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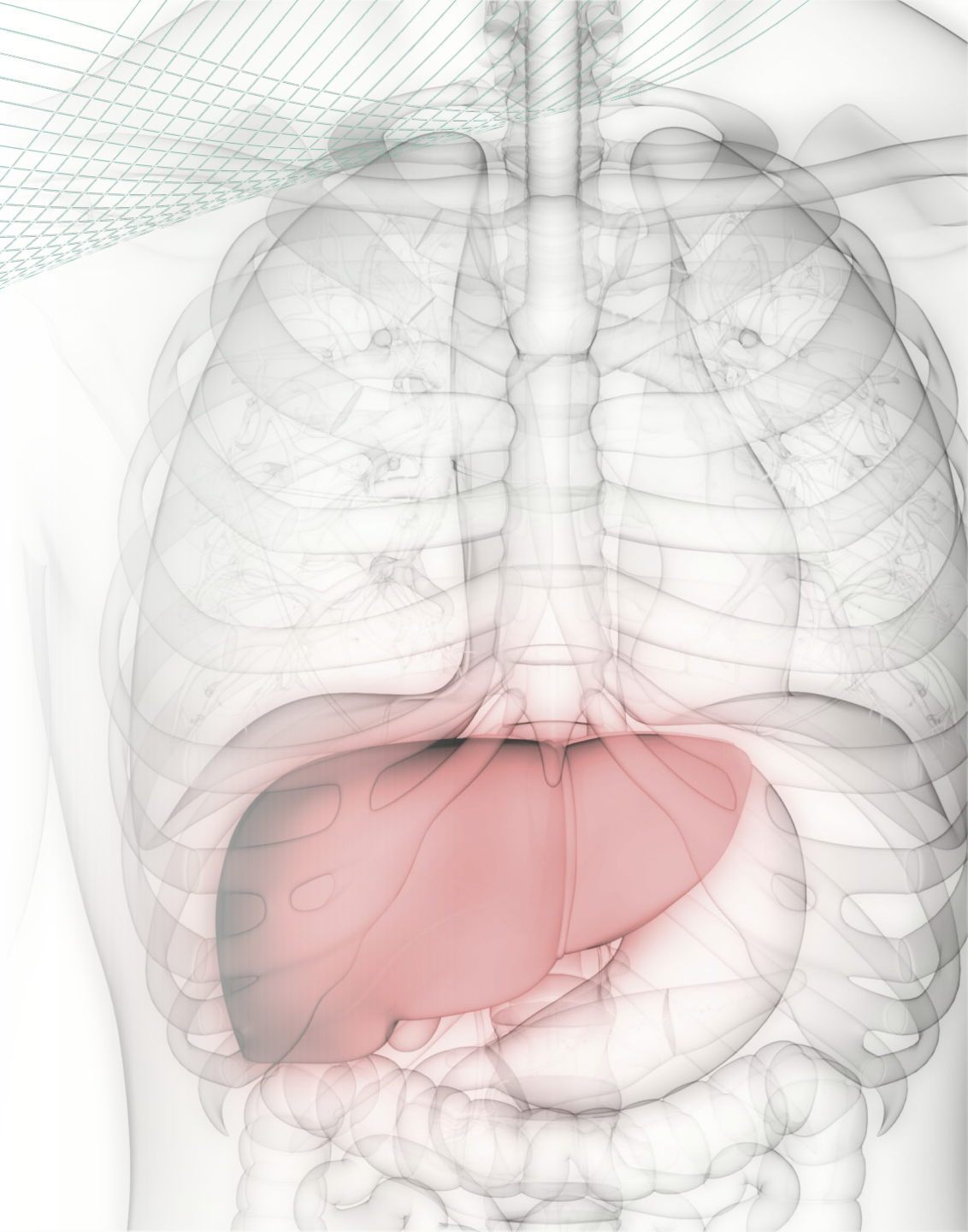
A New Mechanism of Action in Treating Acne: Update on Positive Phase 3 Denifanstat Trial for the Treatment of Moderate to Severe Acne

June 16, 2025



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Agenda

2:00pm ET	2:10pm ET	2:15pm ET	2:35pm ET	2:45pm ET
Introduction	Acne Market	Clinical Data	TVB-3567 Clinical Development Program	Q&A and Conclusion
Dave Happel CEO	**Rob D'Urso** SVP New Products	**Neal Bhatia, MD** KOL	**Eduardo Martins, MD, DPhil** CMO	**Dave Happel** CEO

Dr. Neal Bhatia, M.D. Biography

- Board-certified dermatologist in San Diego, California
- Director of Clinical Dermatology at Therapeutics Clinical Research
- Past VP of American Academy of Dermatology
- Chief medical editor for *Practical Dermatology*

Disclosures: Consultant or scientific advisor for Abbvie, Advanced Derm Solutions, Almirall, Arcutis, Beiersdorf, Biofrontera, Botanix, BMS, BI, Galderma, J&J, Journey, LaRoche-Posay, Leo, Lilly, Novartis, Ortho, Pfizer, Regeneron, Sagimet, Sanofi, SkinFix, Soligenix, SunPharma, and Verrica

Development Pipeline: Multiple Indications and Clinical Milestones

Therapeutic Area	Indication	Stage of Development	Expected Milestone / Status
Metabolic Disease	MASH	Denifanstat (Preclinical → Phase 2)	Phase 2b met histology primary and multiple secondary endpoints, data announced 1Q2024; FDA Breakthrough Therapy designation; Phase 3 F2/F3 ready
		Denifanstat (Preclinical → Phase 1)	Phase 1 hepatic impairment results reported 1Q2024
		Denifanstat/resmetirom (Preclinical → Phase 1)	Phase 1 clinical PK trial initiation planned 2H 2025
Dermatology	Acne	TVB-3567 (Preclinical → Phase 1)	Phase 1 FIH initiated in June 2025
		歌礼 ascletis Denifanstat (ASC40) (Preclinical → Phase 3)	Phase 3 met all primary and secondary endpoints, data announced June 2025*
Oncology	Solid tumors	TVB-3567 (Preclinical → Phase 1)	Identifying FASN-dependent tumor types for potential FASN inhibitor development
		Denifanstat (Preclinical → Phase 1)	
	Recurrent glioblastoma (GBM)	歌礼 ascletis Denifanstat (ASC40) (Preclinical → Phase 3)	Phase 3 enrollment of 120 patients achieved in 3Q2023*

* Trials conducted in China by Ascletis, who has licensed development and commercialization rights to all indications in Greater China

Acne Market

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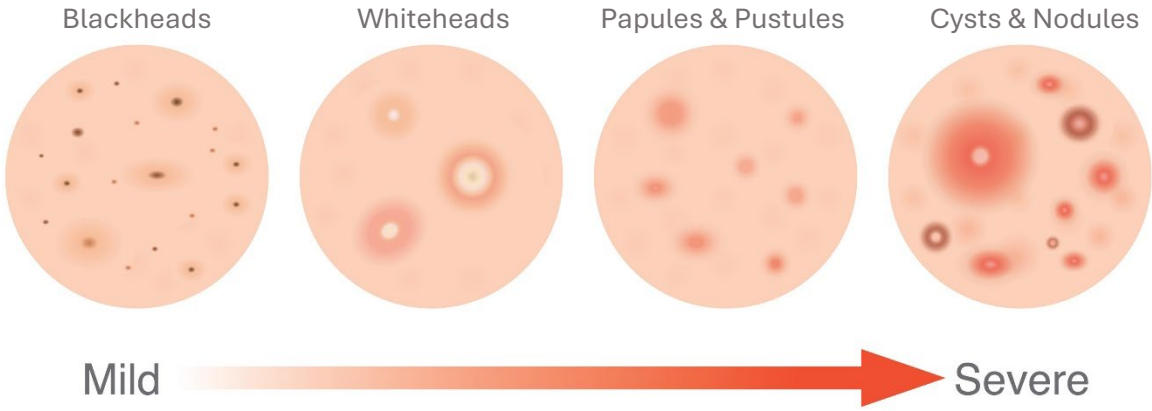
Acne Market Overview

Global acne market is expected to reach $17B in next decade[1]



5.1 million US acne patients are treated by dermatologists annually (total US acne market is 50 million people)[2,3]

- Acne is the #1 or #2 patient concern in dermatology offices and 65%+ of patients in dermatology offices have private insurance[4]
- Although acne treatments are currently available, dermatologists are open to new therapies (Seysara® Tablets & Winlevi® Cream)
- There is no cure for acne; due to its pathology, most patients require chronic management and multiple courses for flare control annually

Acne patients visiting a dermatologist are highly aligned to our TPP's value proposition and positioning[4]

- 70% of patients presenting to dermatologists have moderate to severe disease[4]
- Approximately 70% of patients have inflammatory lesions, and 16% of patients are post-menopausal women[4]

1. www.expertmarketresearch.com/reports/acne-treatment-market
2. Bickers DR, Lim HW, Margolis D, Weinstock MA, Goodman C, Faulkner E et al. The burden of skin diseases: 2004 a joint project of the American Academy of Dermatology Association and the Society for Investigative Dermatology. Journal of the American Academy of Dermatology 2006;55:490-500
3. American Academy of Dermatology/Milliman. Burden of Skin Disease. 2017. www.aad.org/BSD
4. Sagimet market research conducted in July 2024 among 50 dermatologists, data on file

Acne Treatment Algorithm

Disease management involves flare and prevention intervention

Mild Disease	Moderate to Severe Disease	Severe (Cystic) Disease
Treatment includes topical agents used as mono-therapy, combination therapy, or with fixed dosed combination products	**Treatment approach adds oral products on top of the topical agents**	**Severe (cystic) patients are generally managed with isotretinoin (Accutane®)**
Main topical therapy categories • Retinoids • Benzoyl Peroxide • Antibiotics • Clascoterone • Salicylic Acid • Azelaic Acid	Main oral therapy categories: • Antibiotics (tetracyclines, sarecycline) • Hormonal contraceptives • Spironolactone (off-label) • Intralesional corticosteroids	Main therapy categories: • Isotretinoin

- Most acne patients receive skin care routines that include OTC cleansers and moisturizers to address AEs associated with their treatment

FASN Inhibition Offers Potential Benefit in Acne

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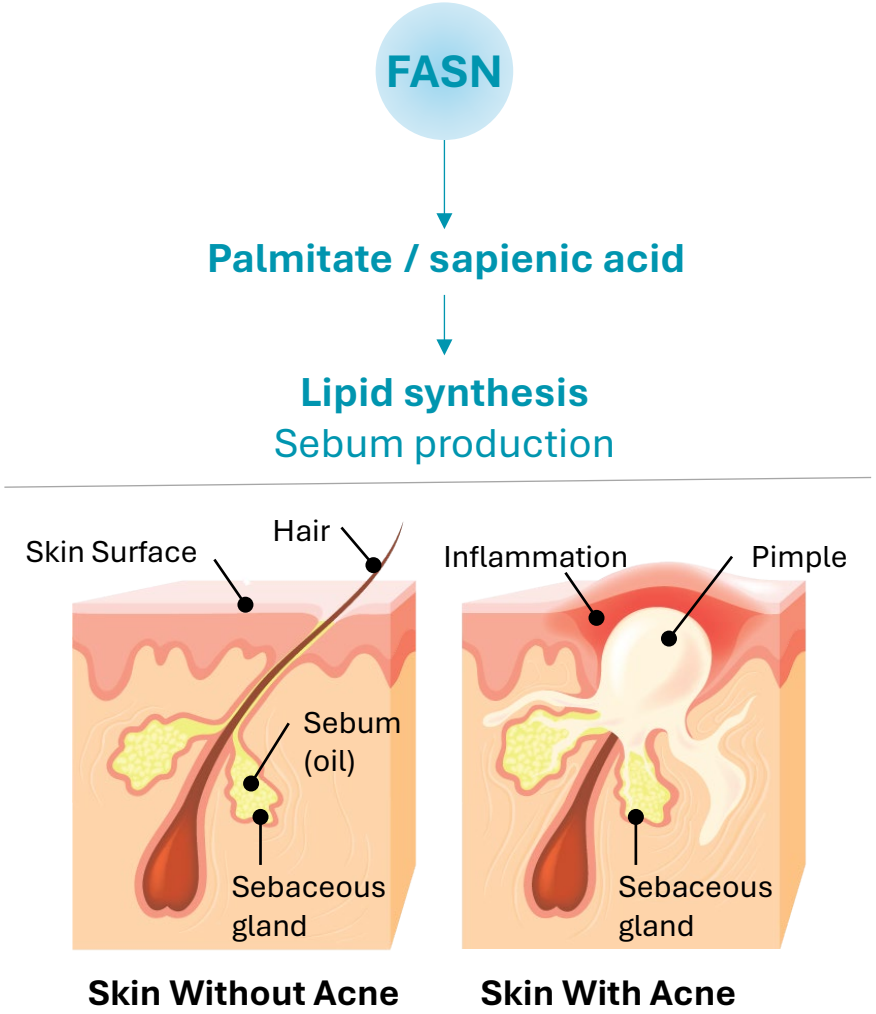
Acne Pathogenesis and Potential Role of FASN Inhibitors

Multifactorial pathogenesis of acne involves 4 key aspects

- Increased sebum in sebaceous glands (80% of lipids produced through DNL)
- Abnormal or excessive follicular hyper-keratinization
- Accelerated bacterial growth (C. acnes)
- Localized inflammatory response

FASN is an attractive therapeutic target for acne

- Denifanstat directly reduced cutaneous (skin) sebum DNL lipids in two Phase 1 studies
- FASN inhibition has potential to reduce inflammation, through decreasing cytokine secretion and Th17 activation[1]



Heng, A.H.S., Chew, F.T. Systematic review of the epidemiology of acne vulgaris. *Sci Rep* **10**, 5754 (2020). https://doi.org/10.1038/s41598-020-62715-3

1. O'Farrell et al., Scientific Reports 2022

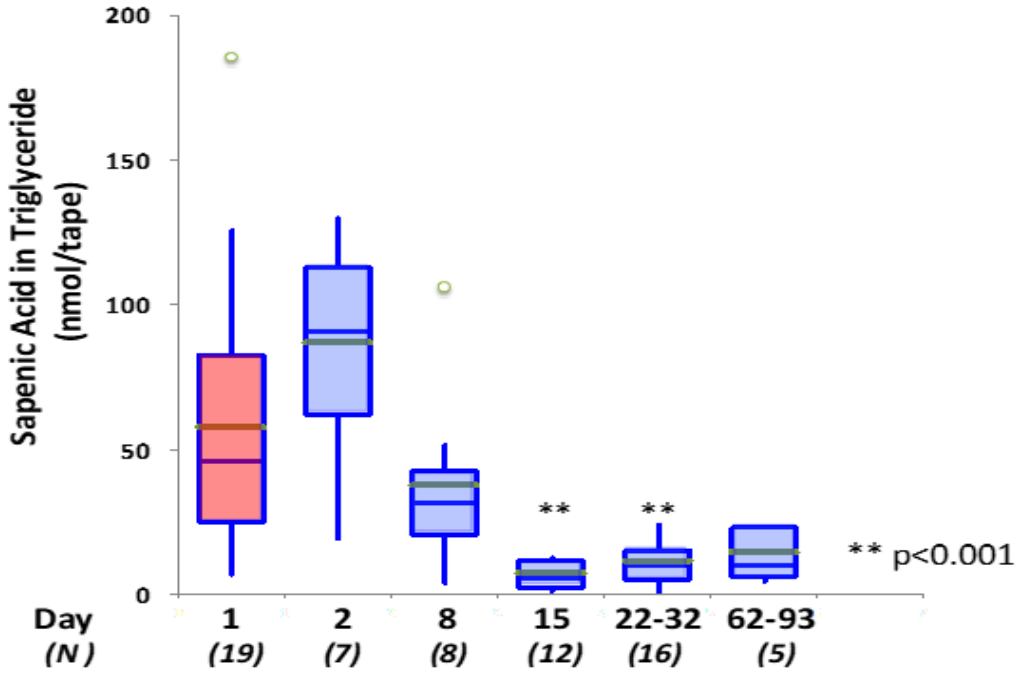
Clinical Data Support Mechanism of Action of a FASN Inhibitor in Acne

In multiple Phase 1 trials, FASN inhibitor demonstrated a decrease in DNL sebum lipids[1,2]

- FASN inhibitor demonstrated a >90% reduction in sebum lipids by day 15[1]
- FASN inhibitor maintained the reduced level of sebum lipids through the entire study[1]
- FASN inhibitor demonstrated a dose responsive impact on sebum lipids[1]

Note: denifanstat dose in this Phase 1 trial in cancer patients is several times higher than 50 mg dose tested in acne and MASH

Phase 1 oncology trial
Sebutape® assessment of cutaneous sebum lipids[1]



Days on therapy (# of subjects)

1 EASL 2017, Duke et al. /https://sagimet.com/wp-content/uploads/2017/05/3VBIO_EASLposter.pdf, Falchook et al. EClinicalMedicine 34 (2021) 100797

2 AASLD 2016, Duke et al., https://sagimet.com/wp-content/uploads/2016/11/2016_AASLD_FASN_NASH_36x60_v10.pdf

Ascletis Acne Phase 2 Clinical Trial

180 adult patients with moderate to severe acne

1. Age 18-40 years old
2. IGA grade 3 or 4
3. Inflammatory skin lesion counts 30-75
4. Non-inflammatory skin lesion counts 30-100

Dose range-finding versus placebo

- Randomized, double-blind placebo-controlled, multi-center study, conducted by Ascletis in China
- Primary Endpoint
  - % change from baseline in total lesion count by subject in each group compared to placebo, and/or,
  - Ratio of subjects who have an IGA score decreased by ≥ 2

* Note: ASC40 is denifanstat

[1] https://www.prnewswire.com/news-releases/ascletis-announces-completion-of-180-patient-enrollment-for-phase-ii-clinical-trial-of-fasn-inhibitor-asc40-for-acne-301690157.html

Ascletis Announced Positive Phase 2 Clinical Trial Data in Acne

Denifanstat Phase 2 in acne

by Ascletis in China

歌礼 ascletis

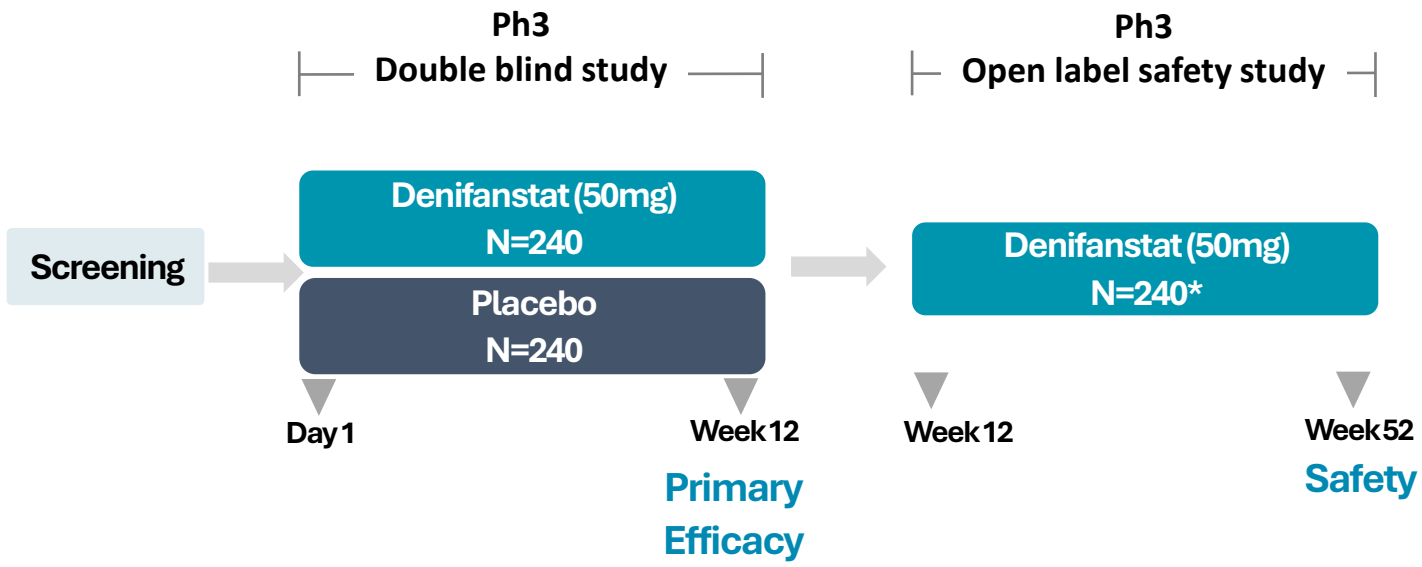
	EFFICACY RESULTS – 12 WEEKS			
	Placebo n=45	25 mg n=45	50 mg n=44	75 mg n=45
Total lesions^	-34.9%	-49.5%**	-51.5%**	-48.4%**
Inflammatory lesions^	-36.5%	-54.7%**	-56.7%**	-49.4%*
Non-inflammatory lesions^	-35.0%	-44.4%	-46.6%	-46.5
IGA (2-grade improvement)	15.6%	31.1%	31.8%	22.2%

* p<0.05. ** p<0.01. ^Lesion data are mean relative reduction from baseline to 12w, n= number in cohort. Ascletis has exclusive rights to denifanstat in Greater China

Ascletis Acne Phase 3 Clinical Trial Design

Denifanstat Phase 3 in acne

- Moderate to severe acne
- Multi-center placebo controlled
- 1:1 randomization
- Double-blind
- Once daily oral dosing
- 480 patients in China



Primary endpoints at week 12

- % patients who receive IGA success (defined as at least a 2-point reduction in IGA from baseline, and an IGA of 0 or 1 at week 12)
- % change of total lesion counts from baseline
- % change of inflammatory lesion counts from baseline

Key secondary endpoint at week 12

- % change of non-inflammatory lesion counts from baseline

* Study ASC40-304. NCT06248008.

Ascletis Acne Phase 3 Clinical Trial: All Primary and Secondary Endpoints Met

Baseline Characteristics	50mg denifanstat (n=240)	Placebo (n=240)
Total lesion count	102.2	102.1
Inflammatory lesion count	42.1	43.1
IGA=3 (moderate), %	85.8	85.8
IGA=4 (severe), %	14.2	14.2

Efficacy endpoints [1]	50mg denifanstat (n=240)	Placebo (n=240)	50mg denifanstat (placebo adjusted)	p value
% Treatment success [IGA] [2] (primary endpoint)	33.2	14.6	18.6	<0.0001
% Change in total lesion count (primary endpoint)	-57.4	-35.4	-22.0	<0.0001
% Change in inflammatory lesion count (primary endpoint)	-63.5	-43.2	-20.3	<0.0001
% Change in non-inflammatory lesion count (key secondary endpoint)	-51.9	-28.9	-23.0	<0.0001
Absolute change in total lesion count (secondary endpoint)	-58.3	-36.2	-22.1	<0.0001
Absolute change in inflammatory lesion count (secondary endpoint)	-26.6	-18.4	-8.2	<0.0001

Baseline demographics and efficacy endpoints of 50 mg denifanstat oral, once daily for 12 weeks versus Placebo (Intent-to-treat, ITT analysis change from baseline).

1. The efficacy data are LSMEANs.
2. Treatment success is defined as an Investigator's Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-point decrease from baseline.

Ascletis Acne Phase 3 Clinical Trial Safety Data

Denifanstat 50mg was generally well tolerated during the 12-week study

Treatment-emergent adverse events (TEAEs):

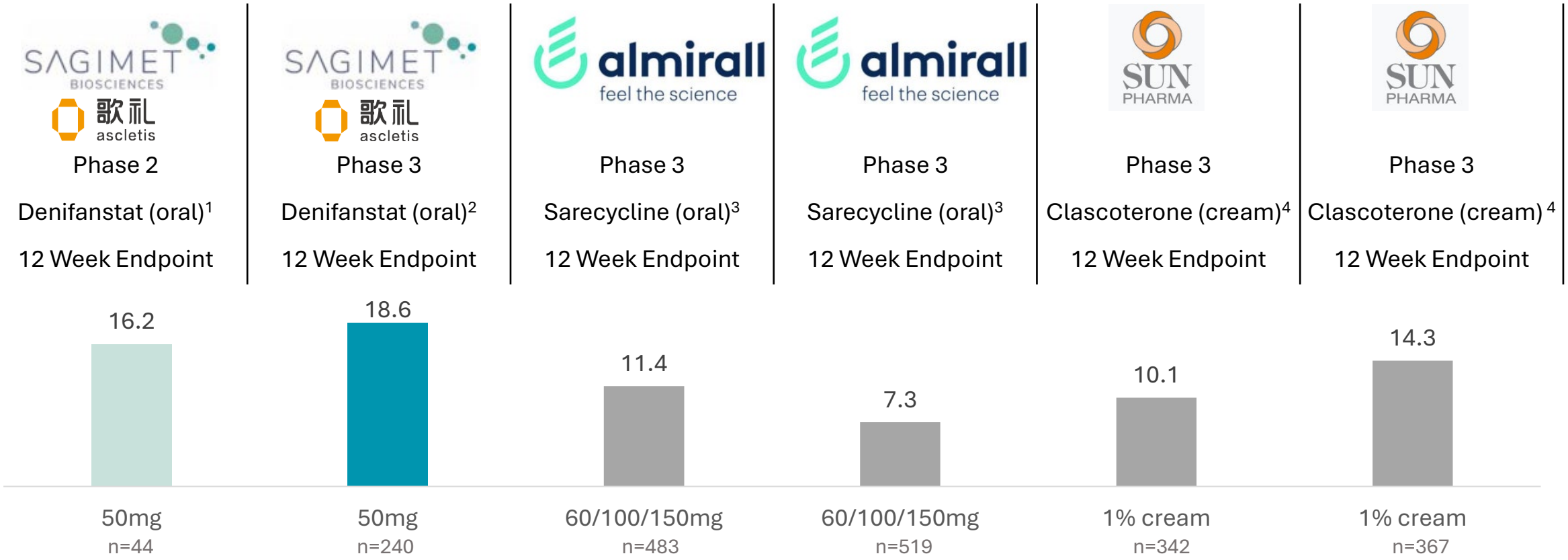
- TAEA incidence rates were comparable between denifanstat and placebo
- No incidence rate of TEAE in any category exceeded 10%
- Only two categories of TEAEs had an incidence rate of more than 5%:
  - Dry skin reported in 6.3% of denifanstat-treated subjects vs 2.9% in the placebo group
  - Dry eye reported in 5.9% of denifanstat-treated subjects vs 3.8% in the placebo group
- Ascletis informed Sagimet that one case of hair thinning occurred in the trial and it was in the placebo group

Adverse events (AEs):

- All denifanstat-related AEs were mild or moderate
- No denifanstat-related grade 3 or 4 AEs
- No denifanstat-related serious AEs (SAEs)
- No deaths were reported

Denifanstat Acne Phase 3 Clinical Trial Efficacy Data in Context

Placebo Adjusted % Treatment Success (≥ 2-grade improvement and score 0 [clear] or 1 [almost clear])

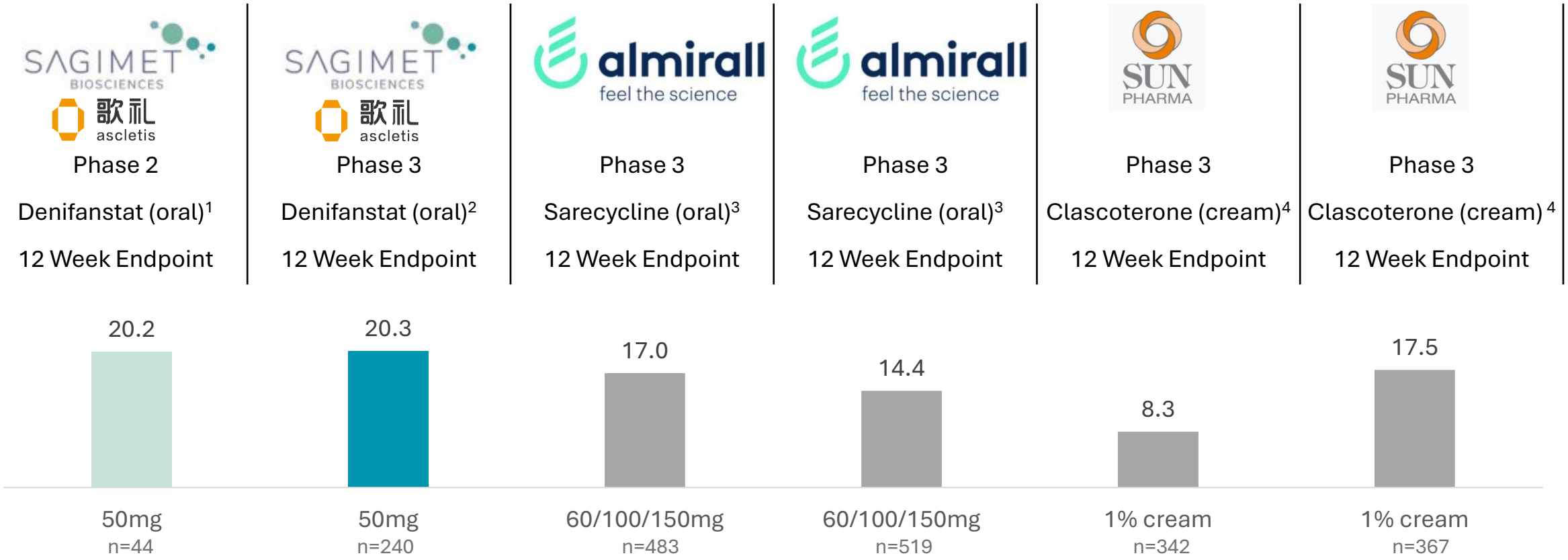


Note: These data are placebo-adjusted, derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted. All trademarks are the property of their respective owners.

1. Data on file at Sagimet and Ascletis; data represents Denifanstat 50mg arm only. 2. Ascletis press release issued June 2025. 3. Sarecycline Prescribing Information. 4. Clascoterone Prescribing Information.

Denifanstat Acne Phase 3 Clinical Trial Efficacy Data in Context

Placebo Adjusted % Reduction in Inflammatory Lesion Count



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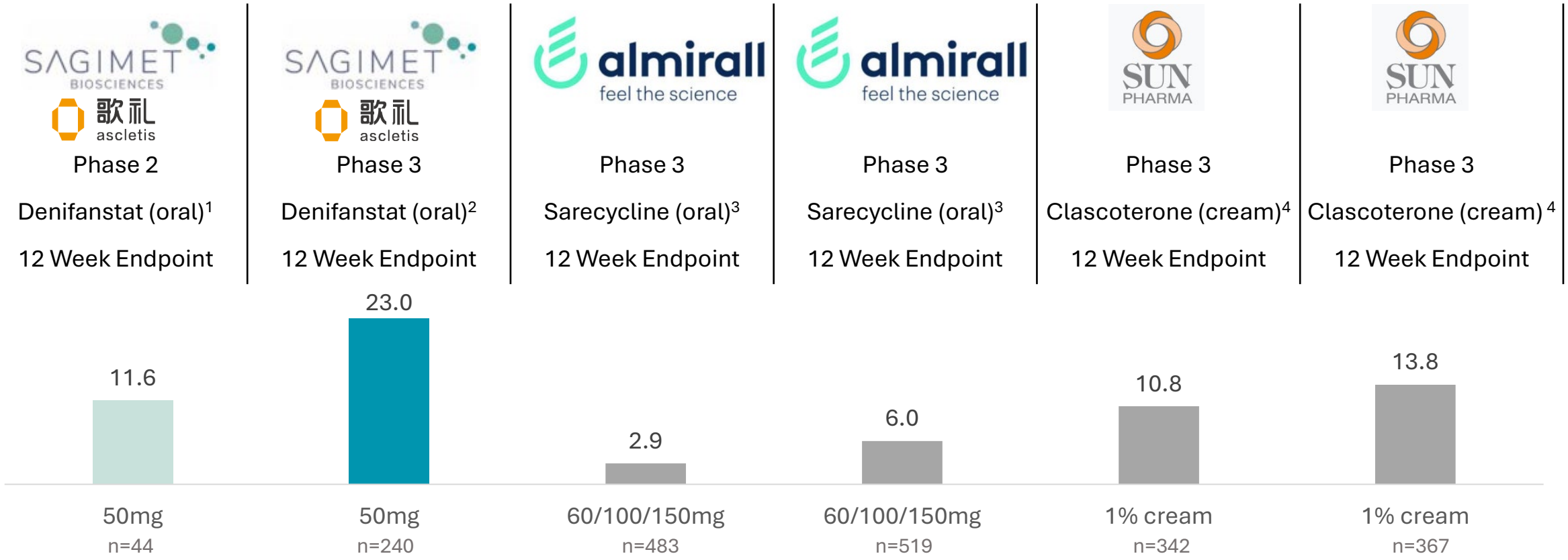
Denifanstat Acne Phase 3 Clinical Trial Efficacy Data in Context

Placebo Adjusted % Reduction in Non-Inflammatory Lesion Count



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1. Data on file at Sagimet and Ascletis; data represents Denifanstat 50mg arm only. 2. Ascletis press release issued June 2025. 3. Sarecycline FDA multi-disciplinary review NDA 209251, 2016. 4. Clascoterone Prescribing Information.

TVB-3567 Clinical Development Program

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Second FASN Inhibitor TVB-3567 Entered FIH Phase 1

Phase 1 clinical trial initiated June 2025

A double-blind, randomized, placebo-controlled trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of TVB-3567 in healthy and acne participants

- **Includes sebum analysis as pharmacodynamic readout**

PART	DESIGN	PLANNED # of PARTICIPANTS
A	SAD	~56
B	Food effect	~12
C	MAD	~32
D	MAD/ACNE	~28

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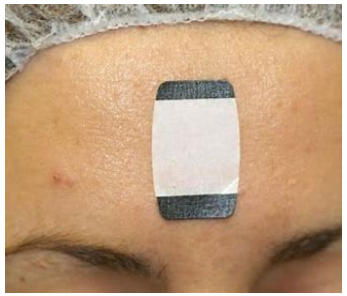
Quantity of Sebum

Sebutape



Quality* of Sebum

Note: SAD = Single ascending dose. MAD = Multiple ascending dose

Each SAD/MAD cohort planned to include 6 participants on active and 2 on placebo.

* Lipidomic analysis with focus on FASN-derived lipids.

Potential Clinical Development Program for TVB-3567 in Acne

Phase 1 trial initiated in June 2025

Goal to initiate Phase 2 trial in 2026, subject to consultation with regulatory authorities

Step 1 - Phase 1 first-in-human pharmacokinetic (PK) clinical trial of TVB-3567 in healthy volunteers

- PK and pharmacodynamics (PD) evaluation to confirm profile
- Assess safety/tolerability
- Confirm potential doses for an acne Phase 2 study

Step 2 - Phase 2 clinical study in moderate to severe acne patients

- Upon completion of Phase 1, will consult with regulatory authorities regarding Phase 2 trial design, with goal of initiating Phase 2 in 2026
- Phase 2 study design will be informed by the results of the Phase 1 trial, anticipate a 12-week dose ranging study in moderate to severe acne patients with lesion reduction, treatment success (IGA) as endpoints

Attractiveness of TVB-3567 in Acne

FASN Inhibitor in Acne

- Oral FASN inhibitors offer a novel mechanism of action for the potential treatment of moderate to severe acne
- Successful outcome of denifanstat Phase 3 clinical trial in patients with moderate to severe acne in China, met all primary and secondary endpoints; Denifanstat was generally well tolerated

Potential of TVB-3567 in Acne

- Acne market in dermatology is large (>50m people in the US) and aligned to those patients most likely to be prescribed an oral FASN inhibitor
- TVB-3567 IP:
  - Method of use application for TVB-3567 for acne filed 2025; if granted—2046
  - Composition of matter patent—2035; potential PTE to 2038

Next Steps

- Our second FASN inhibitor, TVB 3567, received Investigational New Drug (IND) clearance in March 2025
- First-in-human Phase 1 clinical trial of TVB 3567 initiated in June 2025, for development in acne
- Upon completion of Phase 1, will consult with regulatory authorities regarding Phase 2 trial design, with goal of initiating Phase 2 in 2026

Q&A

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