## **OUR SKIN TELLS A STORY**





2020 Financial Results Public Presentation March 25, 2021

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### Agenda

- 2020 Consolidated Financial Results
- Winlevi (clascoterone cream) 1% Update
- Clascoterone Solution Update



### **2020** Cassiopea Consolidated Financial Results



# Consolidated Income Statement and Statement of Comprehensive Income

EUR/1,000	2020	2019
Revenue	_	-
Other income	594	686
Cost of sales	(-)	(-)
Research and development costs	(6,440)	(7,875)
Selling, general and administrative costs	(5,175)	(3,879)
Net Operating expenses	(11,021)	(11,068)
Operating Result	(11,021)	(11,068)
Financial income	26	90
Financial expenses	(1,313)	(722)
Profit (loss) Before Taxes	(12,308)	(11,700)
Income tax expenses	-	-
Profit (loss) For The Period	(12,308)	(11,700)
EUR/1,000	2020	2019
Profit (loss) for the period (A)	(12,308)	(11,700)
Other comprehensive income that will be not reclass. to P/L	-	-
Other comprehensive income that will be reclassified to P/L	612	11
Total other comprehensive income, net of tax (B)	612	11
Total comprehensive income (A)+(B)	(11,696)	(11,689)



- No revenues were generated in 2020 and 2019
- Net operating expenses are detailed by nature below

	2020	2019
Other income	594	686
Raw materials and consumables used	(611)	(242)
Personnel expenses	(3,216)	(2,480)
Outsourced preclinical and clinical trial costs	(2,112)	(4,062)
Other operating expenses	(5,615)	(4,915)
Depreciation and amortization	(61)	(55)
Total net operating expenses	(11,021)	(11,068)

- Other income refers to the tax credit for research and development pursuant to Law No. 190 of December 23, 2014 and subsequent implementation decrees
- Raw materials and consumables mainly include purchase of laboratory supplies and materials for clinical trials



- Personnel expenses increase from EUR 2,480 in 2019 to EUR 3,216 in relation to the setup of the US Subsidiary
- The average number of employees is 11,5 in both 2020 and 2019
- In 2020, the expense for the value of employees' and executives Directors' services, exchanged for stock options, amounted to EUR 1,168 thousand (EUR 889 thousand in 2019) and it refers to the cost accounted in relation to the options granted by the Board of Directors in the period 2015–2020 and to the options granted by Cosmo Pharmaceuticals N.V.
- The entire staff develop as follows:

No. of people	2020	2019
Managers *	9	9
Junior managers	2	3
Total n. of people	11	12

<sup>\*</sup> Includes the managers provided by Cosmo Pharmaceuticals N.V. as for service agreement

 In addition, Cosmo Pharmaceuticals N.V. group provides research & development, regulatory, secretarial, and accounting services at a cost determined in the Services Agreement



Outsourced preclinical and clinical trial costs are detailed here below:

	2020	2019
Winlevi®	209	2,130
Clascoterone solution	1,888	1,921
CB-06-01	2	-
CB-06-02	13	11
Outsourced preclinical and clinical trials costs	2,112	4,062

Other operating expenses are detailed here below:

	<del>-</del>		
		2019	
Service costs	5,607	4,903	
Other operating costs	8	12	
Total other operating expenses	5,615	4,915	



#### Service costs:

	2020	2019
External consultancy services	2,252	1,642
Patent costs	291	258
Investor relations and web site maintenance	176	169
Technical assistance	11	3
Utilities, telephone, internet	12	4
Insurance	89	90
Non executive directors	140	140
Stock options non executive directors	28	15
Management control committee	11	11
Auditing	36	35
Advertising and marketing costs	1,883	1,459
Freight and customs	8	19
Travel expenses	43	241
External laboratory services	38	70
R&D and Regulatory services	581	732
Other costs	8	15
Total service costs	5,607	4,903



- External consultancy services increased in 2020 by EUR 610 thousand mainly due to activities for Winlevi®
- Advertising and marketing costs in 2020 increased by EUR 424 thousand in relation to Winlevi® precommercial activities
- In 2020 service costs include an amount of EUR 581 thousand (EUR 732 thousand in 2019) for Research, Development, and Regulatory services charged by Cosmo S.p.A. (subsidiary of Cosmo Pharmaceuticals N.V.)
- In 2020 the company has been charged by Cosmo S.p.A. for secretarial and accounting services for an amount of EUR 140 thousand, included in External consultancy services (EUR 141 thousand in 2019)

- Financial income in 2020 is totally composed of foreign exchange differences (in 2019 EUR 78 thousand for foreign exchange differences and EUR 12 thousand for interest received on cash and cash equivalents
- Financial expenses in 2020 include EUR 668 thousand (EUR 654 thousand in 2019) due to Interests on Cosmo Pharmaceuticals N.V.'s unsecured loan and EUR 645 thousand for foreign exchange losses (EUR 68 thousand in 2019)
- Income Tax expenses: on the tax losses for 2020 and 2019 no deferred tax assets have been recognized due to uncertainties concerning the availability of future taxable profits against which such an asset may be offset

### Consolidated Statement of Financial Position

EUR/1,000	31.12.20	31.12.19
Tangible and intangible assets	2,998	2,973
Tax receivables	9,799	9,563
Total non-current assets	12,797	12,536
Inventories	761	-
Other receivables and other current assets	2,423	2,829
Cash and cash equivalents	2,646	696
Total current assets	5,830	3,525
Total assets	18,627	16,061
Total Non-current liabilities	66	10,660
Total Current liabilities	2,946	1,674
Total liabilities	3,012	12,334
Total equity	15,615	3,727
Total equity and liabilities	18,627	16,061



### Discussion of Consolidated Statement of Financial Position

- Tangible and intangible assets include EUR 2,339 thousand for the payment of the fee at the submission of Clascoterone Cream New Drug Application (NDA) and EUR 650 thousand as costs for filing and extension of patents owned by the company
- Tax receivables refer to Tax Credit R&D costs
- Inventories refer to the API required for the commercial launch of Winlevi®
- Other receivables and other assets consist of VAT receivables, current amount of Tax Credit R&D costs and prepaid expenses to the CRO in relation to the clinical trials
- Cash and cash equivalents increased to EUR 2,646 thousand due to the residual cash from June capital increase net of the cash burned in the period
- Non-current liabilities decreased by EUR 10,594 thousand, from EUR 10,660 thousand to EUR 66 thousand, in relation to the setting-off of the amount due to Cosmo Pharmaceuticals N.V. for the credit facility, with the subscription price of the shares in Cassiopea capital increase
- Current liabilities mainly refer to trade payables



### Discussion of Consolidated Statement of Financial Position

EUR1,000	Number of Shares	Share Capital	Share premium	Capital contribution	Stock option plan reserve	Currency translation reserve	Retained earnings	Losses carried forward	TOTAL
_	(n)								
Net equity as at 1 January 2019	10,000,000	10,000	14,524	236	2,408	-	(12,656)	-	14,512
Allocation of prior year result			(12,656)				12,656		-
Cost for stock options				201	703				904
Total comprehensive income for the period						11	(11,700)		(11,689)
Net equity as at 31 December 2019	10,000,000	10,000	1,868	437	3,111	11	(11,700)	-	3,727
EUR1,000	Number of Shares	Share Capital	Share premium	Capital contribution	Stock option plan reserve	Currency translation reserve	Retained earnings	Losses carried forward	TOTAL
Net equity as at 1 January 2020	(n) 10,000,000	10,000	1,868	437	3,111	11	(11,700)	_	3,727
Allocation of prior year result			(1,868)	(437)	,		11,700	(9,395)	
Capital increase	750,000	750	21,638						22,388
Cost for stock options  Total comprehensive income for the period				123	1,073	612	(12,308)		1,196 (11,696)
Net equity as at 31 December 2020	10,750,000	10,750	21,638	123	4,184	623	(12,308)	(9,395)	15,615



#### Discussion of Consolidated Statement of Financial Position

- Equity 2020 is composed by:
  - "Share capital": after the June 2020 capital increase reserved for the existing shareholders 10,750,000 shares issued, fully subscribed and paid up, each share with a nominal value of EUR 1.00, for a total share capital of EUR 10,750 thousand
  - "Share premium" of EUR 21,638 thousand refers to the June 2020 capital increase: premium of EUR 30 for share for a total of EUR 22,500 thousand, net of EUR 862 thousand as expenses related to the capital increase
  - "Capital contribution" relates to the stock option of Cosmo Pharmaceuticals N.V. granted to the employees of the Company
  - "Stock option plan reserve" the 2020 expense for SOP amounts to EUR 1,073 thousand of which EUR 1,045 thousand for management and personnel and EUR 28 thousand for nonexecutive Directors (in 2019 EUR 688 thousand and EUR 15 thousand respectively)
  - "Currency translation reserve" arises from the consolidation of foreign entity with functional currency other than the Euro
  - "Losses carried forward" arise from the previous year's result not allocated

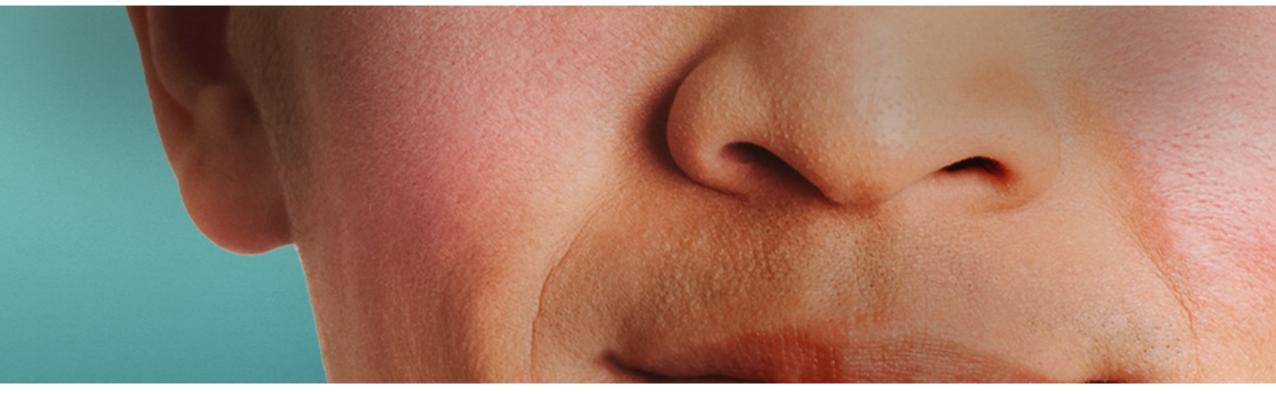




### Consolidated Cash Flow Statement

EUR/1,000	31.12.20	31.12.19
Profit (loss) before taxes	(12,308)	(11,700)
Interest on loan not paid	668	654
Depreciation and amortization	61	55
Share based payment expenses	1,196	904
Tax credit R&D costs	(594)	(686)
R&D credit offset	358	333
Net unrealized foreign exchange differences on cash and cash equivalents	32	10
Change in net working capital	667	(955)
Cash flows from operating activities	(9,920)	(11,385)
Cash flows from investing activities	(86)	(2,514)
Cash flows from financing activities	11,988	9,996
Net increase/(decrease) in cash and cash equivalents	1,982	(3,903)
Cash and cash equivalents at the beginning of the period	696	4,609
Net unrealized foreign exchange differences on cash and cash equivalents	(32)	(10)
Cash and cash equivalents at the end of the period	2,646	696









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. <a href="https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers">https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers</a>. 4. IQVIA National Prescription Audit Sept. 2019.



# Winlevi (clacoterone) 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 treatment of acne in Patients 12 years 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 - <a href="https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf">https://www.winlevi.com/assets/WINLEVI-clascoterone-cream-prescribing-info-08-2020.pdf</a> 3. US FDA Drug Trial Snapshot: WINLEVI. September 3, 2020. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trial-snapshot-winlevi

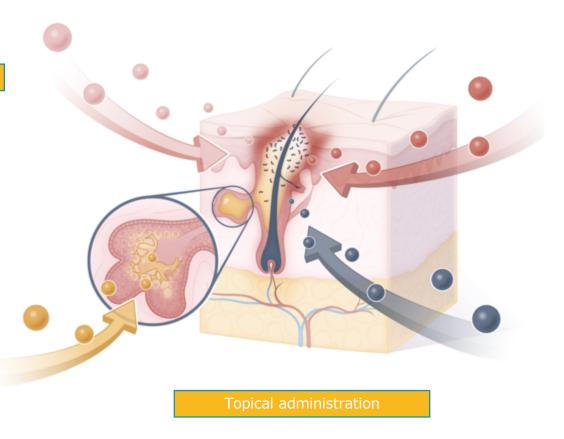
# Approval of Winlevi<sup>®</sup> (clascoterone) cream 1% Fills a Long-Standing Gap in Topical Acne Therapy<sup>1,2</sup> Multi-factorial disease results in a complementary approach to treat acne

Drugs that normalize follicular keratinization

Retinoids

Drugs that inhibit sebaceous gland function

Topical Androgen Receptor Inhibitor



Drugs with antiinflammatory effects

Retinoids

Antibiotics

Benzoyl peroxide

Drugs with antibacterial effects

Benzoyl peroxide

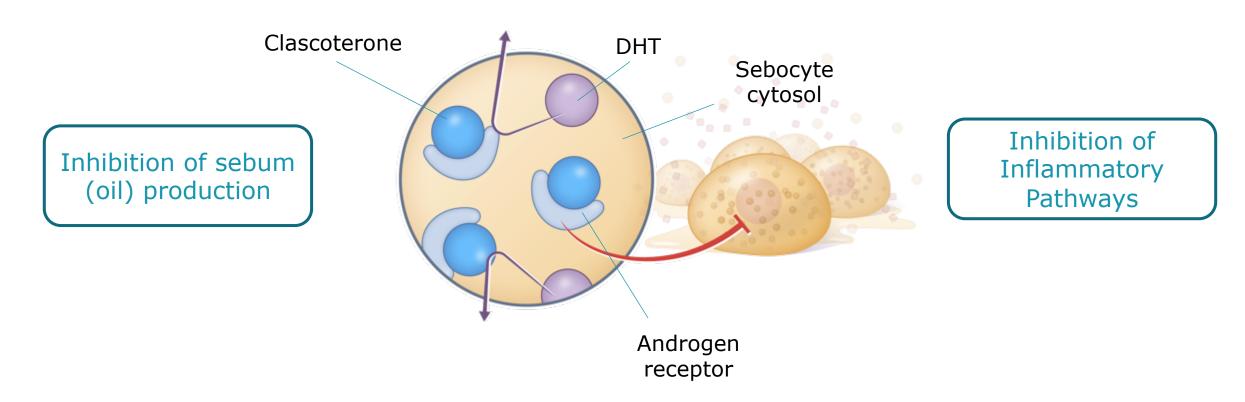
**Antibiotics** 

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



### Clascoterone is an androgen receptor inhibitor: In Vitro Activity

### Clascoterone competes with DHT for binding to the androgen receptor<sup>1,2\*</sup>

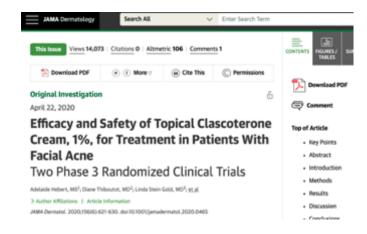


Source: 1. Ferraboschi P et al. Med Chem Commun 2014;5:904-14; 2. Rosette C, et al. J Drugs Dermatol. 2019; 18(5):412-418. https://www.ncbi.nlm.nih.gov/pubmed/31141847



### Winlevi Medical Affairs

#### **Trending as top article** – Over 28,000 views /downloads



- 7 published clinical articles in high profile peer reviewed medical journals by Cassiopea
  - 2 additional published journal articles from KOLs
- 23 Posters and Abstracts



- Robust KOL support in trade journals—Dermatology Times, Dermatology World
- Widely viewed CME programming
- MedScape, JDD acne education on androgen receptors in acne



- 24 Meeting Sponsorships
- Since 2019, 250+ Podium Mentions by KOLS
- 2 accepted presentations at AAD 2020, 2021 (postponed-COVID)



### 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
  - 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



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

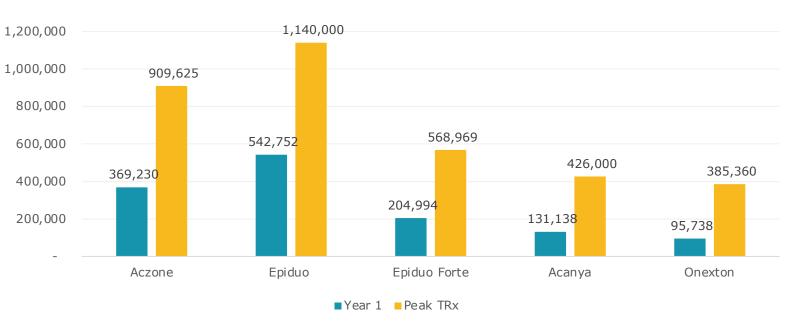
"All acne has a hormone component, 90% of Healthcare it's a matter of to what extent. If Product X **Providers** exposed to Clear Differentiation clascoterone cream treats the hormone as a first in class 1% said they would aspect of it and can work Topical Androgen for both male and be extremely likely Receptor Inhibitor to prescribe the female, then all patients should be on product it, like a retinoid." Derm Overall physicians Almost all Physicians reported a high surveyed agreed: preference share, There is a need for driven primarily by topical treatment to clascoterone's new & target acne triggered unique mode of action by hormones

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:  $1 = Not \ Likely$ ;  $4 = Somewhat \ Likely$   $7 = Extremely \ Likely$ 



## 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%



# Market Access Summary Insights and Coverage Progress

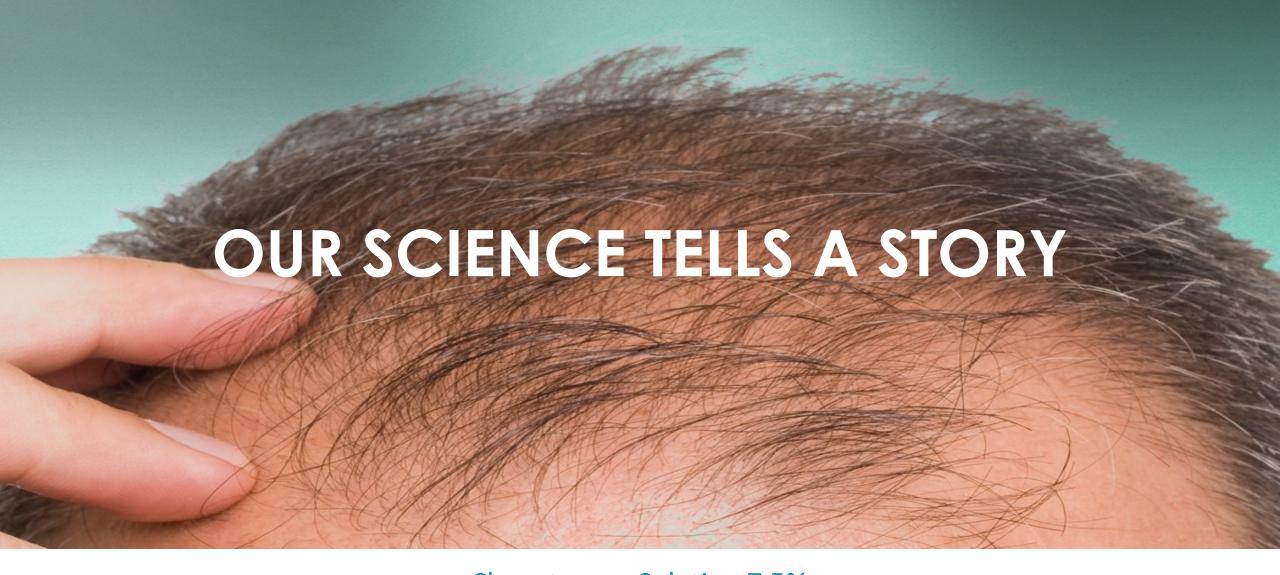
- Payers continue to provide coverage for acne patient visits and products
- While price is a key driver for coverage decisions, innovation and new MOA does matter
  - Drugs over \$600 WAC monthly cost may have higher restrictions
  - Clascoterone in a unique category as a first in class androgen receptor 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 and clascoterone clinical reviews started July 2020
- Contracting Negotiations have been initiated with Payers representing 98% of all Commercial lives (165MM)



### 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
  - M&A options to optimize commercialization and profitability before building own organization



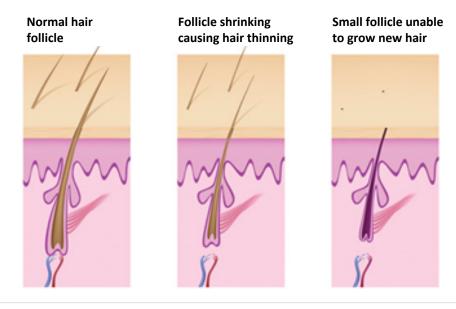


Clascoterone Solution 7.5%
First in Class Androgen Receptor Inhibitor
Targeting Androgenetic Alopecia

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

### Androgenetic Alopecia and Existing Treatments



DHT = Dihydrotestosterone

#### **Existing Treatments**



- Shows anti-androgenic activity on follicle
- However, serious side effects due to hormonal imbalance
- Not indicated for women

#### Minoxidil<sup>®</sup>

◆ Shows a vasodilator effect, ensuring a better flow of nutrients to the papilla

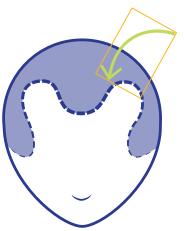
#### Clascoterone Solution

A Novel Androgen Receptor Inhibitor

- Antagonizes DHT's negative effects on dermal papilla
- · Reduces hair miniaturization
- Reduces dermal inflammation

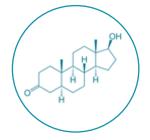


### US Androgenetic Alopecia Market



**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 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
- Special Protocol Assessment for Phase 3 Program to be re-submitted to FDA
- Extensive Medical Affairs program has increased visibility in the Dermatology community
- Phase 2 study in females enrollment completed

#### **Next Steps:**

- Phase 2 data in females top line results 3Q21
- 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

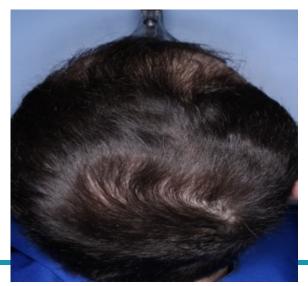
Representative photos.

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

7.5% Solution BID Baseline



Month 6



Clascoterone solution is under investigation and is not FDA approved.

### **Upcoming Company Milestones**

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



### Cassiopea SpA

### **Information**

Number of shares: 10,750,000

Listing: SIX Swiss exchange, Main board

**ISIN:** IT0005108359

Ticker: SKIN

#### **Contacts**

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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

