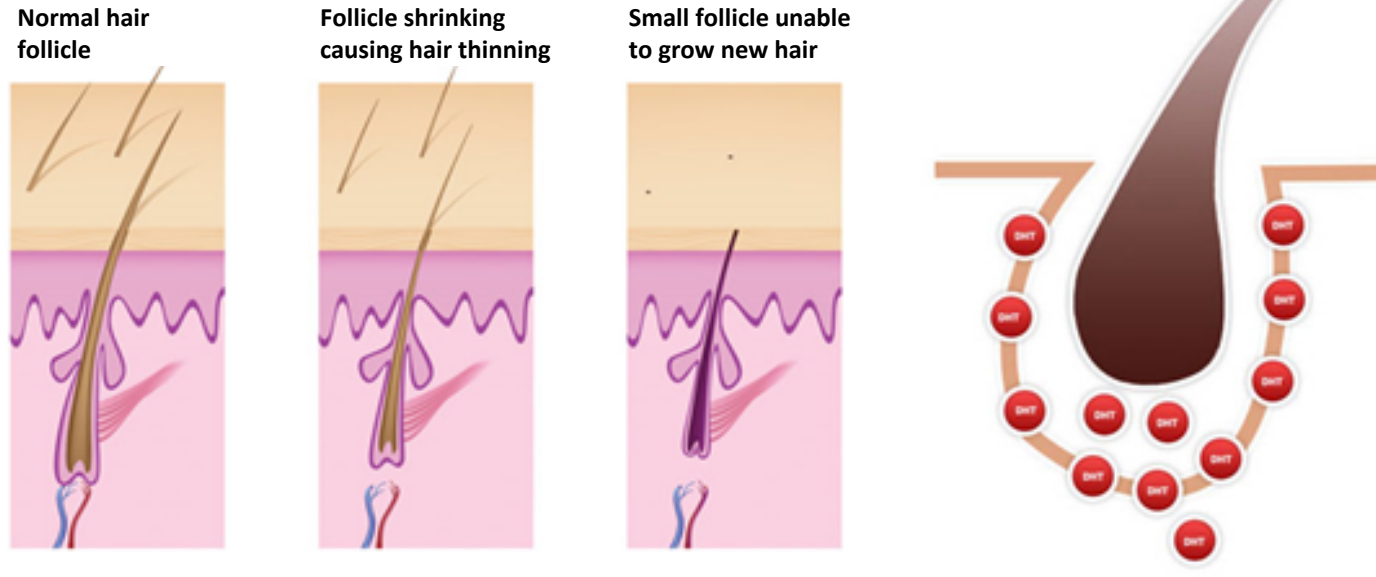
Phase 2 Study Ongoing:

- 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 complete: 293 subjects enrolled
- Topline Results anticipated 2Q21

Androgenetic Alopecia and Existing Treatments

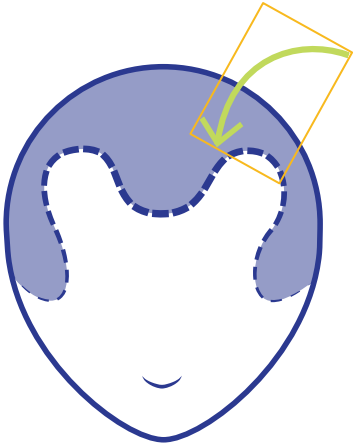


DHT = Dihydrotestosterone

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

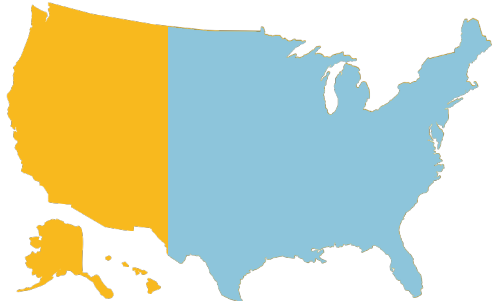
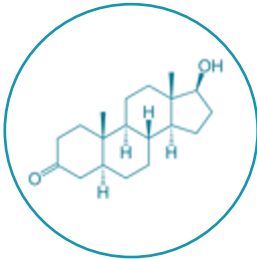
Clascoterone solution is not FDA approved. It is poised as a first in class therapy for androgenetic alopecia

US Androgenetic Alopecia Market



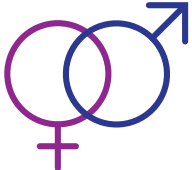
Androgenetic alopecia, also known as **pattern baldness**, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern

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



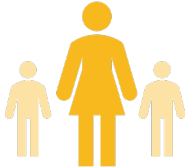
80-95 million Americans suffer from Androgenetic alopecia

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

- Winlevi (clascoterone) cream, 1% launch
 - Market Access launch ongoing, Sales launch mid 2021
- Finalize SPA with FDA on Phase 3 program for Clascoterone Solution in males
- Announce topline results for Phase 2 program for Clascoterone Solution in Females 2Q21

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

dharbort@cassiopea.com

Pierpaolo Guzzo, CFO

pguzzo@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