



Delivering New Therapies to Essential Areas in Dermatology

Jefferies Healthcare Conference

June 5, 2019

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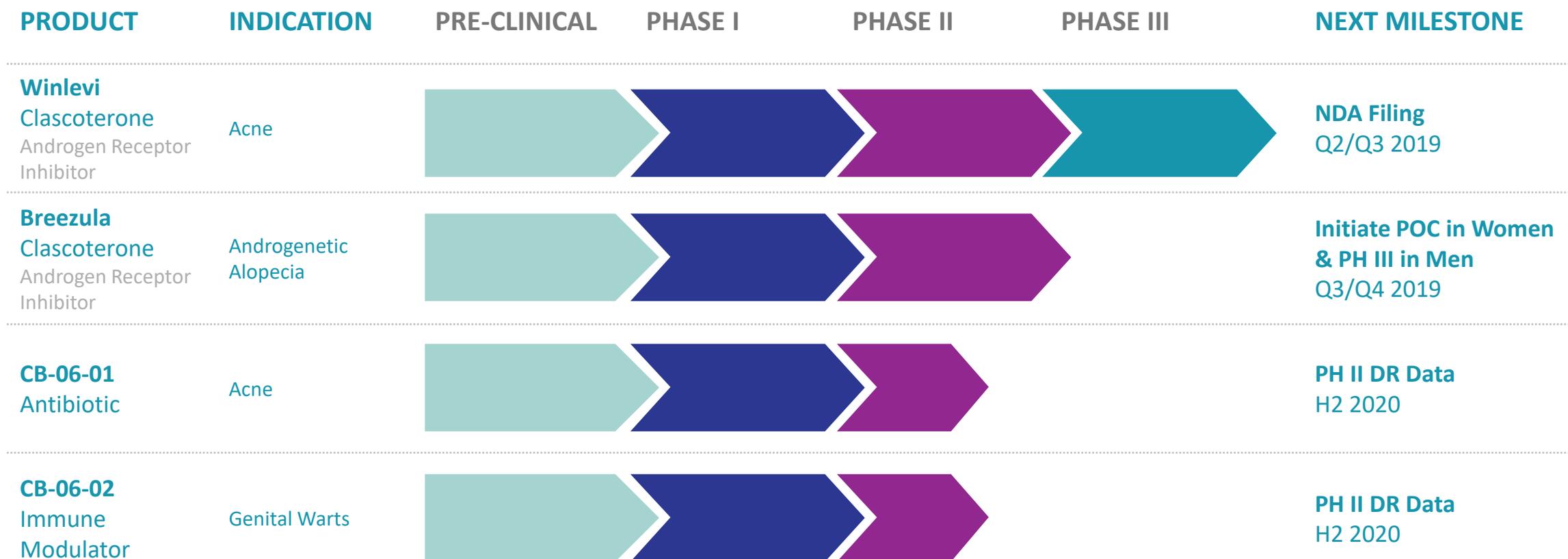
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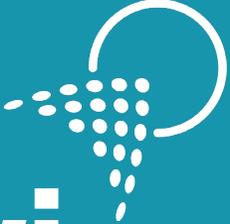
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Cassiopea Overview

- ◆ Publicly traded on SIX - Cosmo Pharma holds 45.1%
- ◆ Innovative late stage pipeline of 4 dermatology NCE products
- ◆ Filing NDA June/July - Winlevi (clascoterone cream) - First in Class Topical Androgen Receptor (AR) Inhibitor Targeting Acne
- ◆ Establishing a leading US commercial organization upon Winlevi[®] approval & partner in ROW

Cassiopea Pipeline



A white icon consisting of a semi-circle on the right and a cluster of dots on the left, resembling a stylized star or a molecular structure.

Winlevi
clascoterone cream 1%

First in Class Topical Androgen Receptor (AR) Inhibitor Targeting Acne

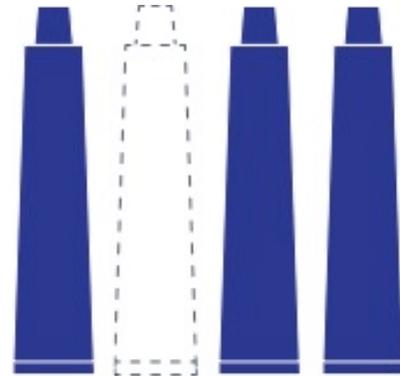
Acne is a medical condition affecting 60 Million people in the US

Acne is a  **BILLION** market



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

Topical options address 3 of 4 factors in acne pathophysiology, **leaving a gap in treatment regimens**



Payors continue to cover acne as a **medical condition** and all research indicates that this will not change



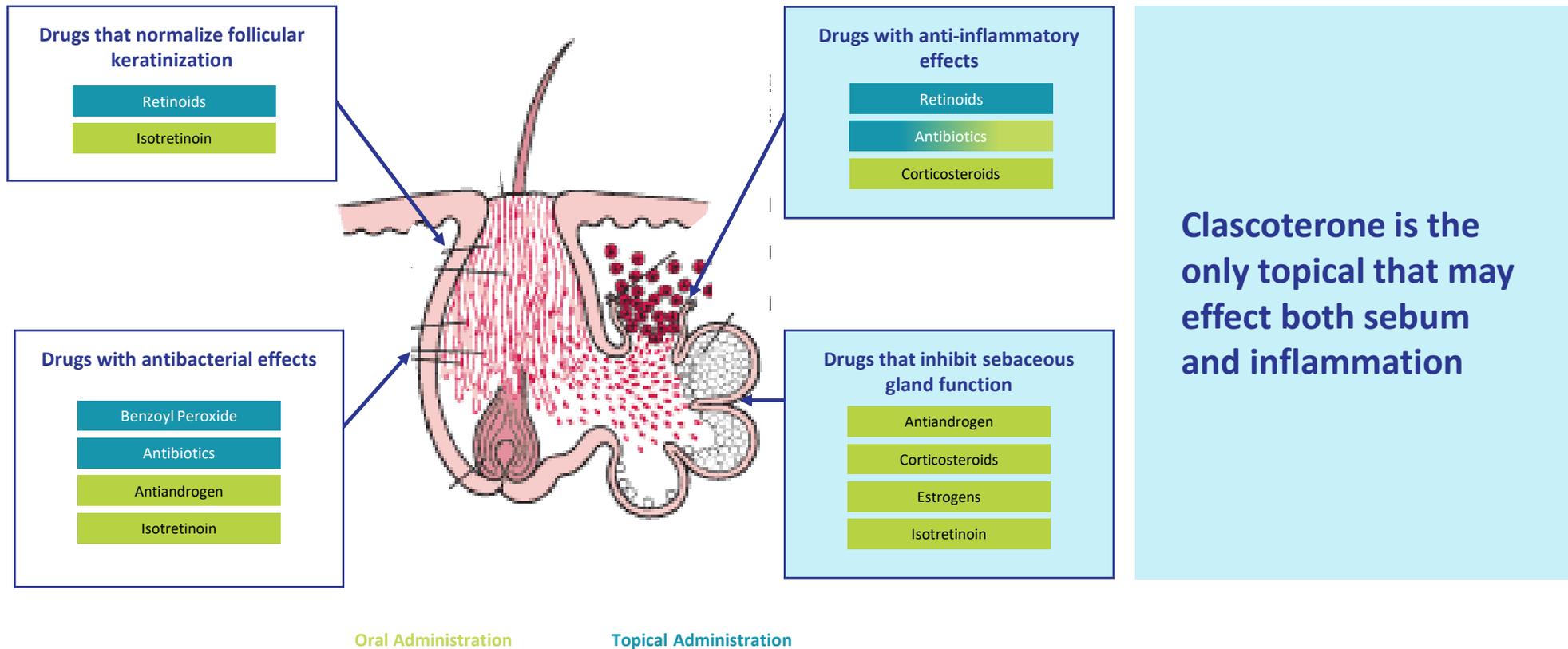
90% of branded prescriptions for acne are written in the Dermatology office



Average branded topicals have annual net revenues of **\$200-400MM**

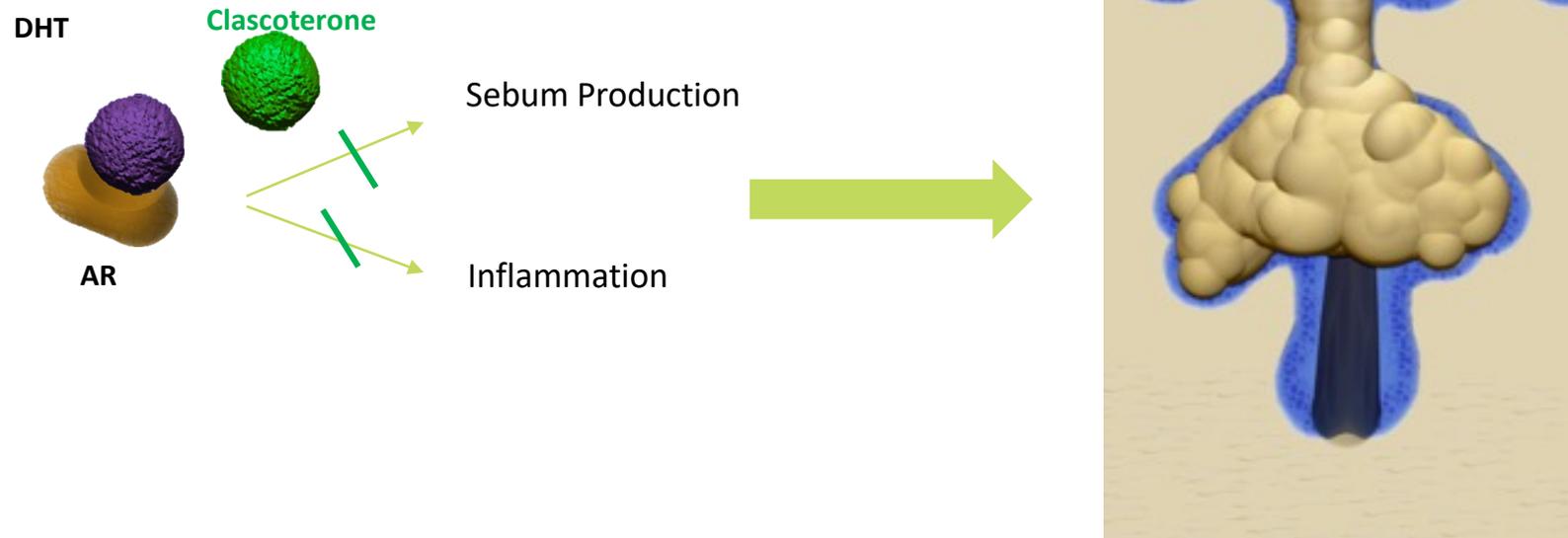
Acne is often treated by polypharmacy in order to address multiple pathways of the disease

Treatment Categories by 4 Key Elements of Acne Pathogenesis



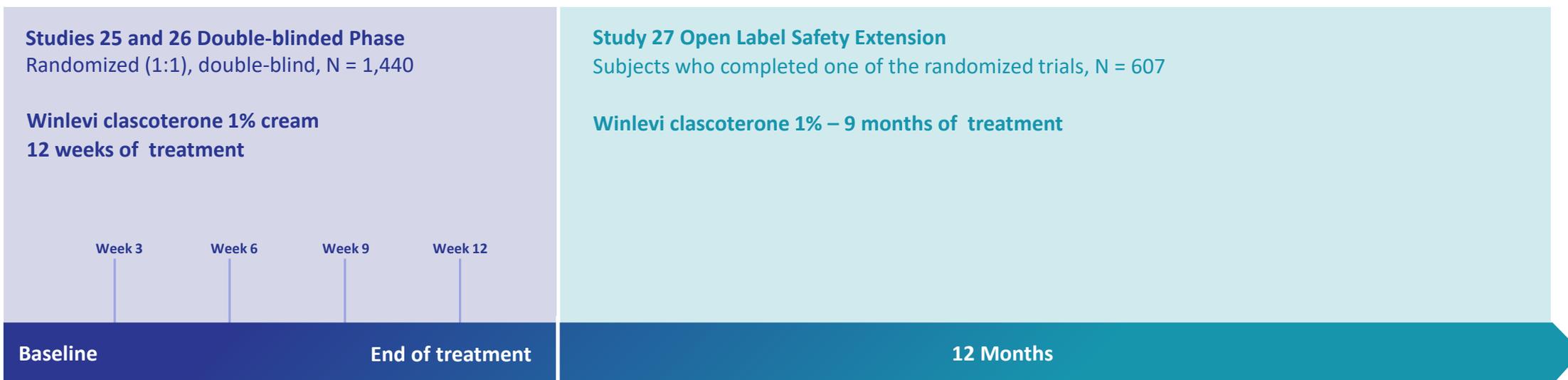
Clascoterone is anticipated to be a first in class Androgen Receptor (AR) Inhibitor

Acne Pathogenesis



Winlevi Phase III Program Design

12-week, randomized, double-blind, vehicle controlled, in subjects with moderate-to-severe acne; followed by 9 month open label safety extension



◆ **Self-apply, twice daily, in the morning and evening, for 12 weeks**

◆ **Inclusion criteria**

- 30-75 inflammatory and 30-100 non-inflammatory lesions
- IGA 5 point scale – Moderate or Severe (Grade 3 or 4)

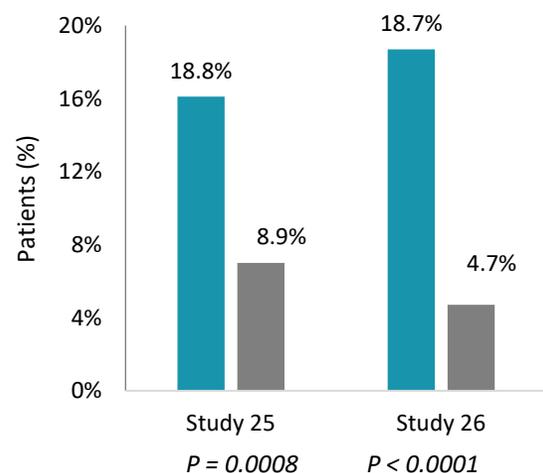
◆ **Co-Primary Efficacy Endpoints**

- Proportion of subjects in each group with at least a two point reduction in IGA from baseline and an IGA score of 0 (clear) or 1 (almost clear) at week 12
- Absolute change from baseline in non inflammatory lesion counts (NILC) at Week 12
- Absolute change from baseline in inflammatory lesion counts (ILC) at Week 12

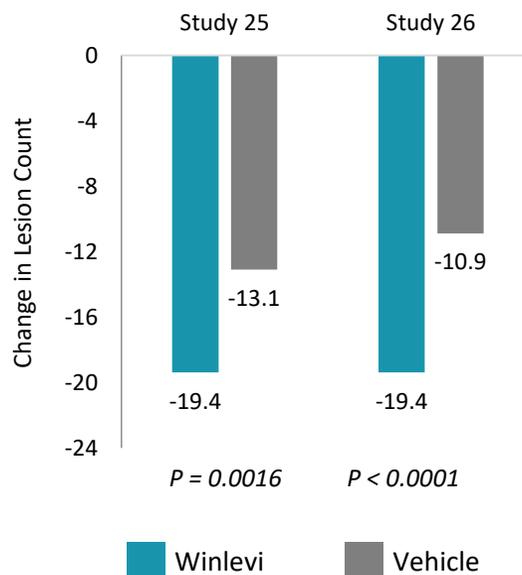
In Phase 3 trials Winlevi demonstrated statistically significant efficacy in primary endpoints with side effects similar to vehicle

Winlevi Safety and Efficacy (Primary Endpoints) ITT (Week 12)

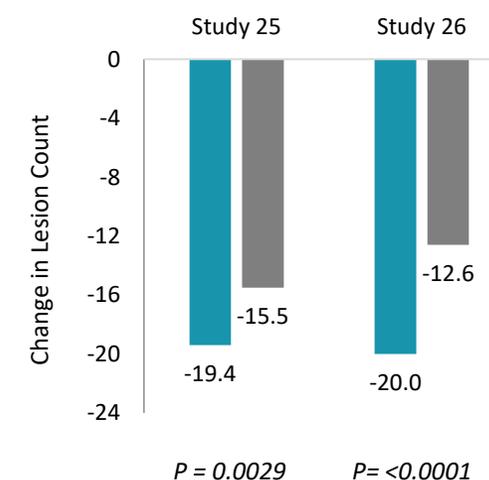
2 Point Reduction in IGA & IGA score of 0 (clear) or 1 (almost clear)



Absolute change from baseline in non-inflammatory lesion count



Absolute change from baseline in inflammatory lesion count



Adverse Events

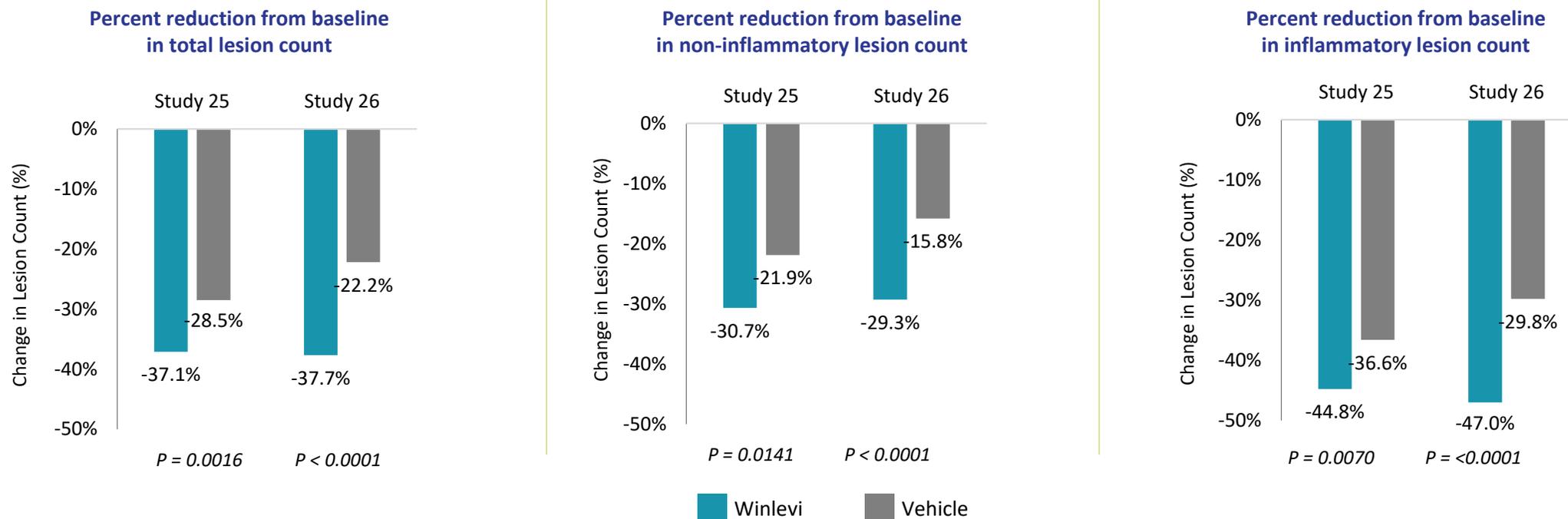
- There were no treatment-related serious adverse events among patients treated with clascoterone
- Local skin reactions, if present, were predominantly classified as mild

Sample Size

- Study 25: N = 708
- Study 26: N = 732

In Phase III trials Winlevi demonstrated statistically significant efficacy in secondary endpoints with side effects similar to vehicle

Clascoterone Safety and Efficacy (Secondary Endpoints) ITT (Week 12)



Adverse Events

- There were no treatment-related serious adverse events among patients treated with clascoterone
- Local skin reactions, if present, were predominantly classified as mild

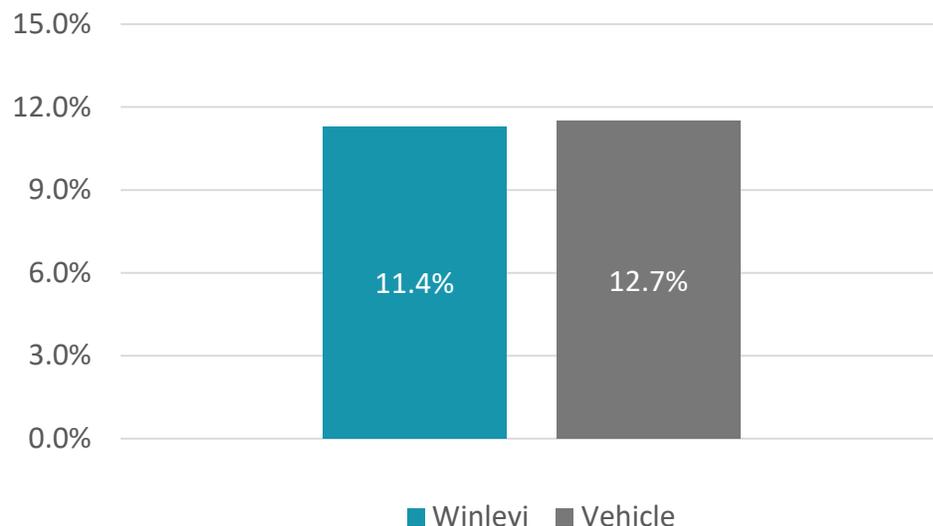
Sample Size

- Study 25: N = 708
- Study 26: N = 732

Clascoterone Cream 1% Safety Profile

Phase 3 trials across 1,440 patients demonstrated side effects similar to vehicle

Pooled Safety Data – TEAE* Study 25, 26

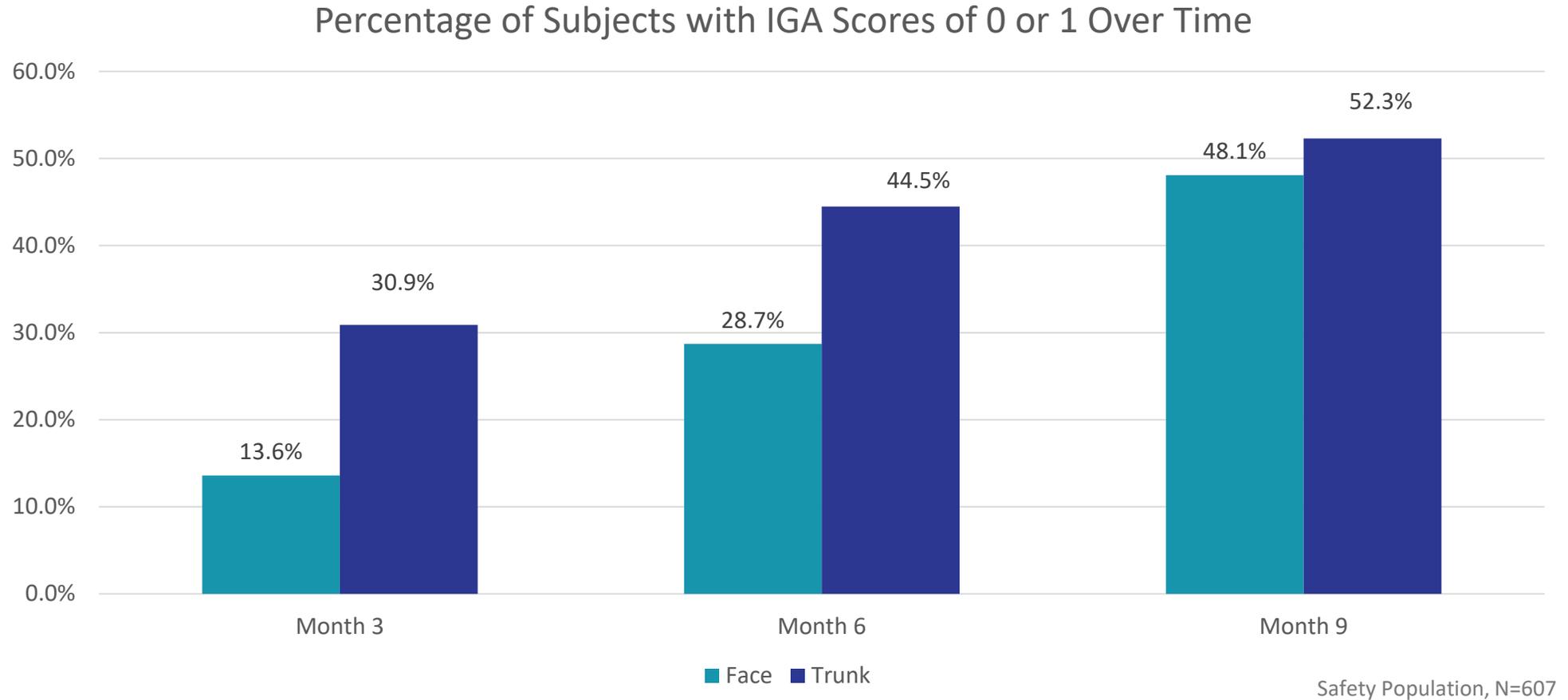


*Treatment Emergent Adverse Events

9 month Open Label Extension Study shows consistent results with Phase 3 trials

- ◆ Consistent with previous studies erythema/reddening was the most common local skin reaction
- ◆ No systemic side effects were noted
- ◆ The mean absolute changes of cortisol values throughout the study were similar among groups, proving no systemic effect on cortisol

Winlevi Phase III Open Label Extension Study Efficacy Summary



Physicians and Payors show positive response to Winlevi Product Profile

- ◆ 69% of Physicians indicated they perceived Winlevi to be highly favorable, very highly favorable or extremely favorable
 - Physicians anticipate using Winlevi first line for mild-moderate patients and second line for severe patients
 - Dermatologists estimate prescribing to be more often than topical antibiotics or benzoyl peroxide.

- ◆ Preliminary Payor interview show coverage for a novel mechanism of action in acne with guidance to price within the range of other topical acne brands (\$400-\$700 WAC)



“Dermatologist are itching for new things. I think Dermatologists are going to go crazy for this stuff.”

- Dermatologist



“I really like the idea of a topical anti-androgen cream. [Winlevi] had really good clinical pictures, so that’s huge.”

- Physician Assistant

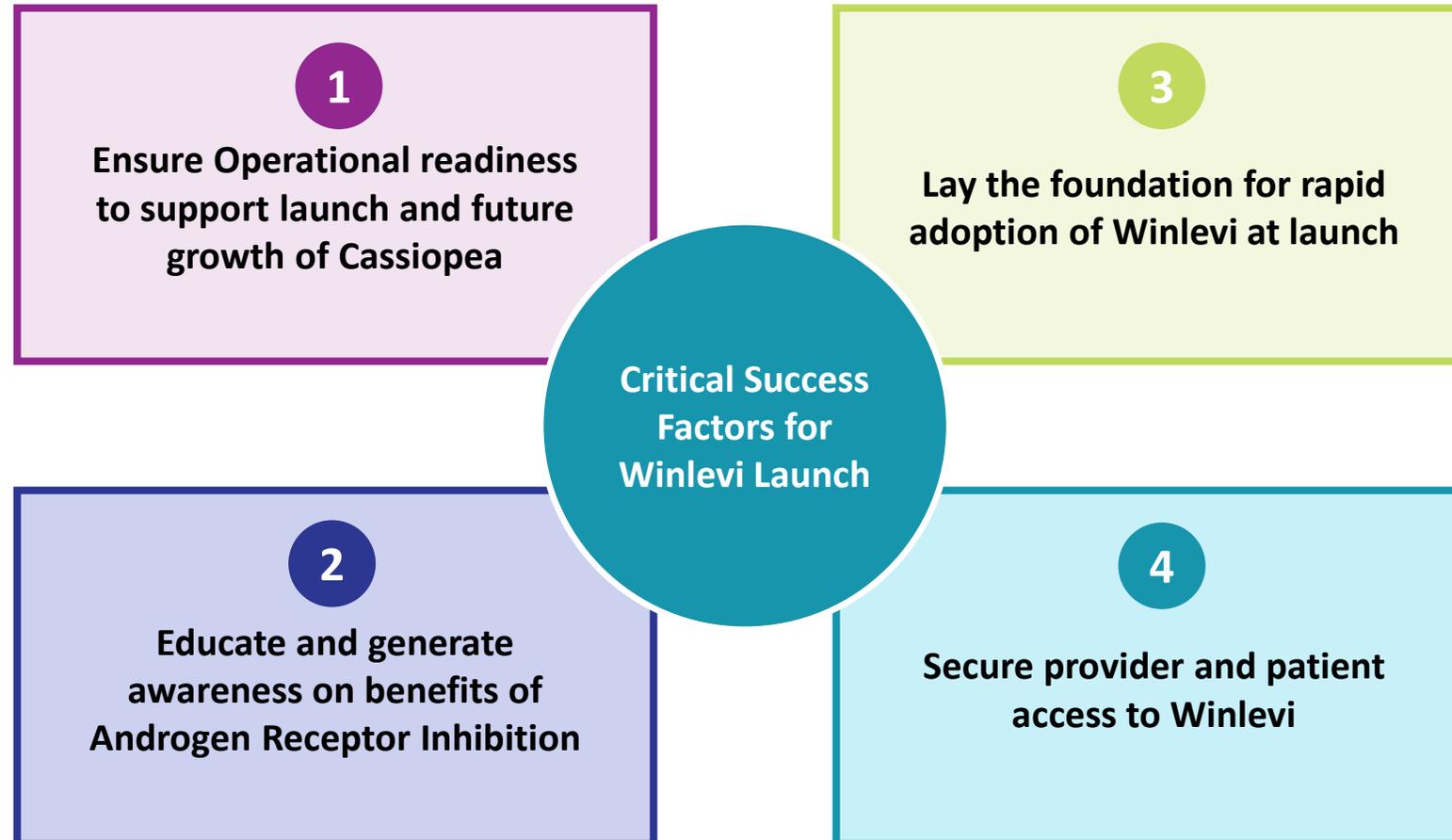


“The clinical results show improvement certainly. [Winlevi] looks like a new and effective mechanism of action.”

- Pharmacy Director

Source: Quantitative survey of 101 dermatologists, 50 primary care physicians, 50 pediatricians, and 40 dermatology nurse practitioner/physician assistants. Conducted September – October 2018 by Triangle Insights Group.

Commercial Launch Preparedness



Winlevi

Early 2019 Achievements:

- ◆ Received conditional approval from FDA on Winlevi proprietary name
- ◆ 17 Published Papers, Posters and Abstracts
- ◆ 20 Meetings Sponsorships
- ◆ 40 Podium Mentions
- ◆ Secured Agency of Record and Public Relations
- ◆ Initiated second round of market access research

Next Steps:

- ◆ NDA Filing
 - Pre NDA meeting held May 6, 2019
 - File NDA June/July 2019

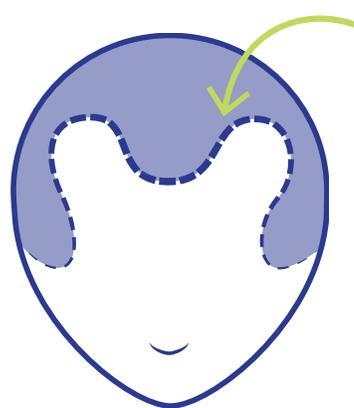


The logo for Breezula, featuring the word "Breezula" in a white, sans-serif font. Above the letter "z" is a white, stylized graphic of three curved lines, resembling a breeze or hair. A trademark symbol (TM) is positioned to the upper right of the word.

Breezula™

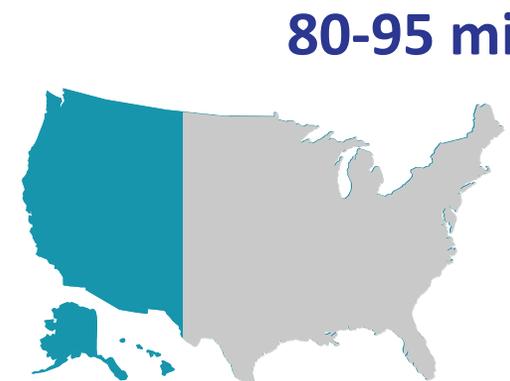
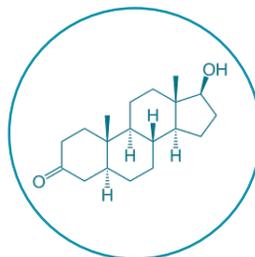
First in Class Topical Androgen Receptor (AR) Inhibitor
Targeting Androgenetic Alopecia

Breezula AGA Market Slide



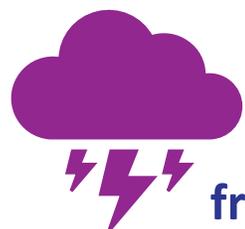
Androgenetic alopecia, also known as **pattern baldness**, is characterized by the progressive loss of terminal hairs on the scalp in a characteristic pattern

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



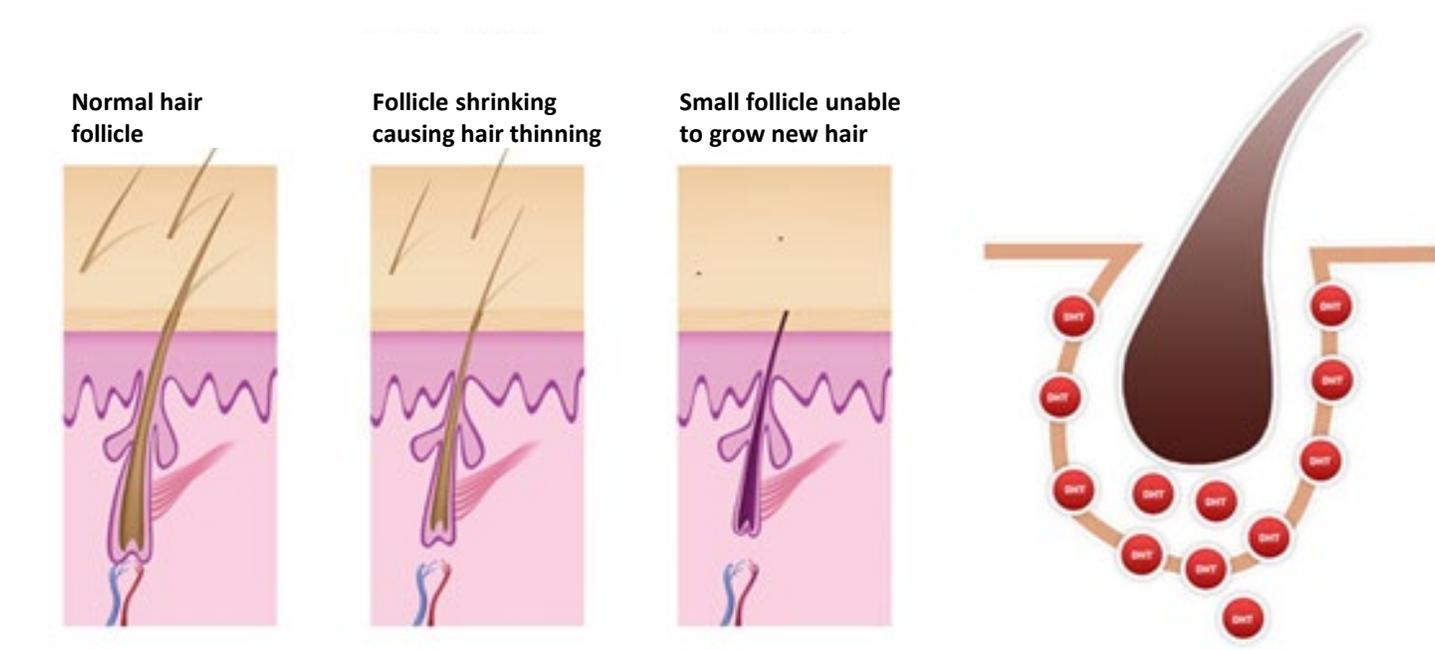
Known psychosocial complications of androgenetic alopecia include **depression, low self-esteem, and less frequent and enjoyable social engagement**

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

Breezula stacks up well against existing options



Existing Treatments		Breezula®
		A Novel Androgen Receptor Inhibitor
 Propecia™ (finasteride)	 Minoxidil®	<ul style="list-style-type: none"> ◆ Antagonizes DHT's negative effects on dermal papilla ◆ Reduces hair miniaturization ◆ Reduces dermal inflammation



DHT = Dihydrotestosterone

Breezula Phase II Dose Ranging Study Design

Study 034

52-week, randomized, double-blind, vehicle controlled, in subjects with AGA

Double-blinded Phase II DRS

Randomized (1:1:1:1:1), double-blind versus Vehicle, N = 404

12 months of treatment with planned 6 months interim analysis



- ◆ DRS Phase II: 404 patients enrolled, double blind, 5 parallel arms, Breezula 2.5%, 5%, 7.5%, vehicle BID plus 7.5% QD, 52 weeks of treatment, co-primary endpoints on TAHC total hair count increase from baseline and HGA patient satisfaction
- ◆ The Modified Norwood-Hamilton Scale is used to assess the eligibility of subjects at the Screening Visit
 - Subject has to have mild to moderate androgenic alopecia in temple and vertex region rating Modified Norwood-Hamilton Scale III vertex to V (IIIv, IV, V) with ongoing hair loss to be eligible for this study
- ◆ Six month interim results July 2018, twelve month results April 2019

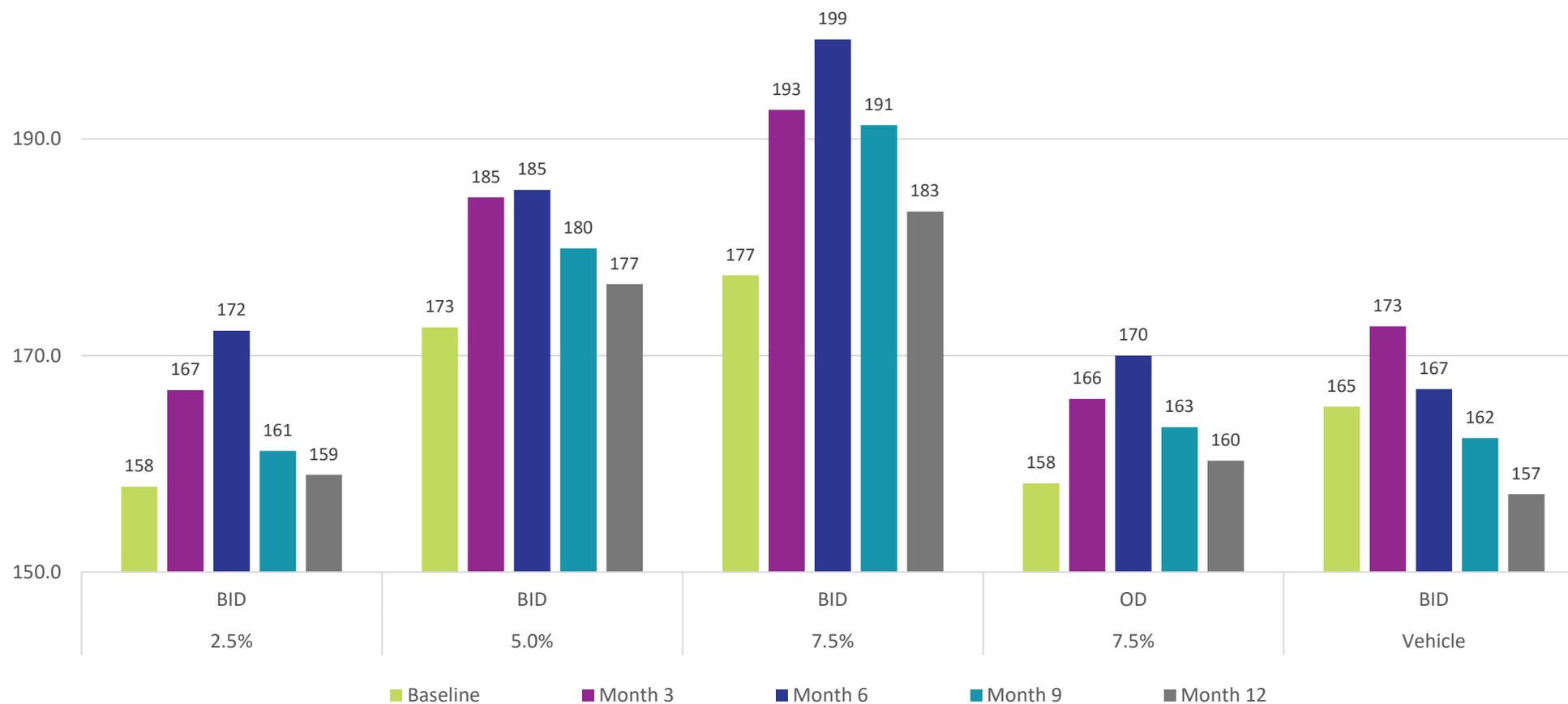
Breezula Phase II Dose Ranging Study Demographics

Total number of subjects :	344
Mean age:	40.0
Norwood-Hamilton Scale:	IIIIV=38.1% IV=39.0% V=23.0%
Ethnicity:	Hispanic/Latin=2.3% Not Hispanic/Latin=97.7%

Primary Population - PP Population					
	Breezula 2.5% BID (N = 74)	Breezula 5% BID (N = 66)	Breezula 7.5% BID (N = 68)	Breezula 7.5% QD (N = 66)	Vehicle (N = 70)
Baseline Age					
Mean (SD)	40.4	42.3	38.8	39.4	39.3
Median	40.5	43.0	39.0	40.0	40.0
Range (min-max)	21-55	24-55	21-55	21-54	21-55
Baseline Norwood-Hamilton Scale:					
IIIIV	37.8%	30.3%	48.5%	42.4%	31.4%
IV	37.8%	50.0%	25.0%	39.4%	42.9%
V	24.3%	19.7%	26.5%	18.2%	25.7%

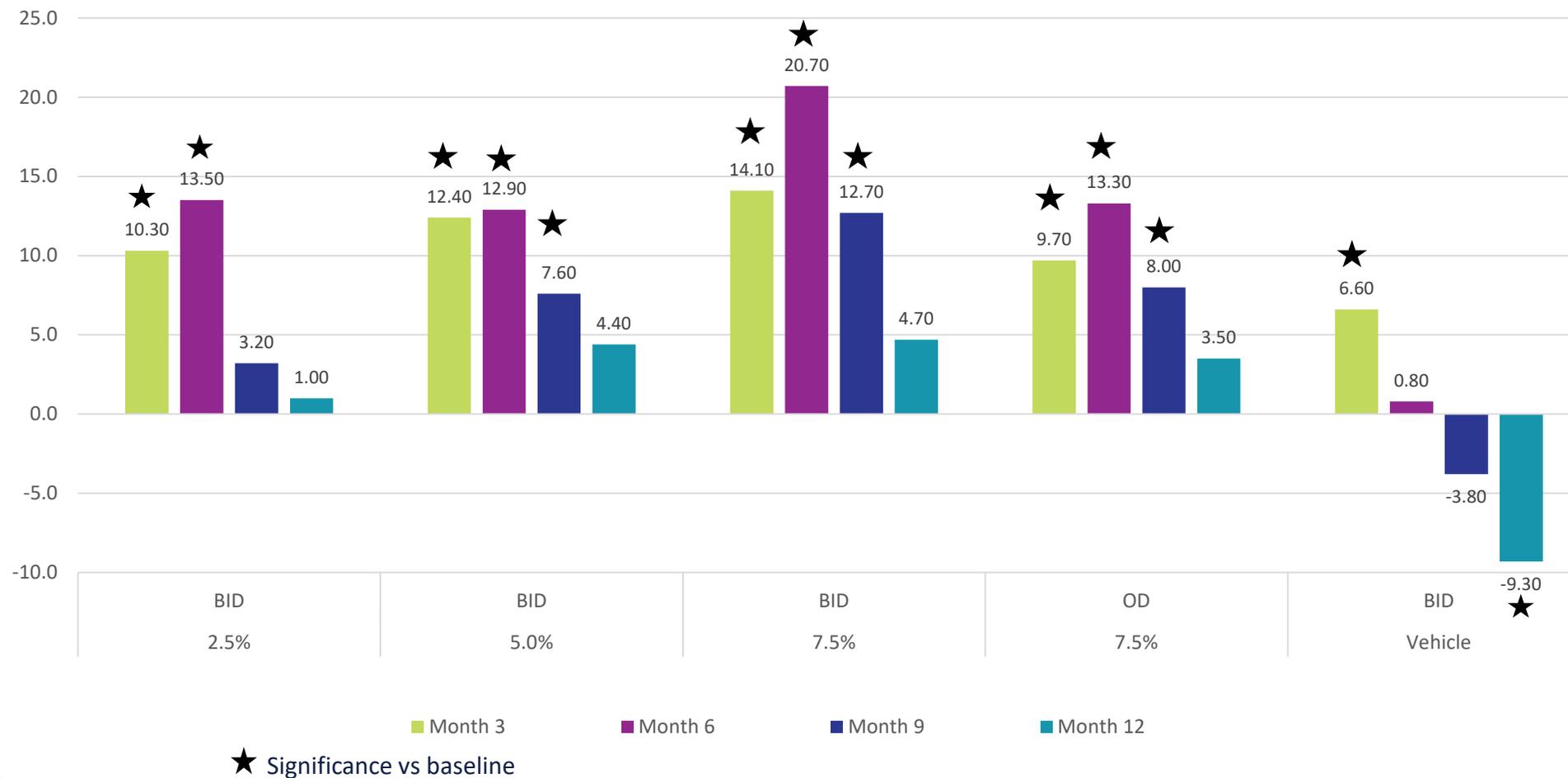
Breezula Phase II Dose Ranging Study

Target Area Hair Count – Absolute Values (PP)

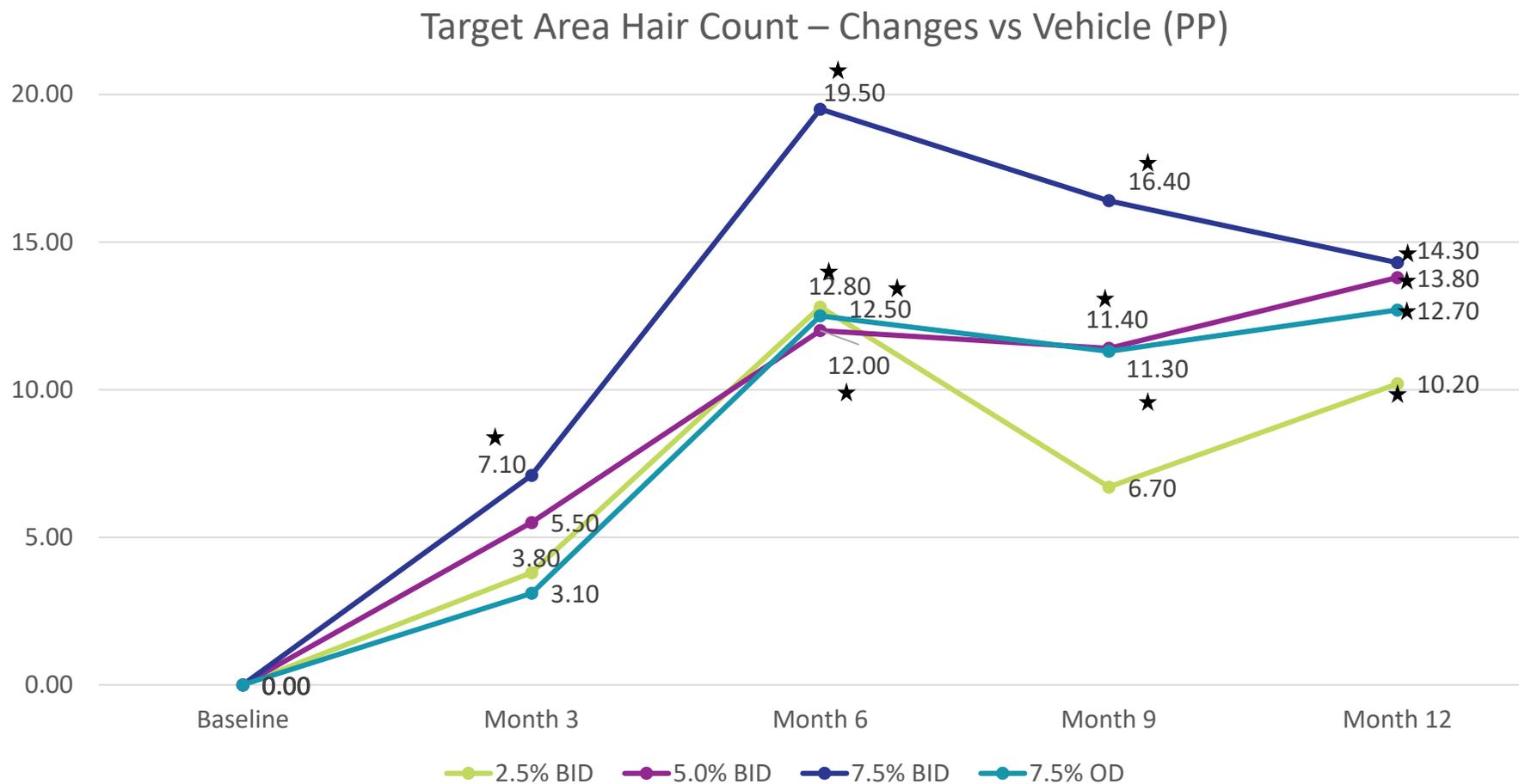


Breezula Phase II Dose Ranging Study

Target Area Hair Count – Changes vs Baseline (PP)



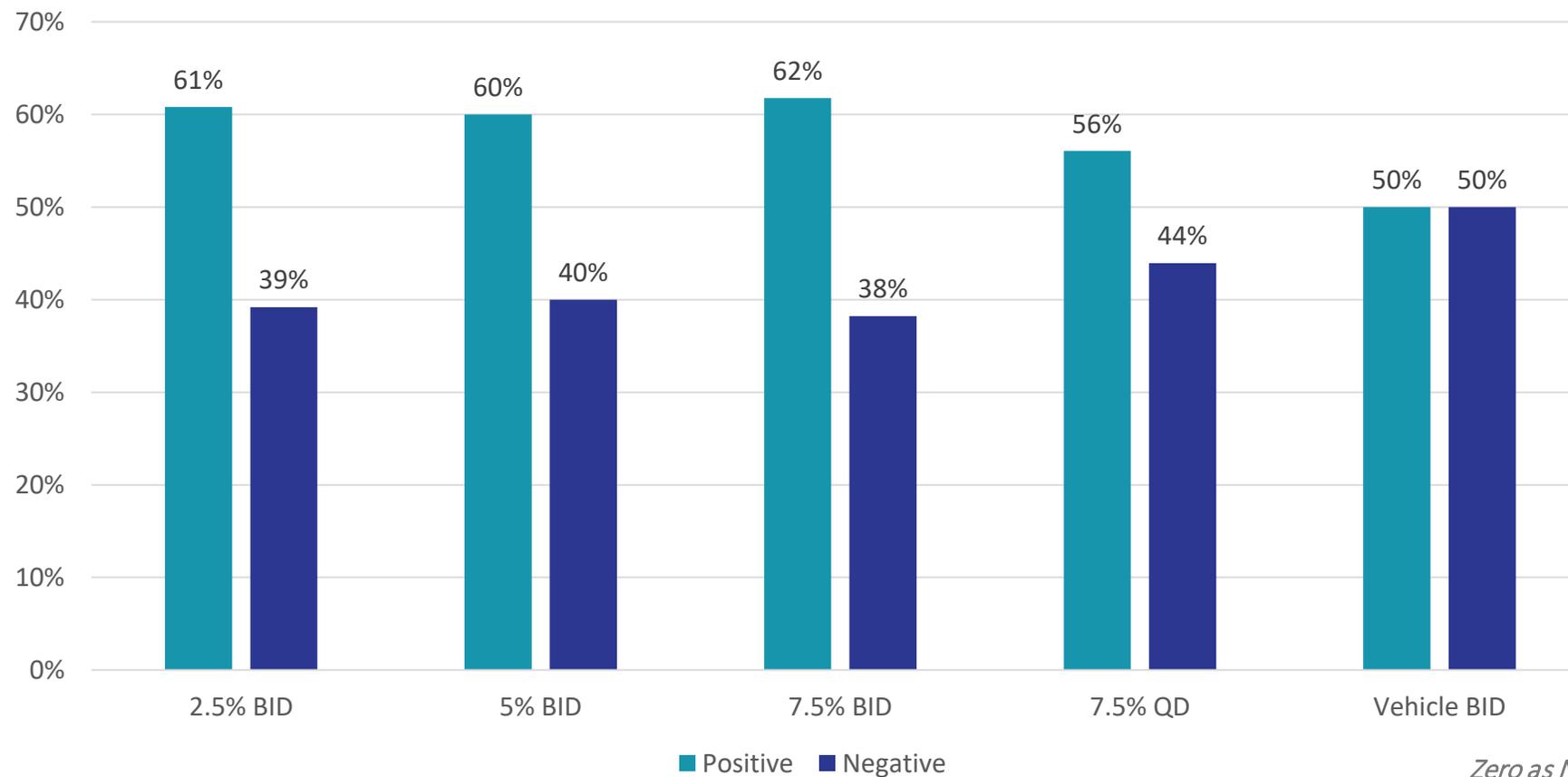
Breezula Phase II Dose Ranging Study



★ Significance vs vehicle

Phase II Dose Ranging Study

Hair Growth Assessment - Month 12 (PP)



Zero as Negative Result

Phase II Dose Ranging Study Safety Summary – Side effects similar to vehicle

- ◆ TEAE were similar across all treatment groups and similar to vehicle
- ◆ Most TEAE were moderate in severity
- ◆ Most TEAE were not related to study drug
- ◆ No serious TEAE were observed in 7.5% BID clascoterone group

Providers and Patients are excited about Breezula

- ◆ 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 Breezula from their physician
- ◆ Breezula 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

Breezula

Early 2019 Achievements:

- ◆ Published Mechanism of Action Manuscript
- ◆ 9 Published Papers, Abstracts and Posters
- ◆ Late Breaker Poster and Presentation at 2019 AAD
- ◆ Study design for POC in women complete

Next Steps:

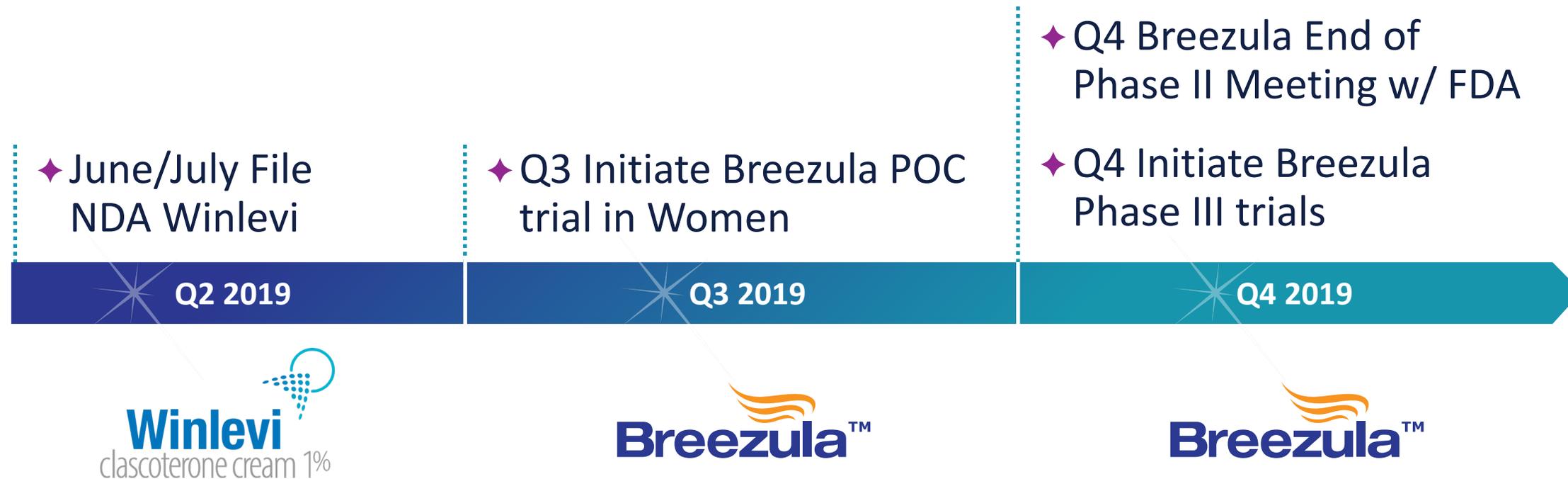
- ◆ Clinical and Regulatory Pathway:
 - Q3 Initiate Breezula POC trial in Women
 - Q4 Breezula End of Phase 2 Meeting w FDA
 - Q4 Initiate Breezula Phase 3 trials



Exciting Time at Cassiopea

- ◆ New corporate campaign
- ◆ Expanding footprint in Dermatology
- ◆ Late stage development projects are progressing on schedule
- ◆ Continued interest and investment into our early stage development pipeline
- ◆ Poised to be the next leader in Dermatology

Key Milestones 2019



Cassiopea SpA

Information

Number of shares: 10,000,000

Listing: SIX Swiss exchange, Main board

ISIN: IT0005108359

Ticker: SKIN

Contacts

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