# **OUR SKIN TELLS A STORY**





HC Wainwright Global Investment Conference September 2021

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- Winlevi Commercialization Update
- Clascoterone Solution Update
- 2021 Outlook and Key Milestones







# **Commercial Update**

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<sup>1,2</sup>







Million sufferers in US<sup>3</sup> Billion US market<sup>4</sup>

Million prescriptions<sup>4</sup>

Total Prescriptions written in the Dermatology Office<sup>4</sup>

70%

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.



### Winlevi (clascoterone) cream 1% Approval Marks the Introduction of a New Class of Topical Therapy to Dermatology<sup>1,2</sup>

First in Class Topical Androgen Receptor Inhibitor<sup>1</sup>



Approved for the topical treatment of acne in patients 12 years of age and older<sup>2</sup>

Tackles the androgen hormone component of acne in both males & females<sup>2,3</sup>

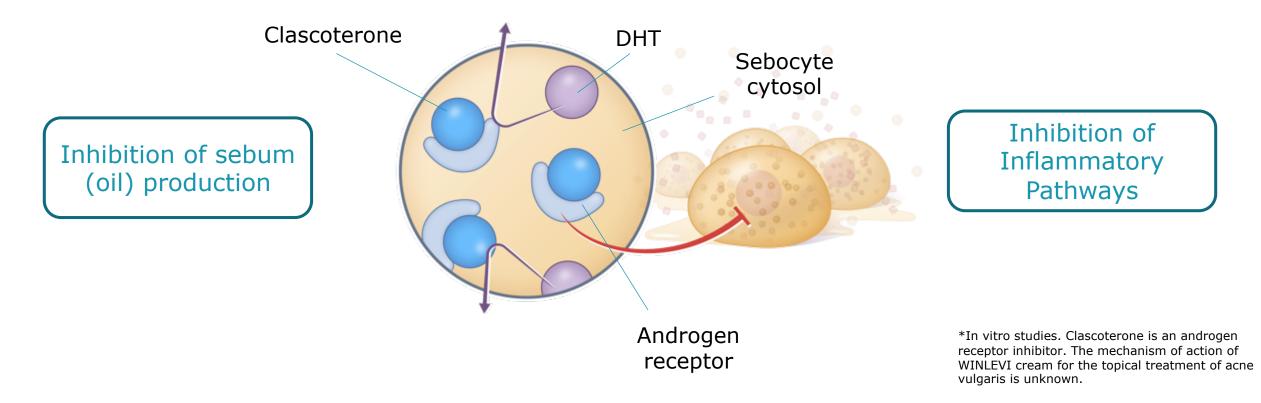
### The most frequent observed local skin reaction was mild erythema<sup>1,3</sup>

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-clascoterone-cream-prescribing-info-08-2020.pdf 3. US FDA Drug Trial Snapshot: WINLEVI. September 3, 2020. https://www.fda.gov/drugs/drugapprovals-and-databases/drug-trial-snapshot-winlevi



### 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

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## Key US Acne Market Insights, Positioning, Status

•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

- •Over the counter retinoids and BPOs are paving the way for innovative prescriptions
- •Antibiotic stewardship in acne has increased the need for alternatives
- •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

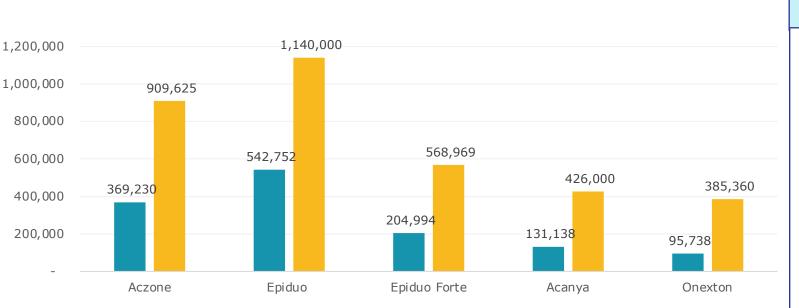
•Acne is treated with polypharmacy, using multiple, complementary drugs to address varying parts of the disease

•Market research demonstrates clear positioning for WINEVI around the unique mechanism of action and significant market share uptake predicted among segmented high value providers

•Significant progress made with US Payors with majority of lives expected to be covered at launch

8

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



#### Acne Launch Surrogates: Year 1 & Peak TRx Volume

■Year 1 ■Peak TRx

"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%

### Sun Pharma Transaction

- On 26 July 2021 the Company announced, the signing of License and Supply Agreements for Winlevi® in the US and Canada with Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries is the world's fourth largest specialty generic pharmaceutical company. Sun has a strong established US dermatology presence and Winlevi complements its oral acne portfolio.
- The agreement closed on 31 August 2021, after the expiration of the HSR waiting period.
- Under the terms of the agreements, Sun Pharma will have the exclusive right to commercialize Winlevi® in the United States and Canada, and Cassiopea will be the exclusive supplier of the product.
- Cassiopea has received an upfront payment of US \$45 million, and is eligible to receive potential commercial milestones totaling up to US \$190 million and customary double digit royalties.
- Winlevi<sup>®</sup> is expected to be available in the US in Q4 2021.
- With the proceeds Cassiopea will be funded to continue the development of its innovative dermatology pipeline and is expecting substantial revenue streams for the foreseeable future.



### Sun Pharma Transaction Rationale

- Establishes Commercial Access for Winlevi with an Established Player Medical Dermatology Provides Winlevi with immediate access to acne prescriber universe with the support of an established organization in medical dermatology who will prioritize Winlevi
- **Reduces Commercialization Risk** Given the recent dermatology environment, the risk and cost associated with building an organization from the ground up is mitigated
- Well Funded for the Foreseeable Feature Revenue from Sun transaction funds the activities of the company for the years ahead
- Enables Internal Focus on R&D Cassiopea can focus its resources on developing its existing
  pipeline including Clascoterone solution for androgenetic alopecia, an area that has not seen innovation
  in 20-30 years



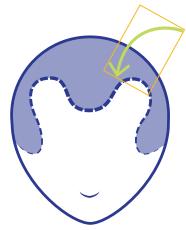
# OUR SCIENCE TELLS A STORY

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

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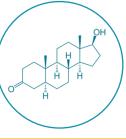
Clascoterone solution is under investigation and is not FDA approved.

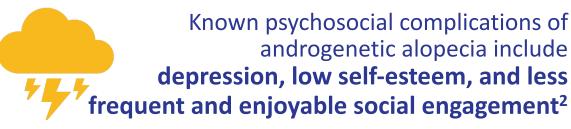
# US Androgenetic Alopecia Market



Androgenetic alopecia, also known as *pattern baldness*, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern<sup>1</sup>

It is caused by high concentrations of **dihydrotestosterone (DHT)** at the hair-follicle, which shortens the hair growth cycle in those with a genetic predisposition<sup>1</sup>





Studies have indicated that women are more likely to suffer from psychological complications than men<sup>2</sup>



80-95 million Americans suffer from Androgenetic alopecia<sup>3</sup>

Both men and women are impacted<sup>2</sup>

Only 4-9 million patients are estimated to get treatment

Treatment options are limited to old therapies developed

20 - 30 years ago<sup>4</sup>

1. Ustuner ET. Plast Reconstr Surg Glob Open. 2013;1(7):e64. Published 2013 Nov 7. 2. Camacho FM, García-Hernández M.. J Eur Acad Dermatol Venereol. 2002 Sep;16(5):476-80 3. Triangle Insights Group Report: Commercial Assessment of Breezula November 9, 2018. Page 6. 4. Gupta AK, et al. Dermatolog Treat. 2020 Apr 13:1-11 Confidential L © 2021 Cassionea. All Bights Reserved Clascoterone solution is under

### Clascoterone Solution: A Potential New Topical Treatment for Androgenetic Alopecia in Males and Females<sup>1,2</sup>

Normal hair follicle	Follicle shrinking causing hair thinning	Small follicle unable to grow new hair		
Mon	ngon 8	ny form		DHT = Dihydrotestosterone
Existing Treatments			Clascoterone Solution A Novel Topical Androgen Receptor Inhibitor	
<ul> <li>Propecta (finasteride)</li> <li>Has anti-androgenic activity on follicle by inhibiting 5 alpha reductase, an enzyme required for synthesis of DHT<sup>3</sup></li> <li>However, serious side effects due to hormonal imbalance<sup>3</sup></li> <li>Not indicated for women<sup>3</sup></li> </ul>	<ul> <li>Minoxidil<sup>®</sup></li> <li>Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla<sup>3</sup></li> </ul>		<ul> <li>Antagonizes DHT's negative effects on dermal papilla by competing with DHT at the androgen receptor<sup>1</sup></li> <li>Reduces hair miniaturization<sup>1</sup></li> <li>Reduces dermal inflammation<sup>1</sup></li> </ul>	

1. Rosette C, Rosette N, Mazzetti A et al. J Drugs Dermatol. 2019; 18(2)197-201. 2. Cassiopea S.p.A.: Elevating the science of dermatology with new therapeutics. Nature Dealmakers. 2020; Nov 30, 2020. 3. Ashique S, et al. . Nat Prod Bioprospect. 2020;10(6):345-365. doi:10.1007/s13659-020-00267-9



### **Clascoterone Solution Clinical Program Status**

#### Status:

- Phase 2 dose ranging study in males successful and most effective dose identified at 7.5% BID
- End of Phase 2 Meeting with FDA held
- Special Protocol Assessment for Phase 3 Program submitted to FDA and Type A meeting held
- Development of Patient Reported Outcome questionnaire underway
- Phase 2 Proof of Concept study in females recently completed

#### **Next Steps:**

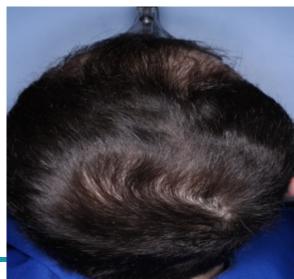
- Phase 2 POC data in females top line results 3Q21
- Finalize Phase 3 Program in males upon FDA feedback on PRO

Representative photos. Blume-Peytavi U, et al. S11223 – ). Presented at the 2019 AAD Annual Conference. S034 Late-breaking Research Saturday March 2, 2019. Washington DC.<u>https://bit.ly/330h2nt</u>

#### 7.5% Solution BID Baseline



Month 6



Clascoterone solution is under investigation and is not FDA approved.

## Key Market Insights & Opportunity for Breezula

Simple Tx Algorithm, poised for market disruption •Few therapeutic options for Physicians, limited to finasteride and minoxidil, results in underdeveloped AGA Market

•No promotional competition on the horizon

HCPs were highly receptive to the product profile, emphasizing the novel mechanism and impressive clinical photographs – 60% reported adoption Highly Engaged & Motivated Patient Base •Over 70% of patients express a high level of concern and impact on their lives

Most common treatment is Rogaine, along with vitamins & supplements
Women have fewer options than men

•Forhims, keeps.com have impacted the distribution model directly to consumers

 Almost half of the patients surveyed said they would be extremely likely to request a Rx, with another 30% moderately likely. Payers call this a "lifestyle" drug category •Finasteride and minoxidil are not considered covered drugs •Payers expresses unlikely to cover future AGA drugs •Cosmetic disease, rather than medical

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 Breezula could be priced \$100-200 per month like other lifestyle drugs

Source: Triangle Insights Group Primary Market Research Among Patients, Payers and Physicians Q3-4 2018





### 2021 Outlook and Key Milestones



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## 2021 Guidance

- Guidance is based on
  - Obtaining HSR clearance for Sun transaction Complete
  - Receiving USD \$45 million upfront payment Complete
  - Launch of Winlevi (clascoterone) cream, 1% by Sun in Q4 2021
- Revenue in the range of 37M-39M Euro
- Operating Expenses in the range of 11M-13M Euro
- Operating Profit in the range of 24M-28M Euro

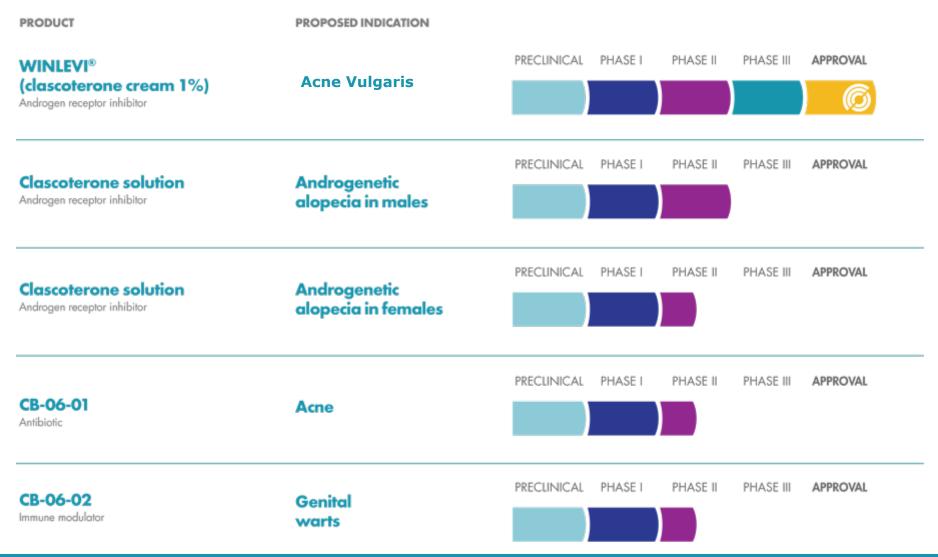
Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information. Clascoterone solution is under investigation and is not FDA approved.

## **Upcoming Company Milestones**

- Announce topline results for Phase 2 study for Clascoterone Solution in Females 3Q21
- Winlevi (clascoterone) cream, 1% launch 4Q 2021
- Finalize Phase 3 program for Clascoterone Solution in males upon FDA feedback on PRO

Local irritation is the most common adverse effect associated with Winlevi therapy. See Important Safety Information and accompanying Full Prescribing Information. Clascoterone solution is under investigation and is not FDA approved. Confidential | © 2021 Cassiopea, All Rights Reserved.

# **Cassiopea Pipeline**





# Cassiopea SpA

### Information

**Number of shares:** 10,750,000

Listing: SIX Swiss exchange, Main board

**ISIN:** IT0005108359

Ticker: SKIN

### Contacts

Diana Harbort, CEO <u>dharbort@cassiopea.com</u>

Pierpaolo Guzzo, CFO pguzzo@cassiopea.com



### WINLEVI® (clascoterone) cream, 1% Indication & Important Safety Information

#### INDICATIONS AND USAGE

WINLEVI<sup>®</sup> (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-creamprescribing-info-08-2020.pdf for full prescribing information

