

# Priovant Overview

February 2025



# Priovant Is Well Positioned to Become a Leader in Specialty I&I



**Commercially validated MOA with first-in-class drug profile**



**Upcoming Phase 3 data in blockbuster indication (dermatomyositis)**

- Clear path to first-to-market position
- Potential for rapid early revenue growth consistent with recent orphan I&I launches



**Phase 3 in second blockbuster indication (NIU) actively enrolling**

- 52-week Phase 2 data confirm potential best-in-indication product profile



**Studies in additional orphan/specialty I&I indications to be initiated in 2025**

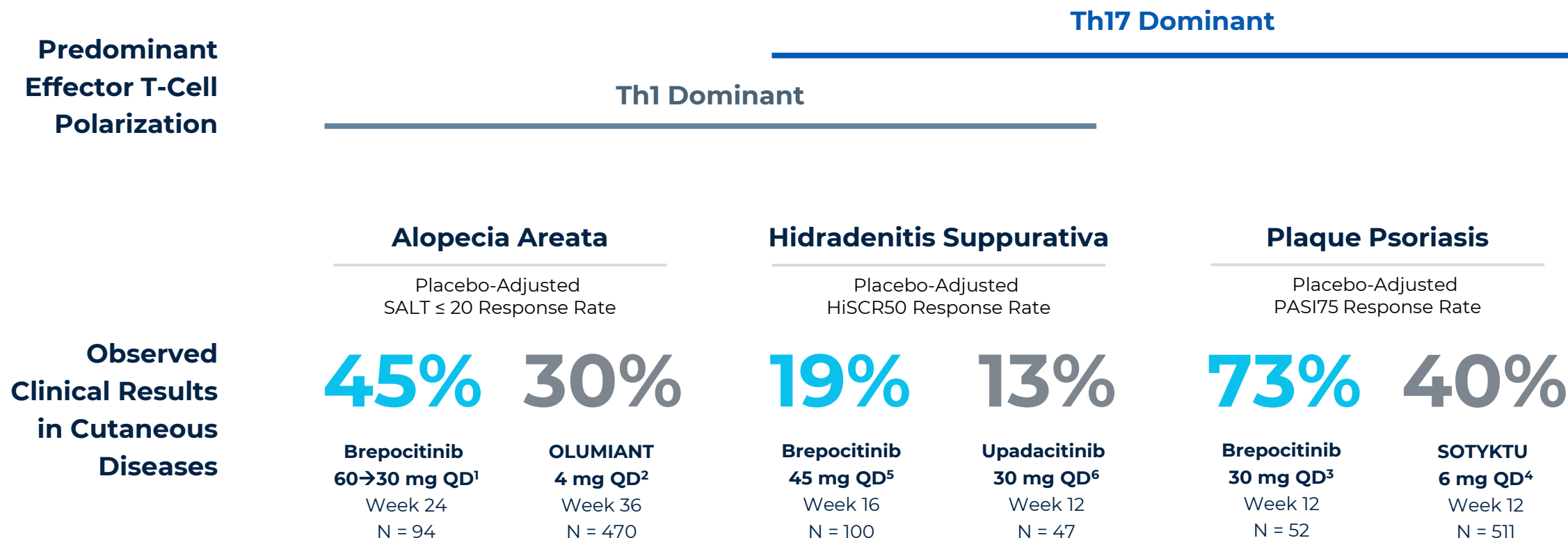
- Newest indication: cutaneous sarcoidosis

# Brepocitinib Is a Potential First-In-Class Dual Selective TYK2/JAK1 Inhibitor, Representing Next Generation of JAK Inhibition

Evolution of JAK inhibitor field highlights market demand for efficacy in treating patients with the most debilitating conditions



# Distinctive Potential Benefits of Dual TYK2/JAK1 Inhibition in Inflammatory Skin Diseases Supported By Clinical Data To-Date



*Disclaimer: Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.*

Note: for agents with more than one pivotal study, the data from the study showing the higher placebo-adjusted response rate is shown.

- 1) Brepocitinib Alopecia: Priovant data on file  
2) Baricitinib Alopecia: Olumiant Prescribing Information

- 3) Brepocitinib PsO: Priovant data on file  
4) Deucravacitinib PsO: Armstrong et al, SDDS 2021 Poster 1042  
5) Brepocitinib Hidradenitis Suppurativa: Priovant data on file  
6) Upadacitinib Hidradenitis Suppurativa: Kimball et al, Poster 43799 AAD 2023

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# Clinically Meaningful Results in Seven Completed Phase 2 Studies

Study Population	N <sup>1</sup>	Brepocitinib Dose	Primary Endpoint Result	
<b>Psoriatic Arthritis</b> Patients with active PsA	218	30 mg once daily	23.4% placebo-adjusted ACR20 RR at week 16	<b>P = 0.0197</b>
<b>Plaque Psoriasis</b> Patients with moderate-to-severe PsO	212	30 mg once daily	-10.1 placebo-adjusted CFB in PASI Score at week 12	<b>P &lt; 0.0001</b>
<b>Ulcerative Colitis</b> Patients with moderate-to-severe UC	167	30 mg once daily	-2.28 placebo-adjusted CFB in Mayo Score at week 8	<b>P = 0.0005</b>
<b>Alopecia Areata</b> Patients with moderate-to-severe AA	94 <sup>2</sup>	30 mg once daily <sup>3</sup>	49.18 placebo-adjusted CFB in SALT Score at week 24	<b>P &lt; 0.0001<sup>4</sup></b>
<b>Hidradenitis Suppurativa</b> Patients with moderate-to-severe HS	100	45 mg once daily <sup>5</sup>	18.7% placebo-adjusted HiSCR Rate at week 16	<b>P = 0.0298<sup>4</sup></b>
<b>Crohn's Disease</b> Patients with moderate-to-severe CD	151	60 mg once daily <sup>6</sup>	21.4% placebo-adjusted SES-CD 50 Rate at week 12	<b>P = 0.0012<sup>4</sup></b>
<b>Non-Infectious Uveitis</b> Patients with active, non-anterior NIU	26	45 mg once daily	29.4% Treatment Failure Rate at week 24 <sup>7</sup>	

1) Overall study N represents patients randomized to all brepocitinib dose levels or placebo and excludes patients randomized to other agents

2) Includes patients from initial 24-week study period only

3) 60 mg QD for 4 weeks followed by 30 mg QD for 20 weeks

4) One-sided p-value (pre-specified statistical analysis)

5) Brepocitinib 45 mg once daily was the only brepocitinib dose evaluated in this study

6) Brepocitinib 60 mg once daily was the only brepocitinib dose evaluated in this study

7) Study did not include a placebo arm

CFB: change from baseline; RR: response rate; NC: not calculated



# Dermatomyositis

# Dermatomyositis: Key Features in Common with Recent Orphan I&I Launches that Rapidly Achieved Blockbuster Revenue



## Mid-tens-of-thousands prevalence

Prevalence of approximately 40,000 adults in US<sup>1</sup> with approximately 35,000 patients receiving advanced chronic therapy<sup>2</sup>

## High morbidity with poor/no modern treatment options

Skin and muscle disease lead to pain, disfigurement, highly impaired mobility, and extensive comorbidities (e.g., cardiometabolic, GI, depression)

## Orphan price point and concentrated prescriber base

Approximately half of treated DM patients at ~200 tertiary centers of excellence<sup>2</sup>

All disease photos courtesy of Priovant.

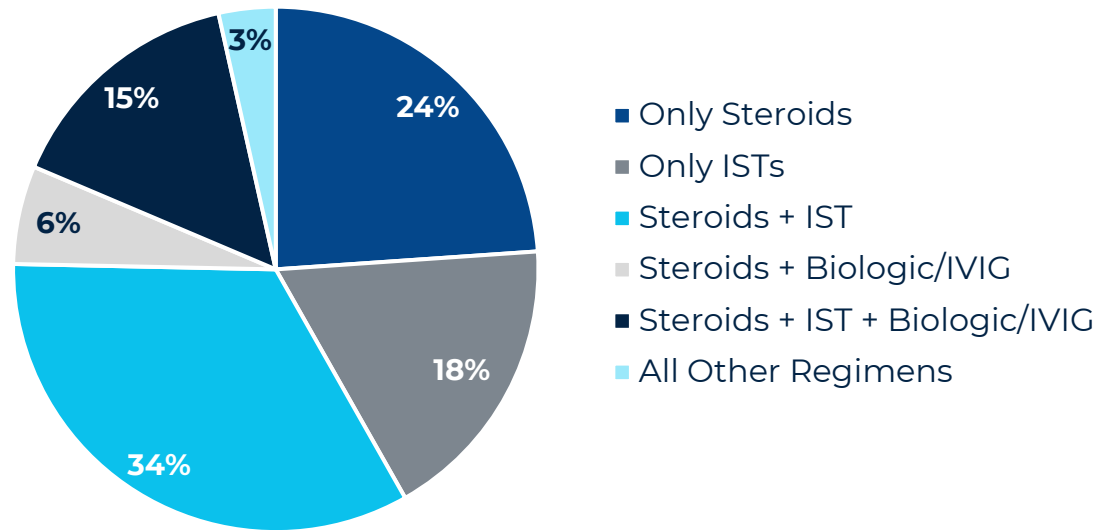
1) PriovantTx estimates based on Reeder 2010, Smoyer-Tomic 2012, and claims analysis

2) PriovantTX claims analysis

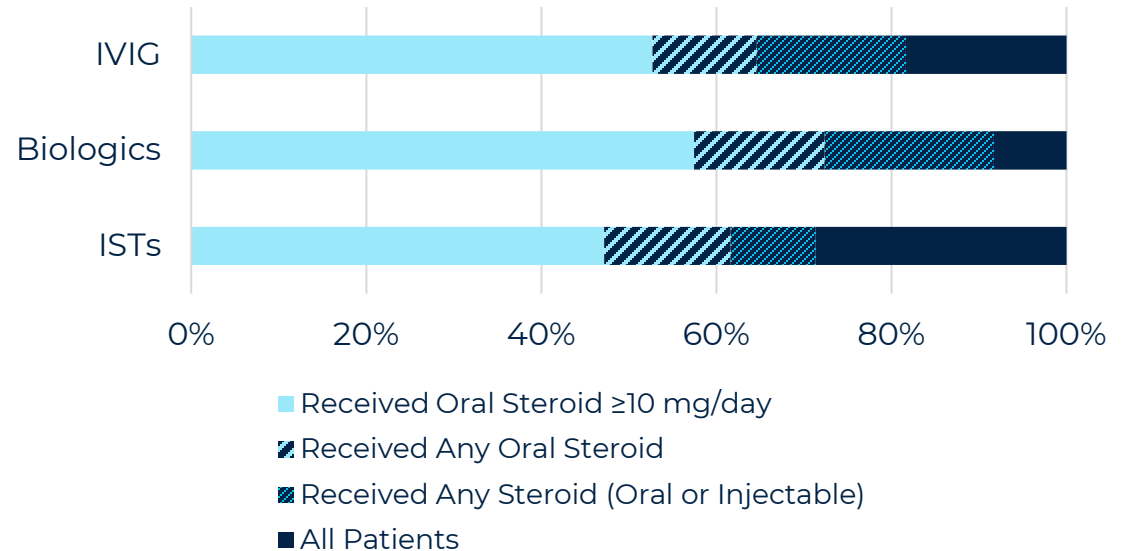
# Dermatomyositis Pharmacy Claims Highlight Widespread Polypharmacy Use and Large Steroid Burden Among DM Patients

Given limitations of current therapies, all DM patients in active treatment funnel would be potential candidates for treatment with brepocitinib if approved

**Therapies Received by ~34K Treated Dermatomyositis Patients in 2022**



**Steroid Use Among Patients Receiving Steroid-Sparing Therapy**

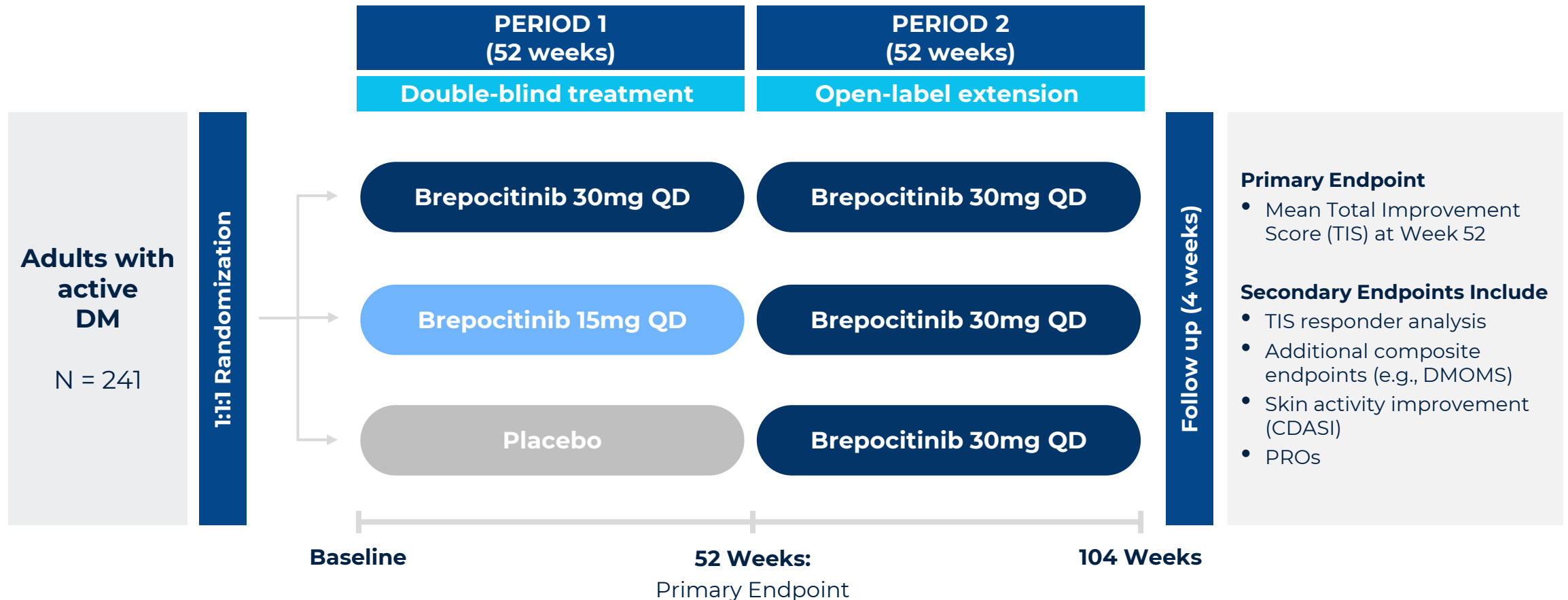


**Despite widespread use of multi-drug steroid-sparing therapy combinations, 62-72% of patients receiving steroid-sparing therapy still use oral corticosteroids, with most requiring doses ≥10 mg/day for ≥100 days/year**



# VALOR: A Single Registrational Phase 3 Study of Brepocitinib in Adults with Dermatomyositis

Pivotal study fully enrolled and topline data expected 2H 2025 → potentially next approved drug for dermatomyositis



# Non-Infectious Uveitis



# Non-Infectious Uveitis: Key Features in Common with Recent Orphan I&I Launches that Rapidly Achieved Blockbuster Revenue



## High tens-of-thousands prevalence

Approximately 70,000-100,000 prevalent patients in the US, with >40,000 patients receiving biologic therapy<sup>1</sup>

## High morbidity and few treatment options

Fourth-leading cause of blindness among working-age population in developed world<sup>2</sup>

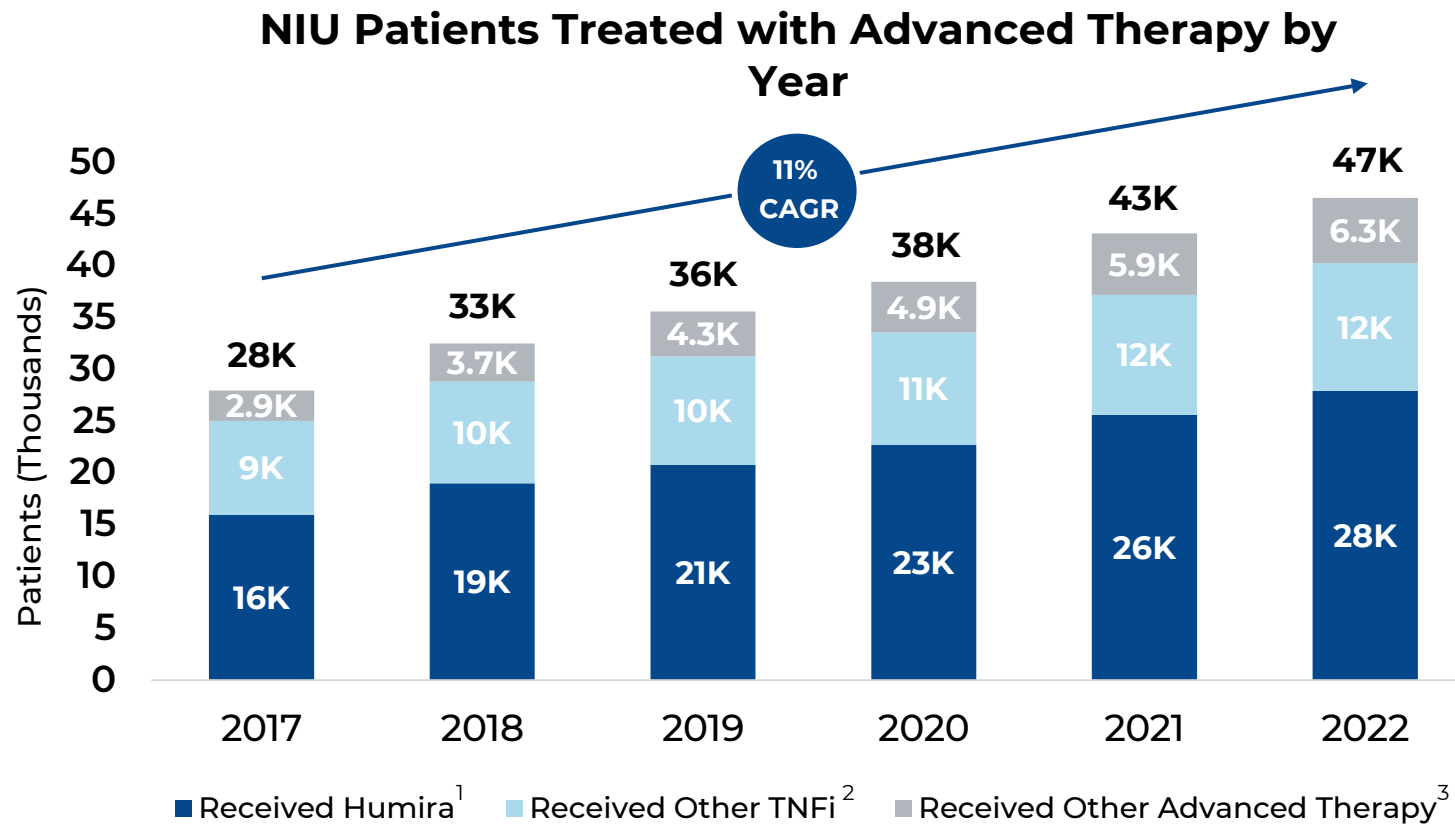
Only approved modern therapy (Humira) has limited efficacy, with >50% ultimately experiencing treatment failure<sup>3</sup>

## Orphan price point and concentrated prescriber base

High concentration of patients treated at dedicated uveitis specialty centers; most of remainder treated by retina specialists

1) Thorne et al, JAMA Ophthalmol. (2016) and IQVIA analysis of pharmacy claims of patients with NIU  
2) Barisani-Asenbauer, T., Maca, S.M., Mejdoubi, L. et al. Orphanet J Rare Dis 7, 57 (2012)  
3) Jaffe et al, NEJM (2016)  
4) Photo sourced from Masuda et al, Am J Ophthalmol Case Rep (2018)

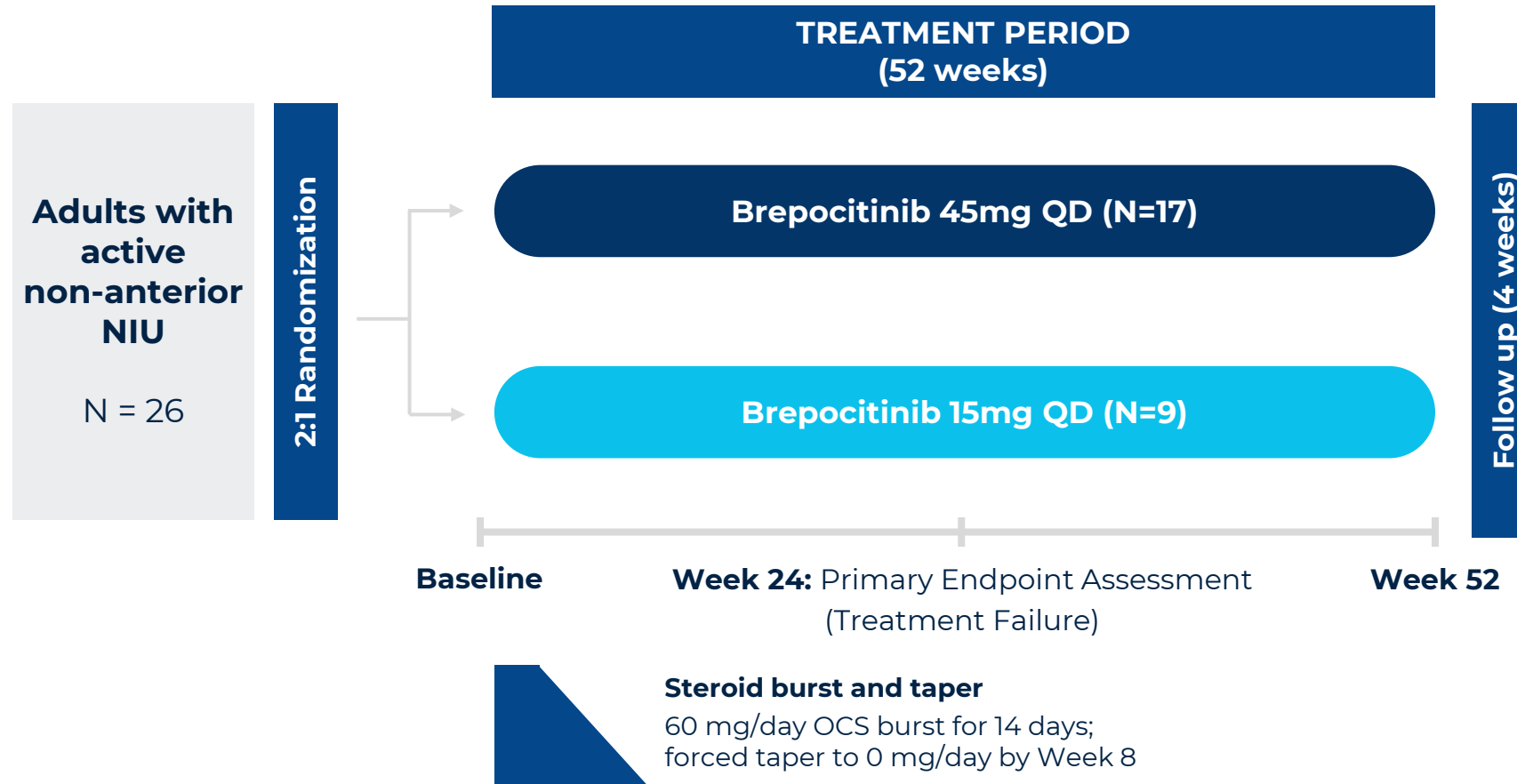
# IQVIA Analysis of the NIU Market Confirms >40,000 Patients Receiving TNFi for NIU, with >10% CAGR for Advanced Therapies



- Widespread use of advanced systemic medication for NIU treatment
- Large commercial opportunity in TNF-refractory population alone, given high TNFi failure rate (>50% in clinical studies)
- Additional potential blockbuster opportunity in broader non-anterior NIU population

1) Analysis includes patients with at least 2 NIU Dx claims at least 30 days in or before 2022 (patients had to have continuous pharmacy and medical benefit enrollment in 2021 - 2023) and medication utilization within one year of index NIU diagnosis in 2022. Includes NIU of any etiology or anatomic area.  
2) Includes any patient who received Humira during calendar year, whether or not they received any additional advanced therapy (including other TNFi)  
3) Includes any patient who did not receive Humira during calendar year, but did receive a different TNFi. Includes originator molecules (e.g., Remicade, Enbrel) and biosimilars (e.g., Inflectra, Renflexis, Avsola) targeting TNF-α  
4) Other advanced therapies used include JAK inhibitors and biologic agents/monoclonal antibodies targeting IL-6, IL-12/23, IL-17, IL-1β, IL-1Ra, CD-20, and CD-28  
5) The statements, findings, conclusions, views, and opinions contained and expressed on this page are based in part on data obtained under license from IQVIA PharMetrics Plus, January 2018 – December 2023, Iqvia, Inc. All Rights Reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not those of IQVIA Inc. or any of its affiliated or subsidiary entities.

# Design Of Phase 2 NEPTUNE Study of Brepocitinib in Non-Infectious Uveitis

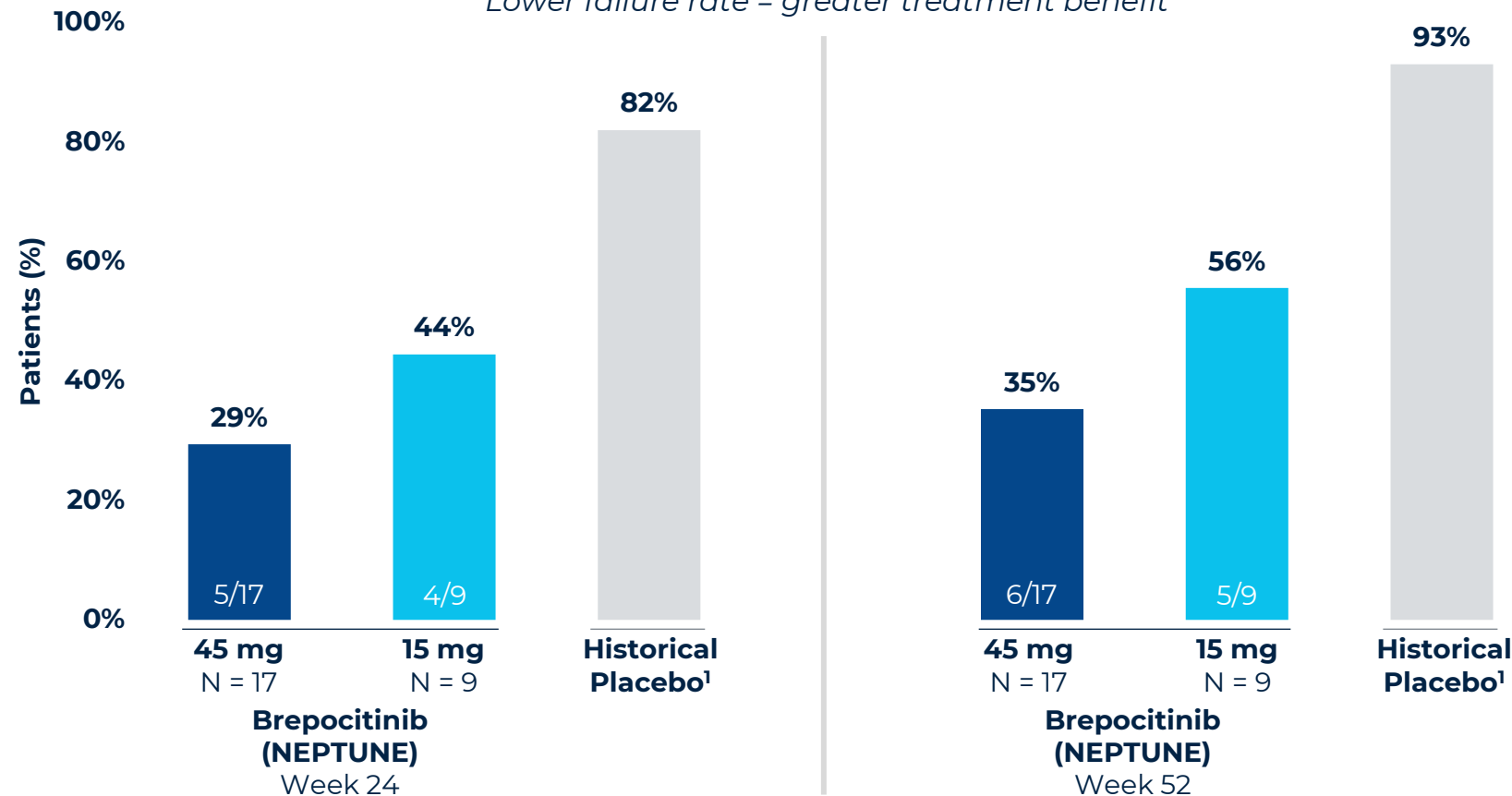




# 52-Week Data from the Phase 2 NEPTUNE Study of Brepocitinib in NIU Showed Potential Best-in-Indication Efficacy Sustained to One Year

## Treatment Failure at Week 24 and 52, compared to historical placebo\*

Lower failure rate = greater treatment benefit



### Reminder:

Better Treatment Failure results for brepocitinib in NEPTUNE achieved despite 6-week steroid taper in NEPTUNE compared to 13-week taper in precedent studies, in both cases following two-week steroid burst

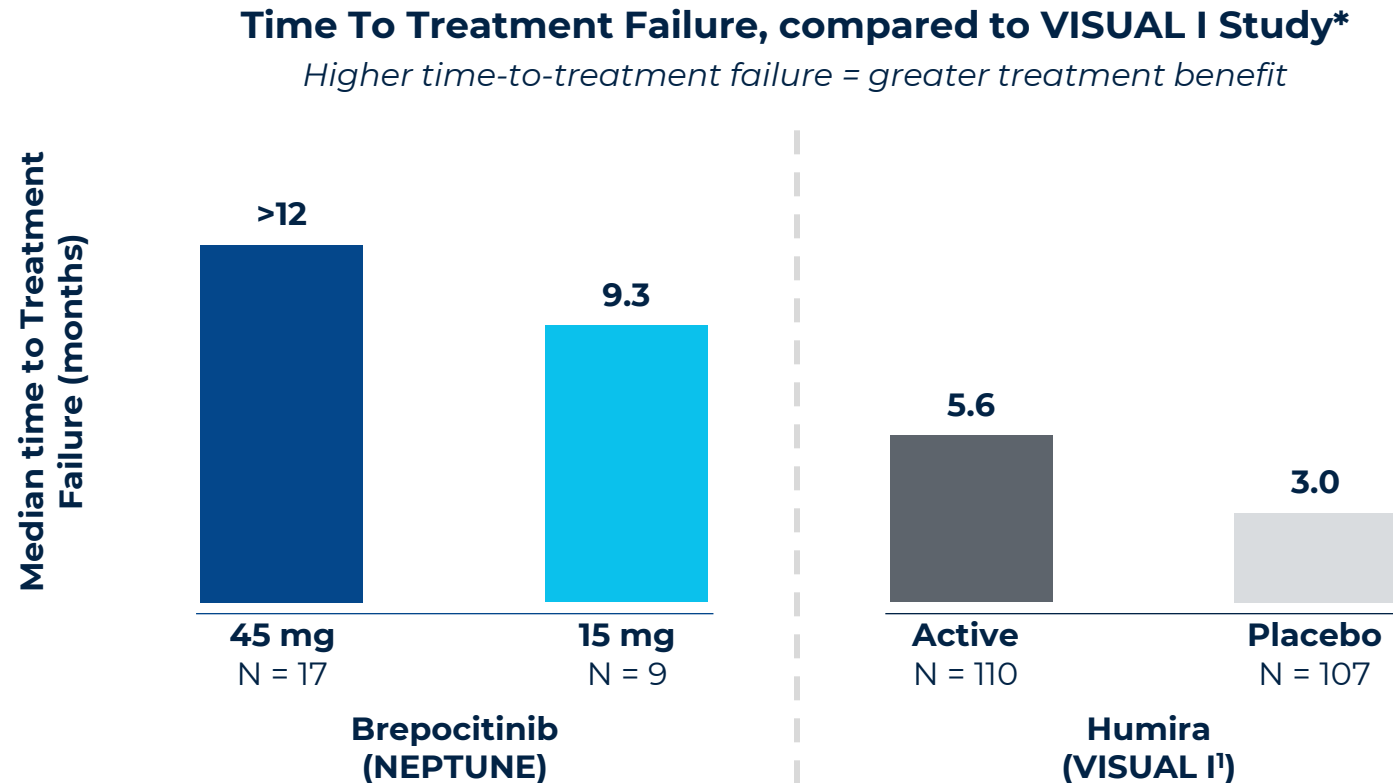
- Requires that brepocitinib act more quickly
- Increases difficulty of maintaining best state achieved
- Reduces steroid burden

*Disclaimer:* Figure reflects cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.

\*Treatment Failure calculations include all discontinuations as failures, per pre-specified endpoint definition in NEPTUNE study

1) Historical placebo data from Humira VISUAL 1 study - Jaffe et al, NEJM, 2016. Placebo failure rate was calculated by subtracting the reported No. of patients remaining over the total initial placebo population from 1 at weeks 25 and 55 (N=107)

# Brepocitinib Potential Best-in-Indication Efficacy Profile Also Seen on Median Time-to-Treatment Failure



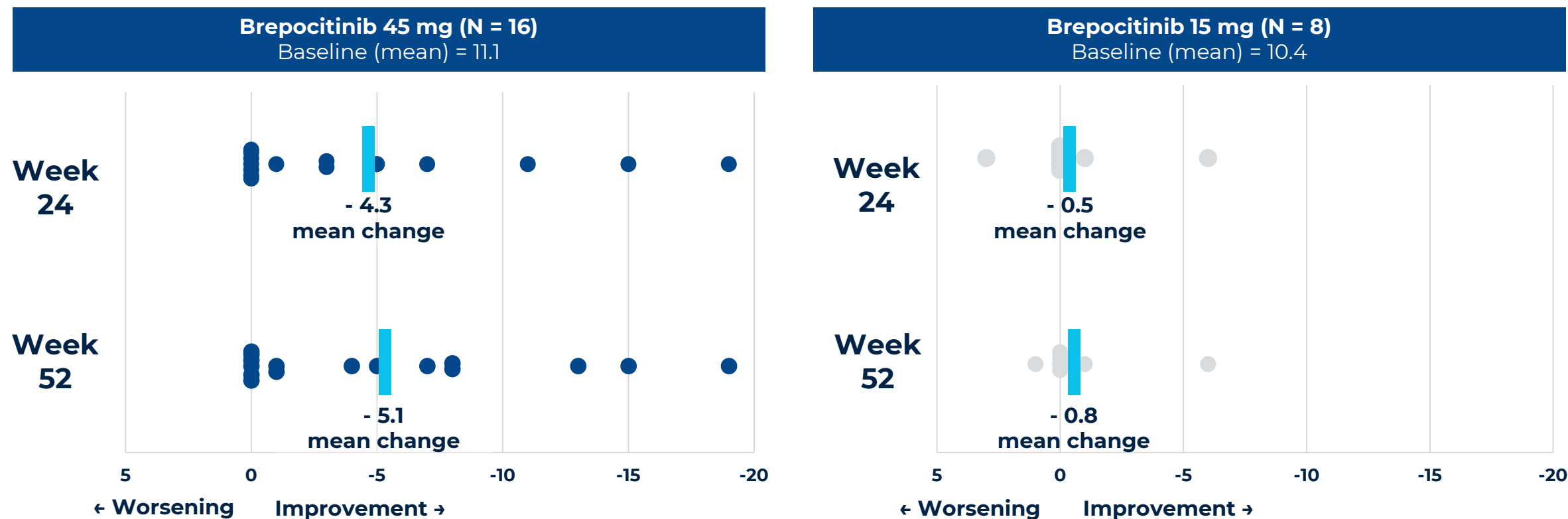
*Disclaimer: Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.*

\*Time-To-Treatment Failure was primary endpoint in VISUAL I study. VISUAL I calculations do not include discontinuations as treatment failures, per pre-specified definition in VISUAL I. NEPTUNE calculations include discontinuations as treatment failures.

1) As reported at <https://www.humirapro.com/uveitis>

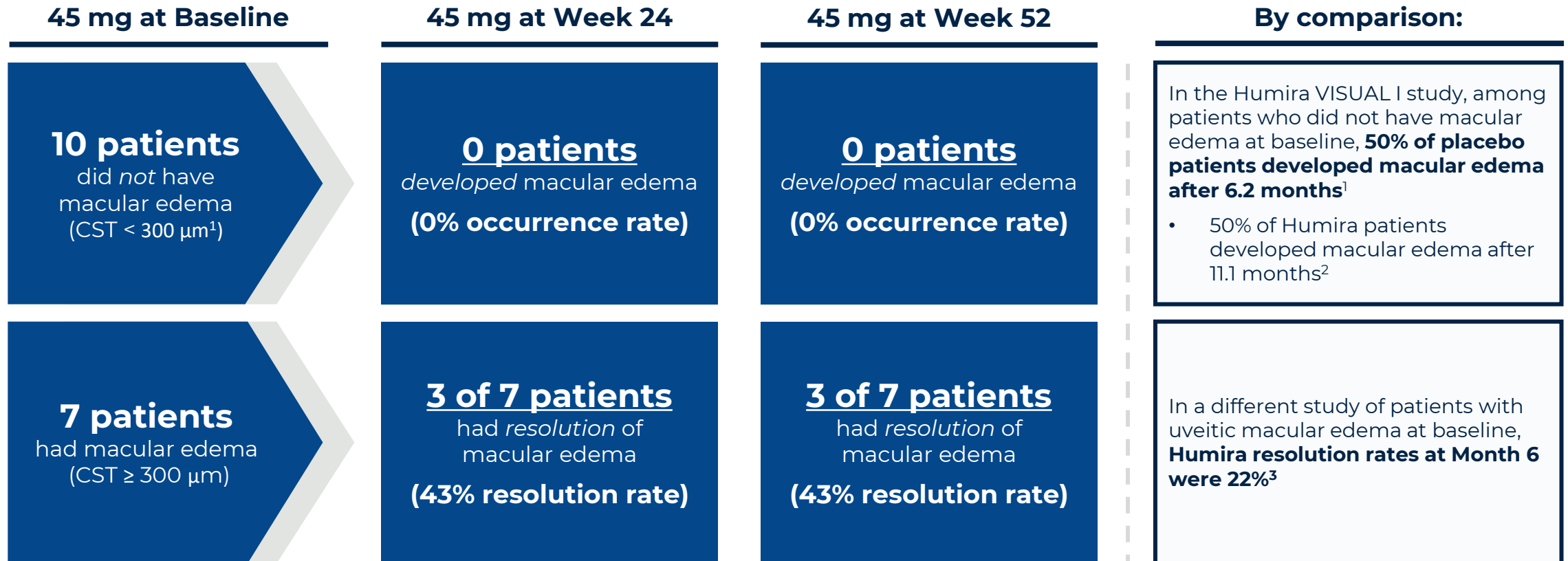
# Dose Dependent Benefit on Posterior Segment Inflammation Seen, with Sustained Improvement at 52 Weeks

Measurement of retinal vascular leakage by wide-field fluorescein angiography (FA) score change from baseline at Week 24 and Week 52; centrally assessed using ASUWOG, a multi-domain, semi-quantitative scoring system<sup>1</sup>



No patients on brepocitinib 45 mg worsened from baseline

# Potential Brepocitinib Benefit on Prevention and Treatment of Macular Edema Also Sustained to 52 Weeks



*Disclaimer: Figures reflect cross-trial comparison and not results from a head-to-head study. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.*

CST: central subfield thickness

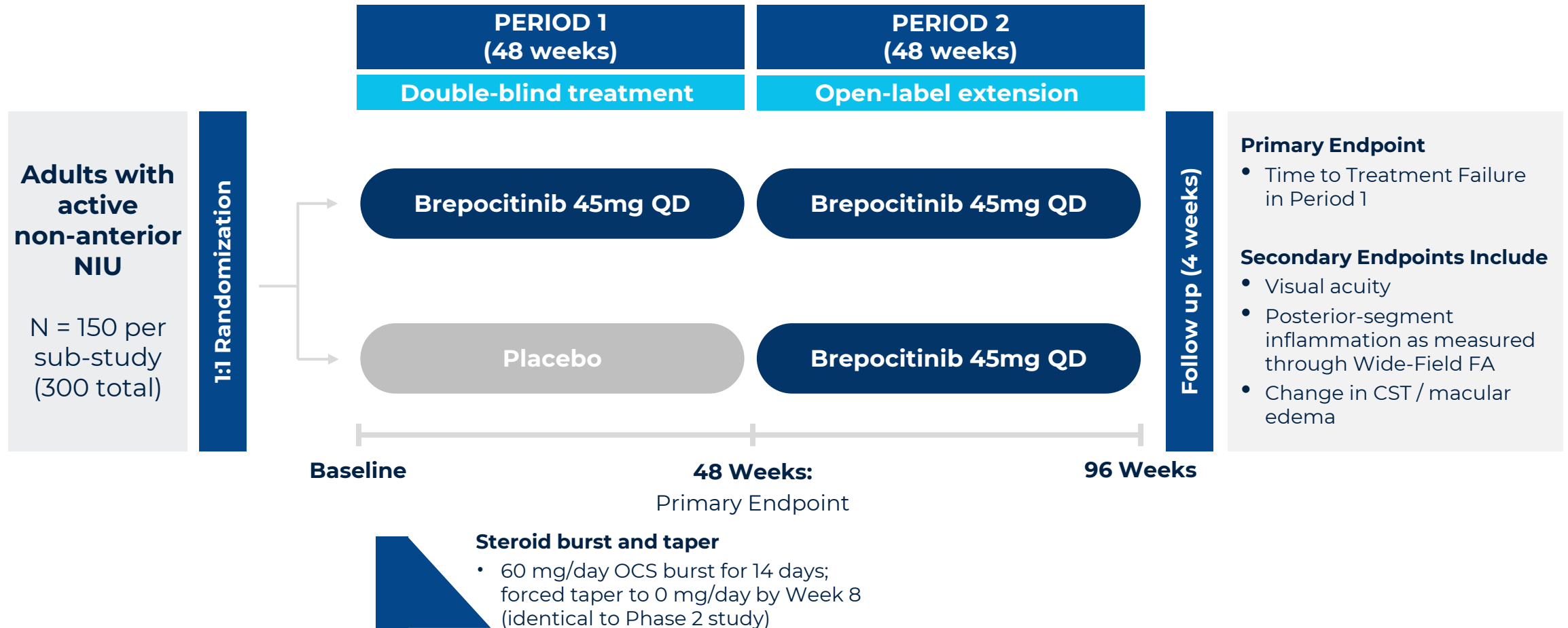
1) Definition of macular edema in NEPTUNE was CST  $\geq$  300  $\mu\text{m}$ , normalized by central reader across instrument types

2) Jaffe et al, NEJM 2016

3) Leclercq et al, Ophthalmology 2021

# CLARITY: A Phase 3 Study of Brepocitinib in Adults with Active, Non-Infectious, Non-Anterior Uveitis

Two identical sub-studies, CLARITY-1 and CLARITY-2, actively enrolling under a single protocol; topline results expected in 1H 2027





# Cutaneous Sarcoidosis

# Cutaneous Sarcoidosis: Next Proof-of-Concept Indication for Brepocitinib



## Mid tens-of-thousands prevalence

30,000-50,000 affected US cutaneous sarcoidosis patients<sup>1</sup> with no approved therapies; uncontrolled disease can result in severe disfigurement<sup>2</sup>

## Proof-of-concept data from ~20 JAK-treated patients

Dual TYK2/JAK1 inhibition well-suited to Th1 immunophenotype of sarcoidosis; case reports and investigator-initiated trial with JAKi agents have shown clinically meaningful responses

## Alignment with DM and NIU

Orphan price point; concentrated prescriber base overlapping with DM

1) Grunewald et al, Nat Rev Dis Primers 2019  
2) Culver, Curr Clin Med 2010  
Image adapted from Patel et al, 2011

# Yale IIT Provides Proof-of-Concept for JAK Inhibition in Cutaneous Sarcoidosis

## Open label study of tofacitinib in 10 patients with longstanding cutaneous sarcoidosis<sup>1</sup>

Cutaneous Sarcoidosis Activity and Morphology Instrument (CSAMI) is an established, reproducible endpoint to assess sarcoidosis skin disease symptoms<sup>2</sup>



**Results supported by multiple case reports indicating complete or near-complete resolution of longstanding, recalcitrant disease in JAK-treated patients<sup>4,5,6,7,8,9</sup>**

1) Damsky et al, Nat Comm 2022  
2) Noe et al, JAMA Dermatol 2019  
3) MCID = 5 point reduction from baseline  
4) Damsky et al, N Engl J Med. (2018)

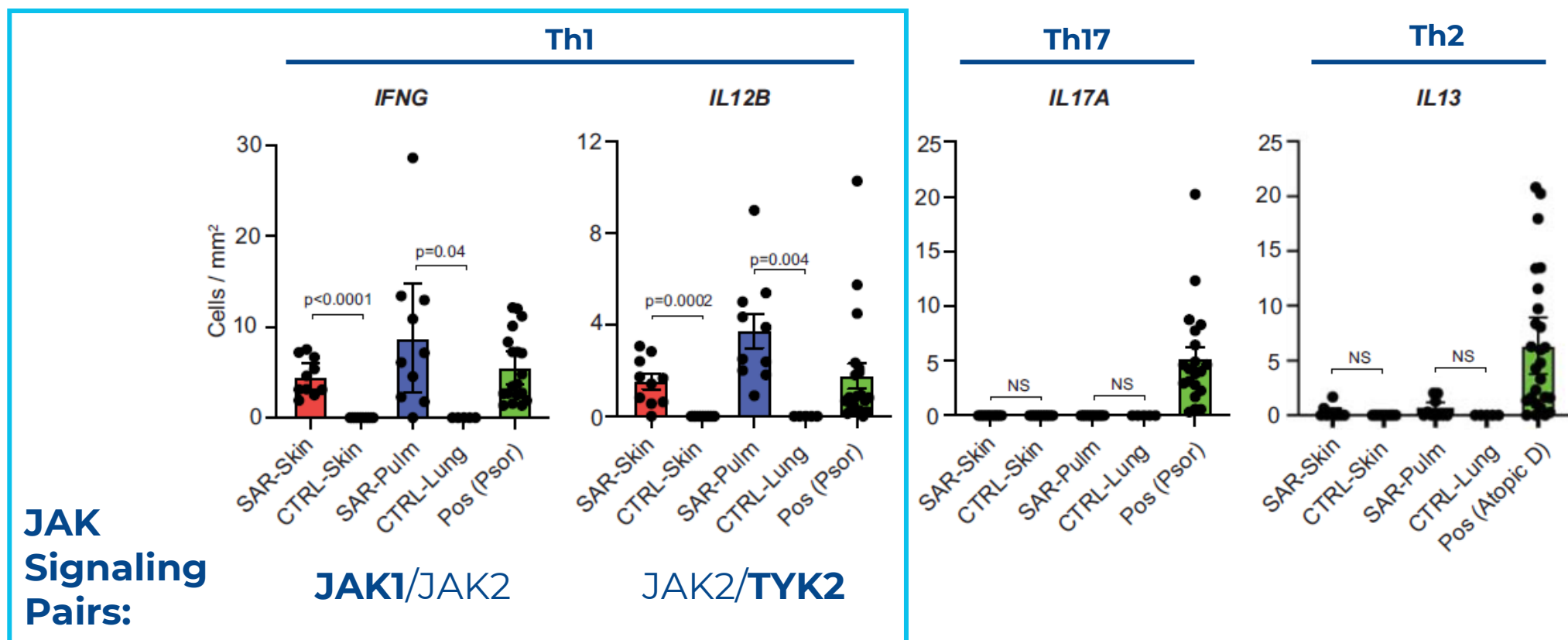
5) Damsky et al, J Am Acad Dermatol. (2020)  
6) Damsky et al, ACR Open Rheumatol. (2020)  
7) Kerkemeyer et al, J Am Acad Dermatol. (2021)  
8) Rotenberg et al, Eur Respir J. (2018)

9) Wei et al, JAAD Case Rep. (2019)

# Pronounced Th1-type Immunity Is the Predominant Polarization in Sarcoidosis Skin and Lung Tissue

Marked upregulation of key Th1 cytokines, including Type II IFN and IL-12, suggests potential best-in-indication selectivity profile for brepocitinib's dual inhibition of TYK2 and JAK1

## Quantitation of RNA In-Situ Hybridization for Key Immunoregulatory Cytokines



Adapted from Damsky et al, Nat Comm 2022. RNA in situ hybridization quantitation in control skin (n = 10), control lung (n = 5), cutaneous sarcoidosis (n = 10), and pulmonary sarcoidosis (n = 10). Data presented as means  $\pm$  95% CI.

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# BEACON: A Phase 2 Study of the Safety and Efficacy of Brepocitinib in Adults with Cutaneous Sarcoidosis

Start of enrollment expected in 2Q 2025; topline results expected in 2H 2026

