

AAD ANNUAL MEETING

# AEDV highlights

SAN DIEGO   
8-12 MARZO



#AEDVENAAD2024



ACADEMIA ESPAÑOLA  
DE DERMATOLOGÍA  
Y VENEREOLOGÍA

AAD ANNUAL MEETING

**AEVDV**  
*highlights*

**SAN DIEGO** ●  
8-12 MARZO



# Psoriasis y otras enfermedades inflamatorias





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**highlights**  
**AEDV**

SAN DIEGO  
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**He proporcionado asesoramiento científico/recibido becas para investigación o pagos por presentaciones en reuniones médicas y/o asesoría o asistencia a congresos de:**

***Janssen, Lilly, Novartis, AbbVie, UCB, Leo Pharma, Cantabria Labs, Pfizer, ISDIN, LaRochePosay, Galenicum, UCB, Amgen, Gebro***



# 1. Psoriasis

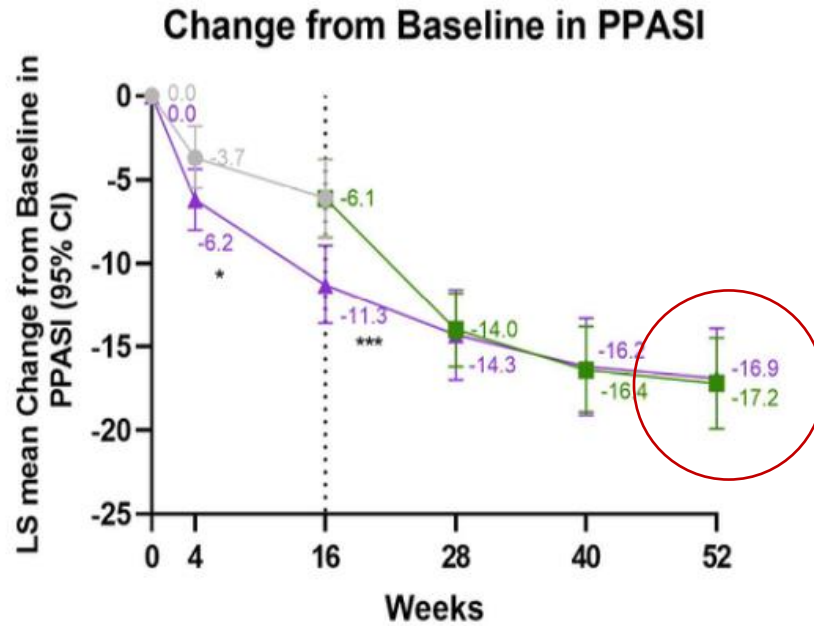
1. Localizaciones especiales
2. Psoriasis pustulosa generalizada
3. Futuros tratamientos

# 2. Vitíligo

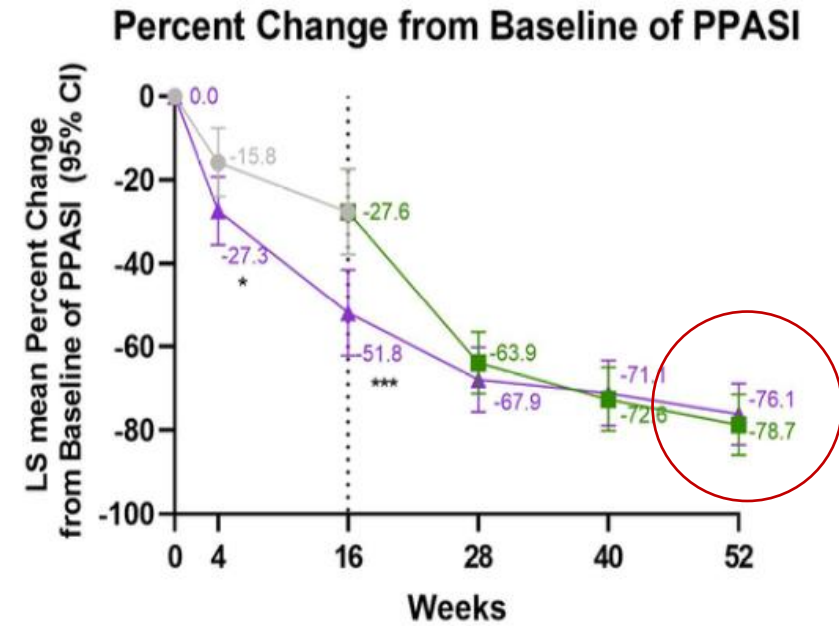


# Psoriasis palmoplantar

- IMMprint
- Fase 3b
- Psoriasis palmoplantar
- 174 pacientes 1:1 placebo vs risankizumab



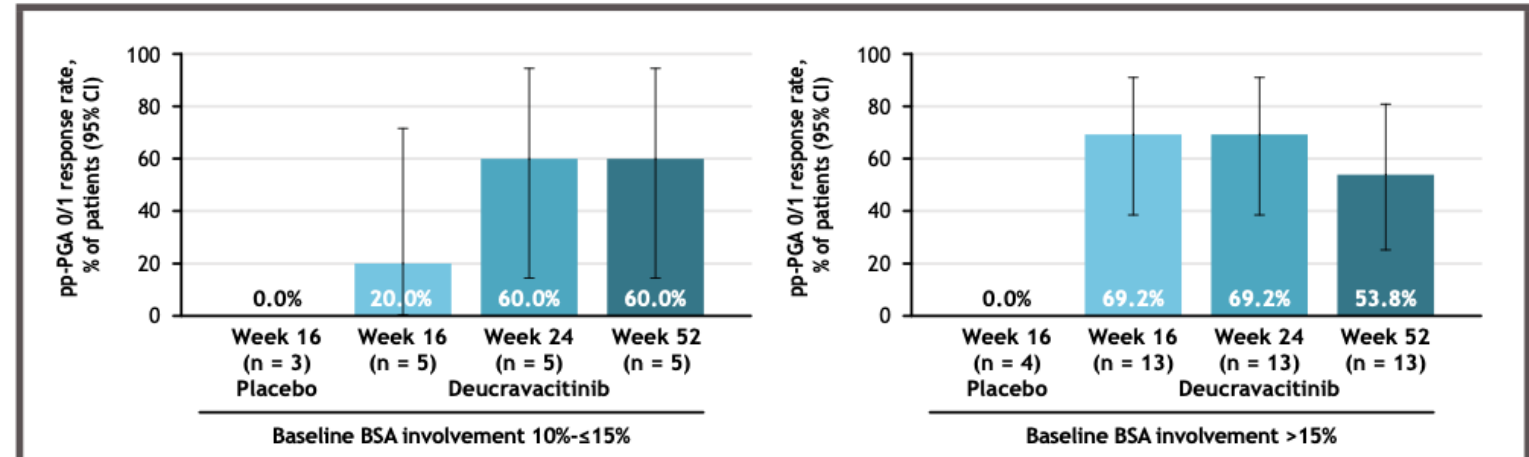
PBO	87	87	83			
PBO/RZB				81	77	75
RZB	86	86	81	79	78	75



PBO	87	87	83			
PBO/RZB				81	77	75
RZB	86	86	81	79	78	75

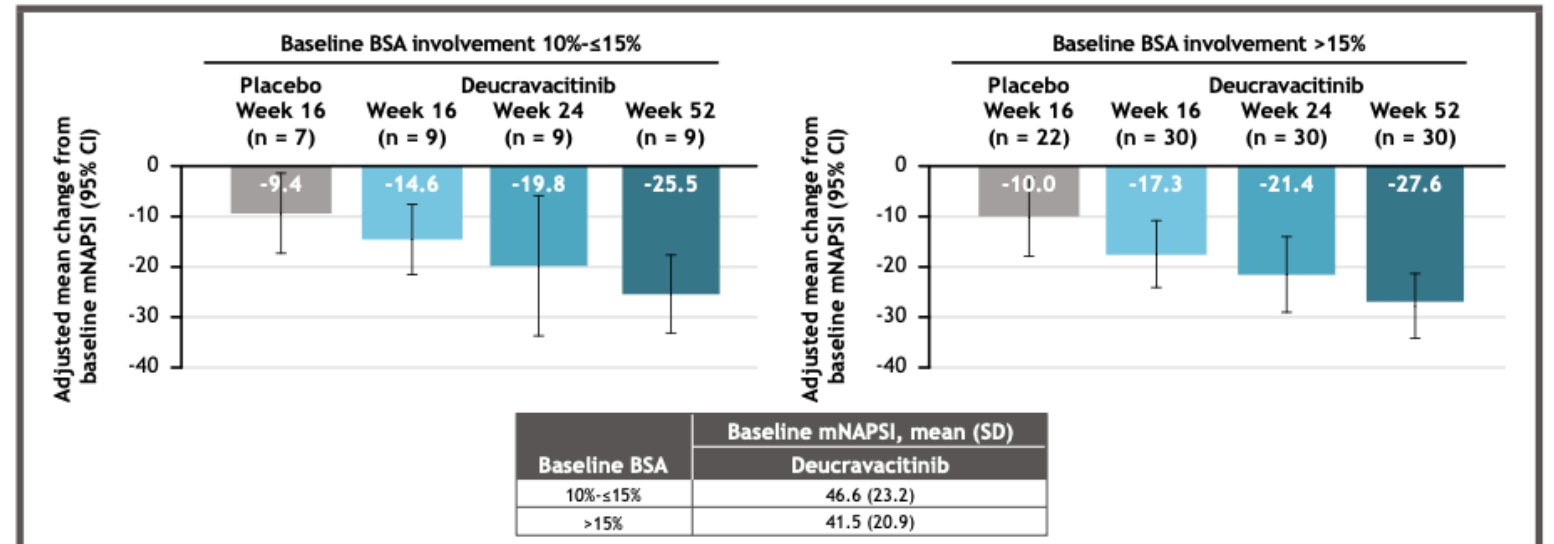
# Psoriasis palmoplantar

Figure 3. pp-PGA 0/1<sup>a</sup> response rates through Week 52 by baseline BSA involvement and PASI score (POETYK PSO-1, NRI)



POETYK PSO-1&2  
Deucravacitinib

Figure 9. Change from baseline mNAPSI<sup>a</sup> through Week 52 by baseline BSA involvement and PASI score (POETYK PSO-1, mBOCF)



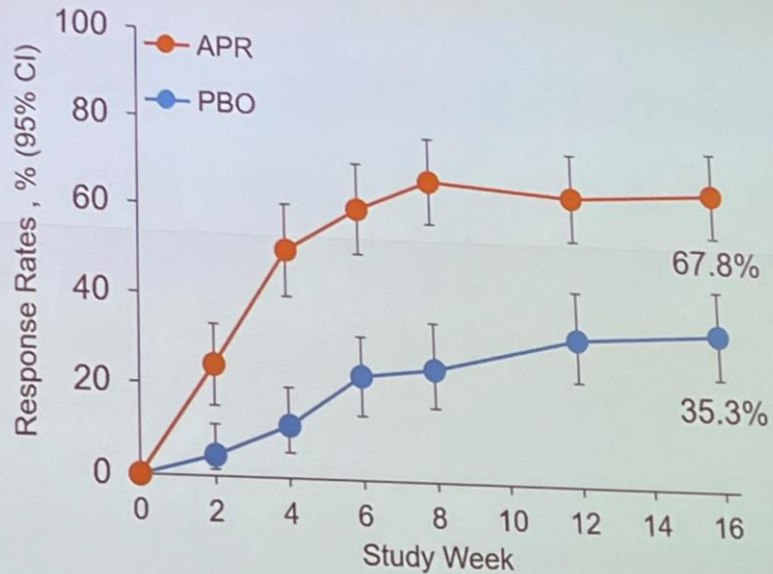
# Pustulosis palmoplantar

AAD

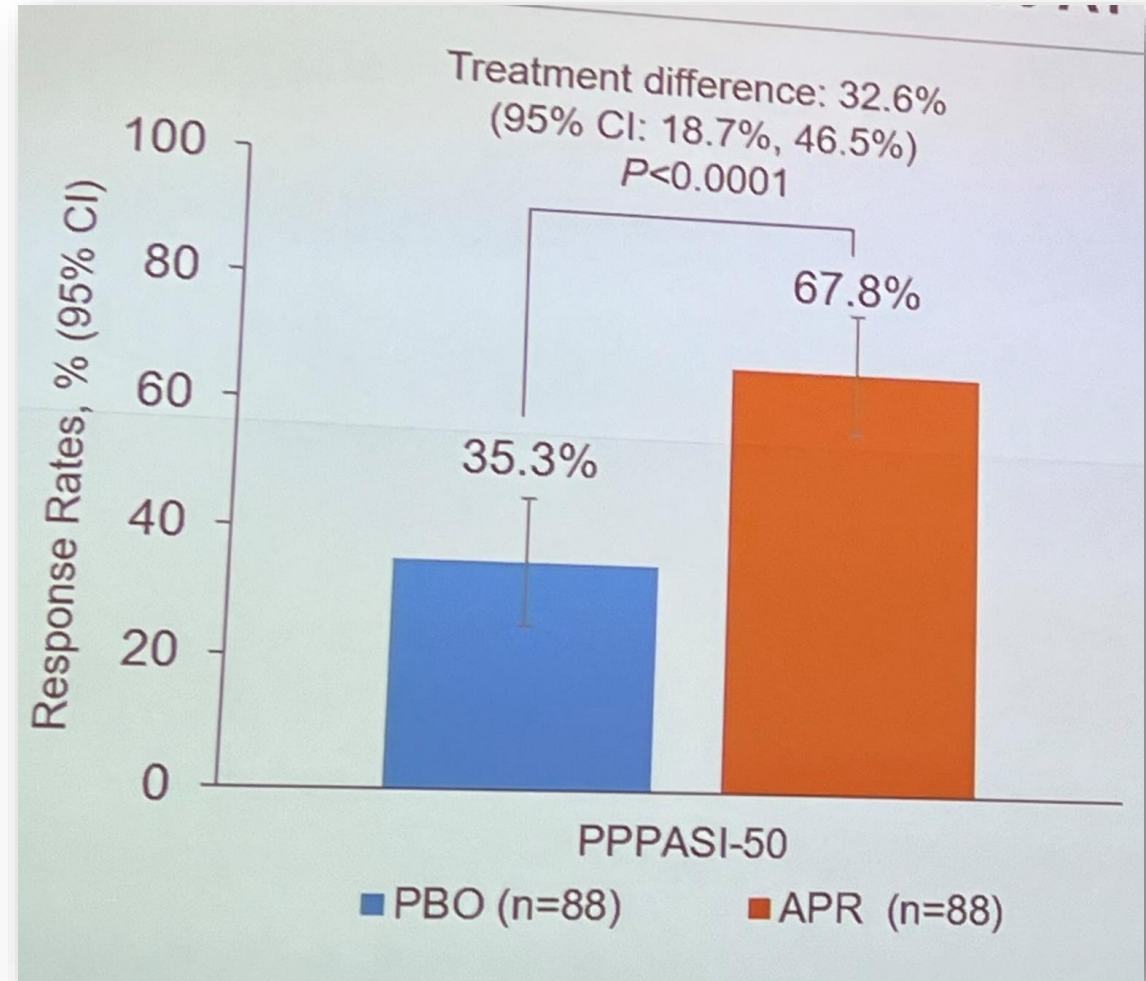
Late-breaking research session 1  
AAD Annual Meeting, March 8-12, San Diego, CA

## Efficacy and Safety of Apremilast for the Treatment of Japanese Patients With Palmoplantar Pustulosis (PPP): 16-Week Results From a Phase 3, Randomized, Placebo-Controlled Study

Tadashi Terui<sup>1</sup>; Yukari Okubo<sup>2</sup>; Satomi Kobayashi<sup>3</sup>; Akimichi Morita<sup>4</sup>; Shinichi Imafuku<sup>5</sup>; Yayoi Tada<sup>6</sup>; Bruce Strober<sup>7</sup>; Wendy Zhang<sup>8</sup>; Junichiro Shimauchi<sup>9</sup>; Melinda Gooderham<sup>10</sup>; Masamoto Murakami<sup>11</sup>



Endpoint primario: PPPASI-50 a la semana 16





# Psoriasis palmoplantar

## 54069 - Bimekizumab effectiveness in the treatment of palmoplantar psoriasis: a case series

Victor García-Rodríguez, Maribel Iglesias-Sancho, Jorge Arandes-Marcocci, Montse Salleras-Redonnet. Department of Dermatology, Hospital Universitari Sagrat Cor, Grupo Quirónsalud, Barcelona, Spain.

Author disclosure information: Authors have no relationships to disclose.

Commercial support information: Authors have no commercial support information to disclose.

Hospital  
Universitari  
Sagrat Cor



Figure 1. Mean absolute PASI at baseline, week 2-4, and week 12-16, respectively.

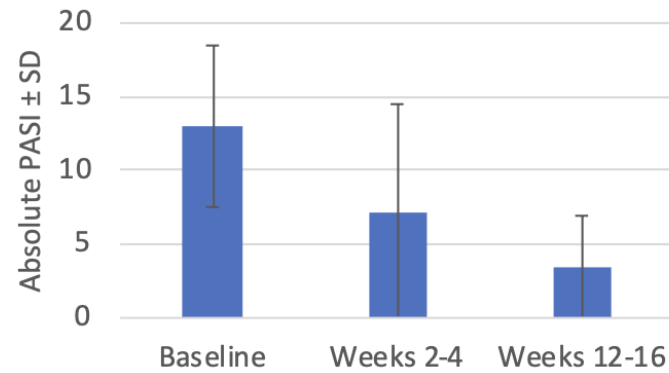
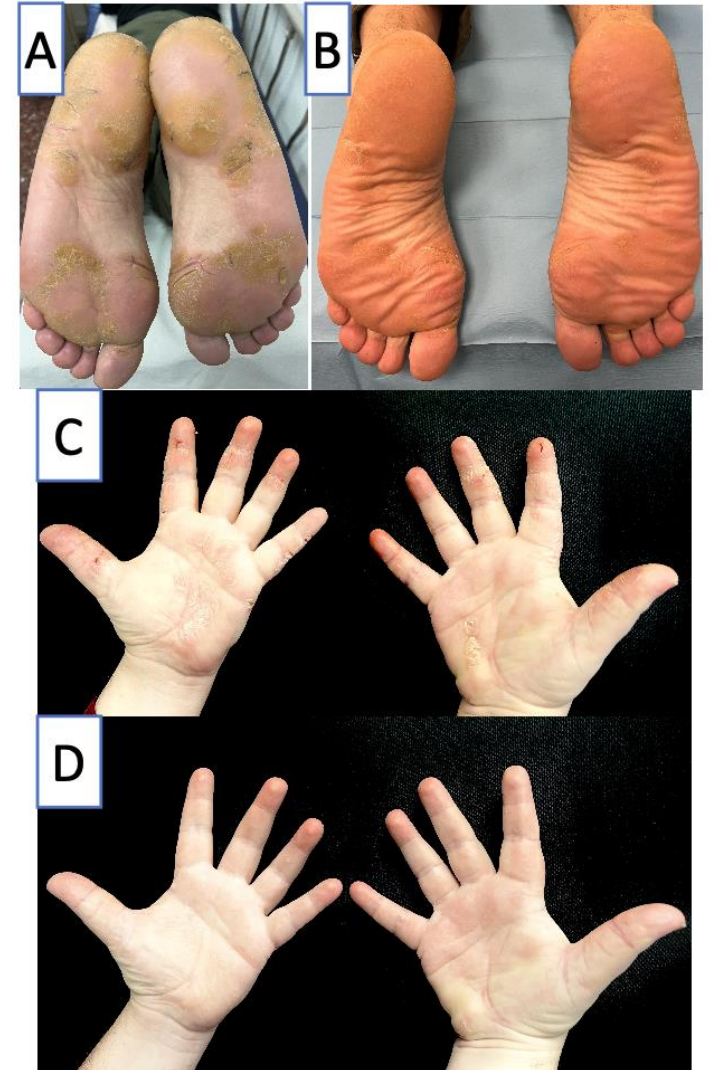
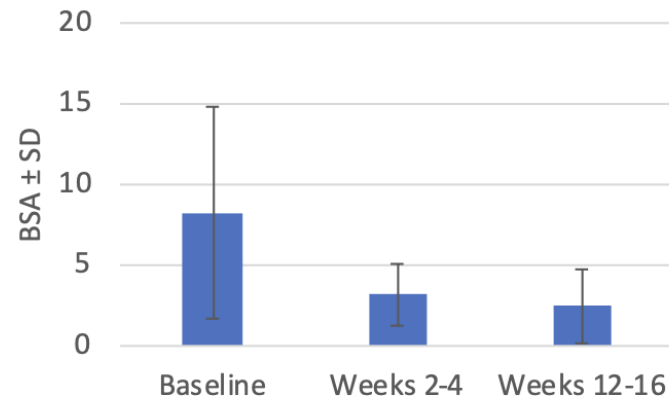


Figure 2. Mean BSA at baseline, week 2-4, and week 12-16, respectively.



# Psoriasis ungueal

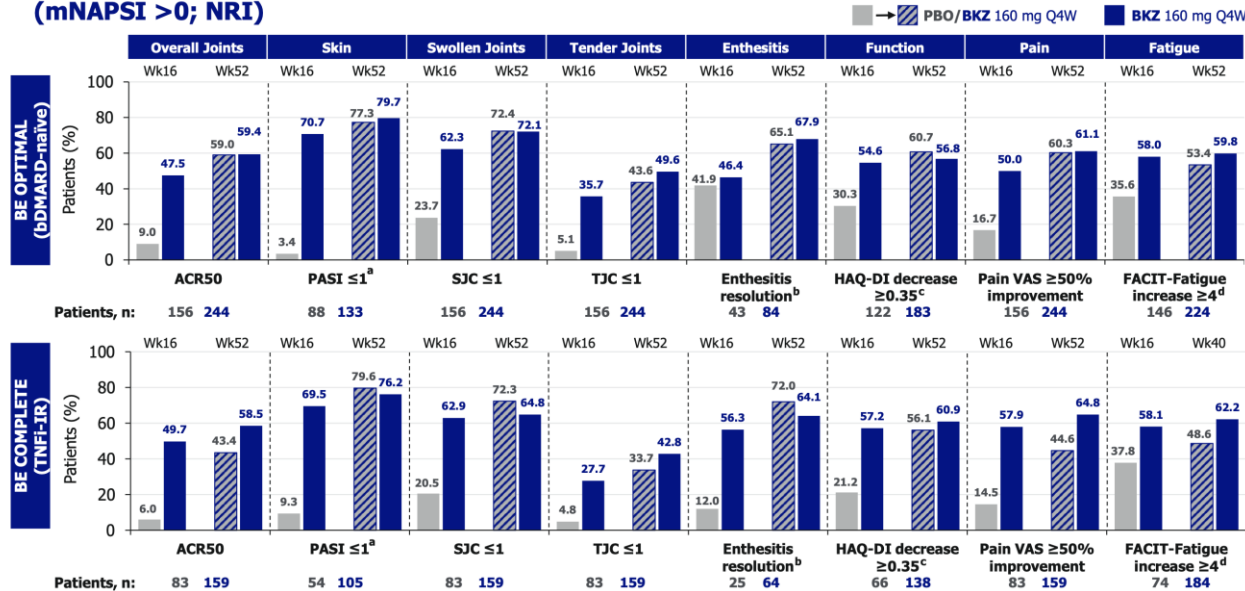
## Bimekizumab treatment resulted in sustained improvements in nail psoriasis and signs and symptoms of psoriatic arthritis in patients with baseline nail disease: 1-year pooled results from two phase 3 studies

Joseph F. Merola,<sup>1,2</sup> Diamant Thaçi,<sup>3</sup> Barbara Ink,<sup>4</sup> Rajan Bajracharya,<sup>4</sup> Jérémy Lambert,<sup>5</sup> Jason Coarse,<sup>6</sup> Alice B. Gottlieb<sup>7</sup>

<sup>1</sup>Department of Dermatology, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA; <sup>2</sup>Division of Rheumatology, Department of Medicine, Harvard Medical School, Brigham and Women's Hospital, Boston, MA, USA; <sup>3</sup>Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Lübeck, Germany; <sup>4</sup>UCB Pharma, Slough, UK; <sup>5</sup>UCB Pharma, Colombes, France; <sup>6</sup>UCB Pharma, Morrisville, NC, USA; <sup>7</sup>Department of Dermatology, The Icahn School of Medicine at Mount Sinai, New York, NY, USA

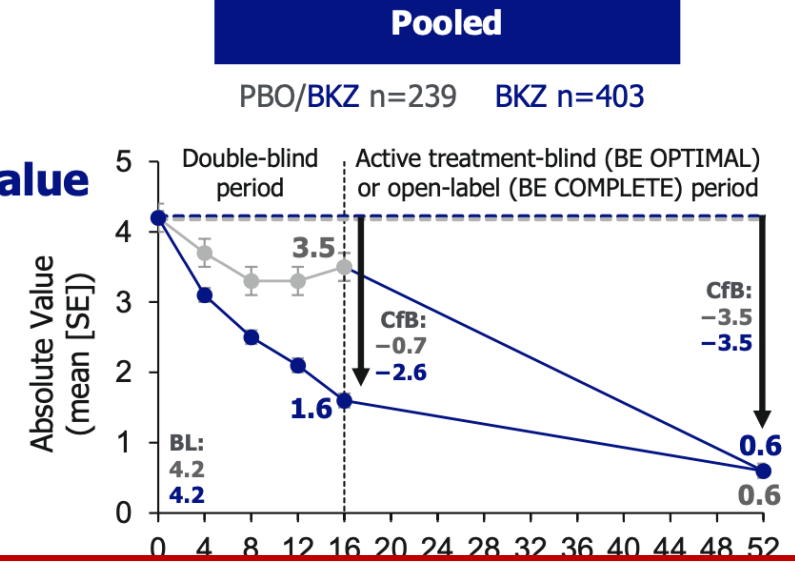
Presentation Number: 51569

### Clinically Meaningful Responses in Patients with PsA and Nail Disease at Baseline (mNAPSI >0; NRI)

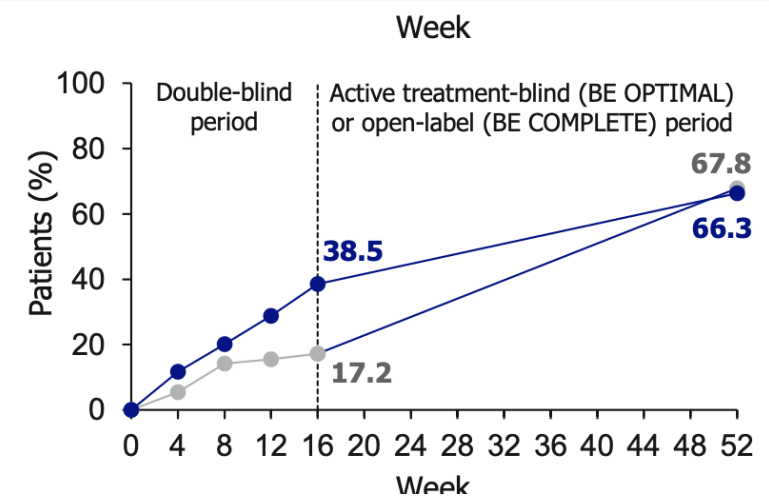


Randomized set, in patients with nail disease at baseline (mNAPSI >0). PBO patients switched to BKZ 160 mg Q4W at Week 16. [a] In patients with psoriasis involving at least 3% of BSA at baseline; [b] in patients with LEI >0 at baseline; [c] In patients with HAQ-DI ≥0.35 at baseline; [d] In patients with FACIT-Fatigue subscale score ≤48 at baseline. ACR50: ≥50% improvement from baseline in American College of Rheumatology response criteria; bDMARD: biologic disease-modifying antirheumatic drug; BKZ: bimekizumab; BSA: body surface area; FACIT-Fatigue: Functional Assessment of Chronic Illness Therapy-Fatigue; HAQ-DI: Health Assessment Questionnaire-Disability Index; LEI: Leeds Enthesitis Index; mNAPSI: modified Nail Psoriasis Severity Index; NRI: non-responder imputation; PASI: Psoriasis Area and Severity Index; PBO: placebo; Q4W: every 4 weeks; SJC: swollen joint count; TJC: tender joint count; TNF-IR: inadequate response or intolerance to tumor necrosis factor inhibitors; VAS: visual analog scale; Wk: Week.

## mNAPSI absolute value and Cfb



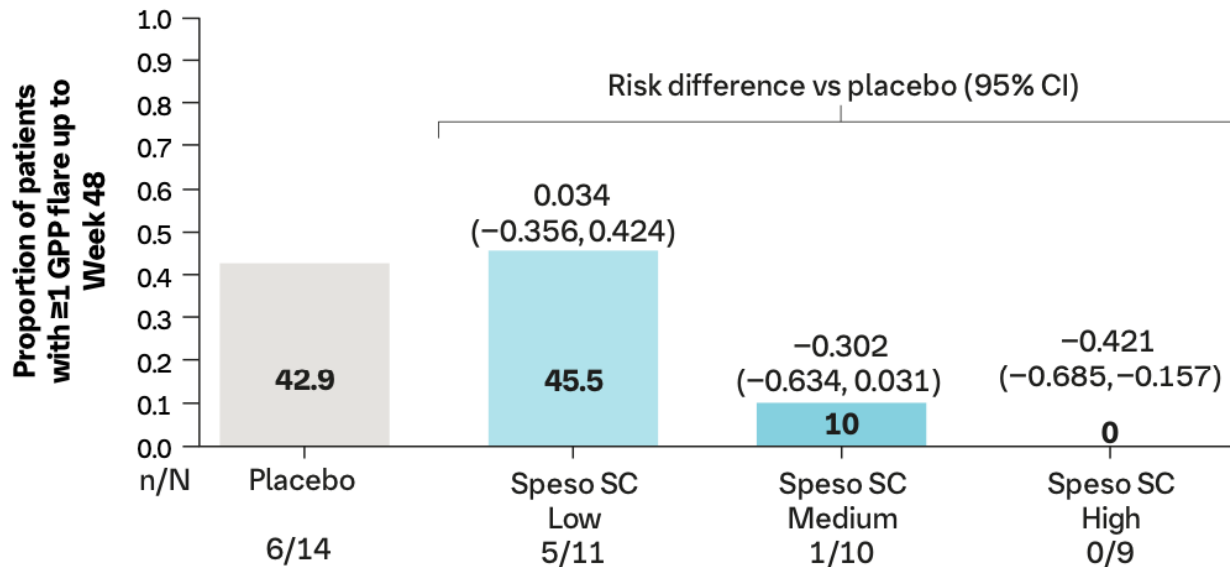
## mNAPSI=0



# Psoriasis pustulosa generalizada

- Spesolimab sbc 600mg vs 300mg vs 150mg
- Demostró superioridad vs placebo en la reducción de brotes 84% (64% origen asiático)
- Dada la heterogenicidad genética de PPG, estudio en caucásicos

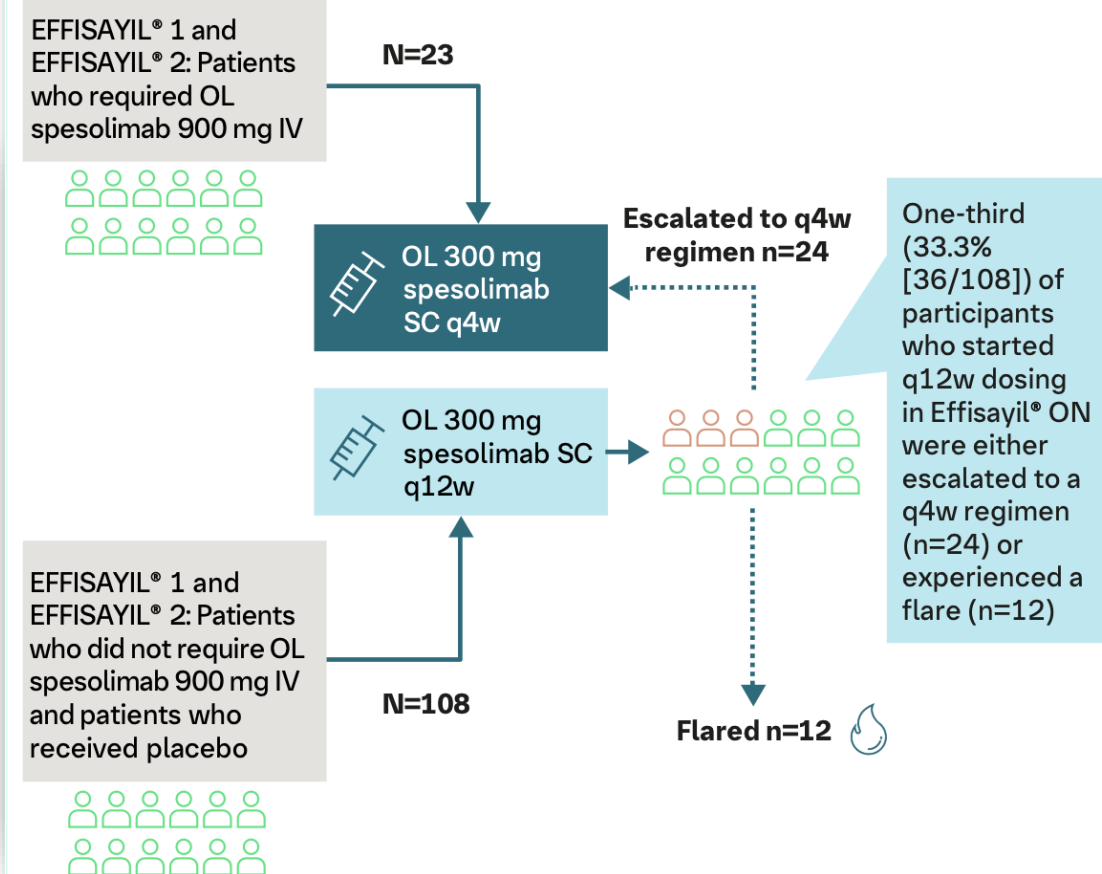
**Figure 2. Proportion of patients with  $\geq 1$  GPP flare up to Week 48**



## Effisayil® ON

- OL spesolimab SC dosing (300 mg q12w) data from Effisayil® ON further support the need for q4w dosing when initiating treatment for prevention of GPP flares

**Figure 3. Effisayil® ON**



# Psoriasis pustulosa generalizada

Eficacia y seguridad de **bimekizumab** en pacientes con **psoriasis pustulosa generalizada (GPP)** y **psoriasis eritrodérmica (EP)** de Japón: datos a 3 años del estudio fase 3 BE BRIGHT.

**GPP**

**EP**

Week 0  
PASI score = 52.2



**IGA 0/1**

Week 0

2/10



0/11



Week 144

6/7



8/10



**DLQI 0/1**

Week 0

3/10



2/11



Week 144

5/7



9/10



**CGI-I Status**  
remission or improved

Week 144

7/7



9/10



**PASI 90**

Week 144

6/7



9/10



Non-responder

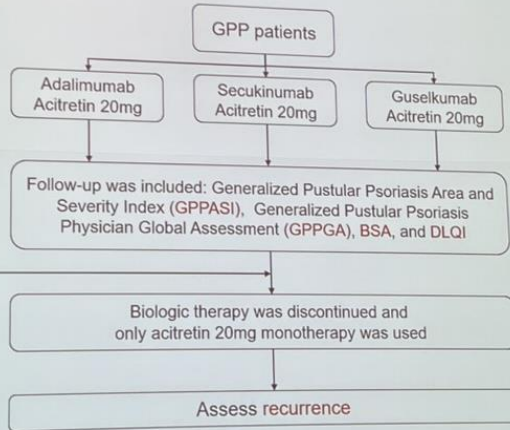
Responder

Missing<sup>a</sup>

# Psoriasis pustulosa generalizada

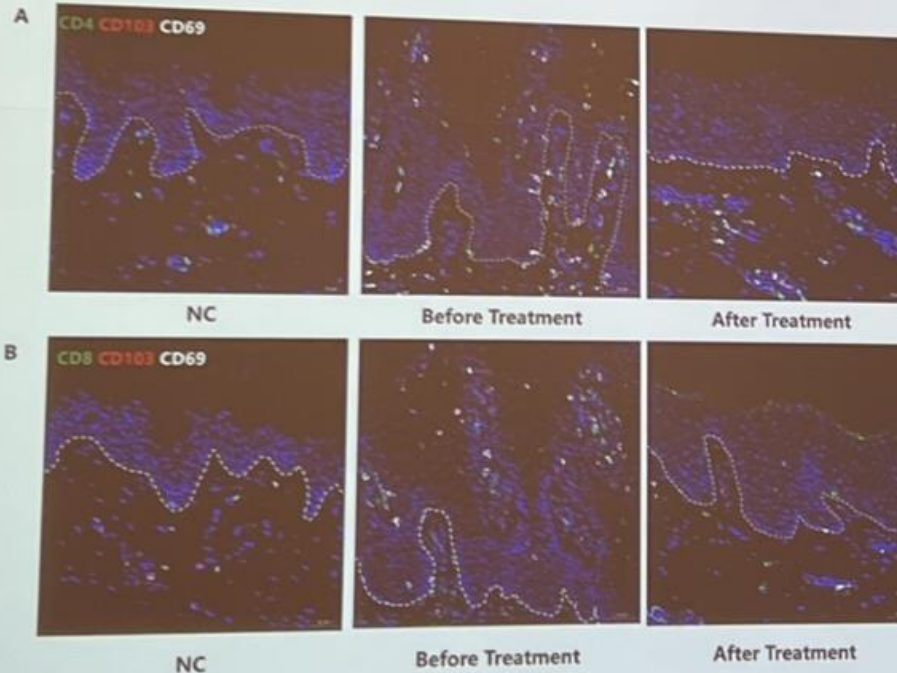
- Eficacia guselkumab en PPG

## AAD Methods—Study protocol



## AAD Results—Assessment of recurrence

- Multiplex immunofluorescence were used to analyze the changes in  $T_{RM}$  cells before and after treatment
- CD69 and CD103 were used as markers of skin  $T_{RM}$  cells



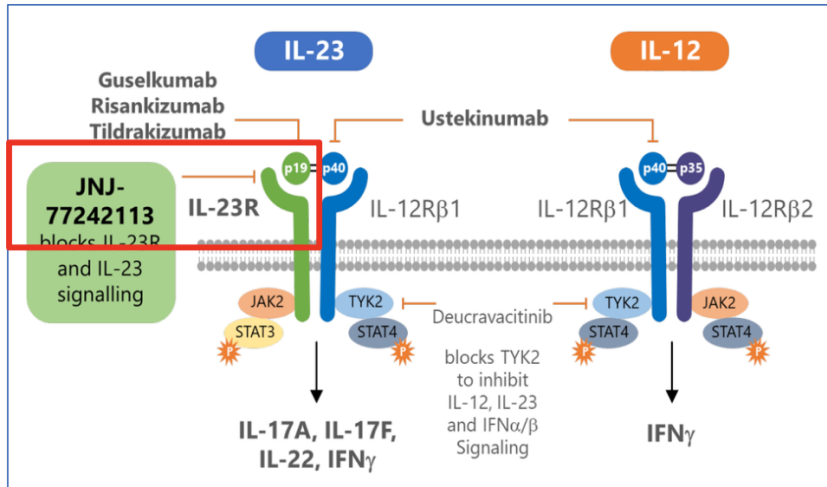
- GPP patients exhibited higher levels of  $CD8^+CD69^+CD103^+$  and  $CD4^+CD69^+CD103^+$  cells in skin lesions compared to NC patients
- After Guselkumab treatment, the proportion of  $CD8^+ T_{RM}$  cells in skin lesions decreased significantly



Imagen creada con IA generativa  
DALL·E

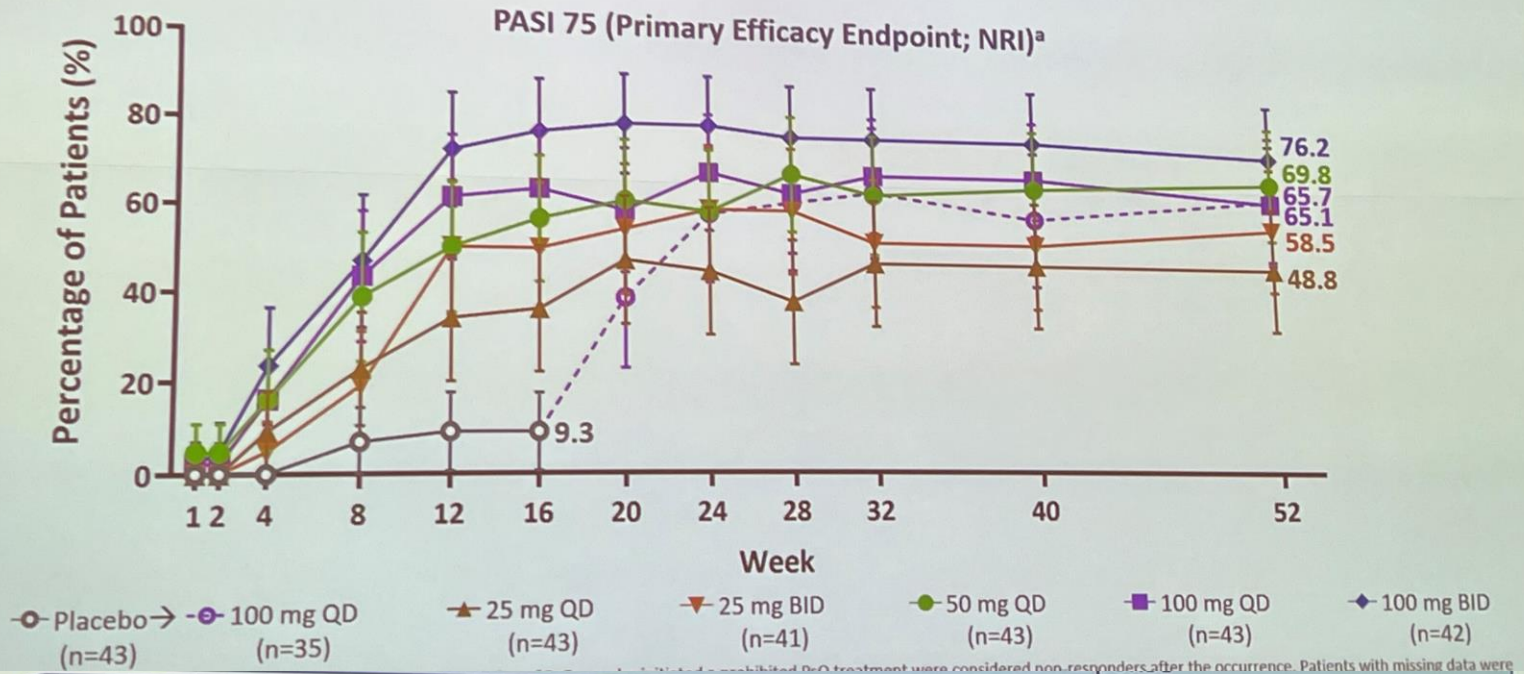
# JNJ-77242113

- Primer péptido oral inhibidor de IL-23R
- Ensayos FRONTIER



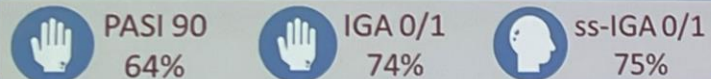
## PASI 75 response rates at Week 16 were maintained through Week 52

- Among patients who crossed over from PBO  $\rightarrow$  100 mg QD at Week 16, PASI 75 response rates rapidly converged with those of JNJ-77242113-randomized patients

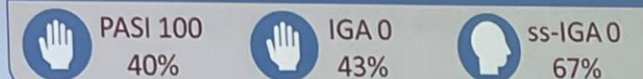


Across all efficacy endpoints, the **highest response rates at Week 52** were achieved in the JNJ-77242113 100 mg BID group, including response rates of:

### Near Complete Clearance



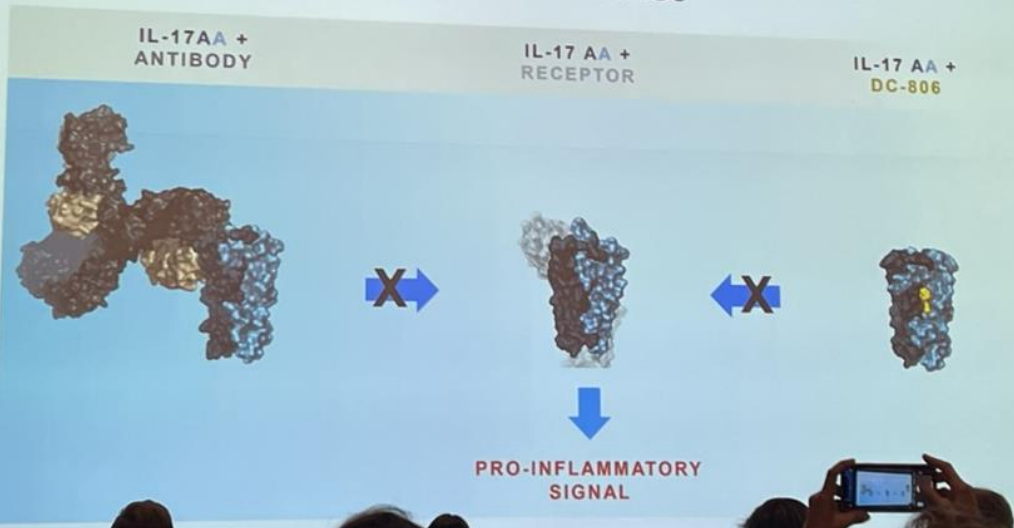
### Complete Clearance



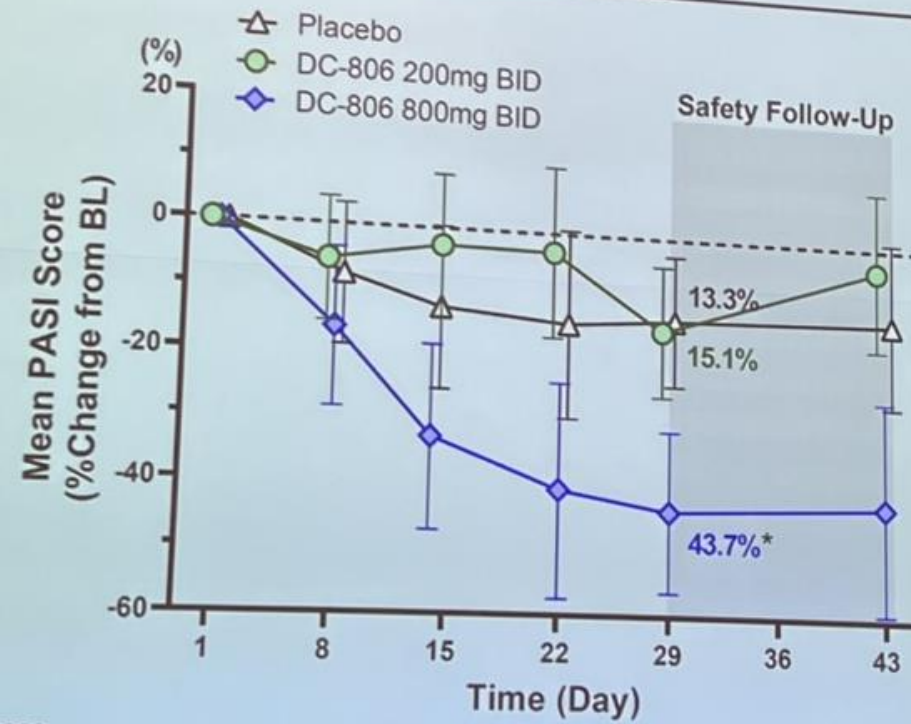
Patient-reported improvements in PsO symptoms and signs were sustained through Week 52

# DC-806

DC-806 allosterically blocks the same biochemical step as the anti-IL-17 antibodies



DC-806 demonstrated clear benefit with reductions in PASI scores



Exploratory  $p = 0.0008$



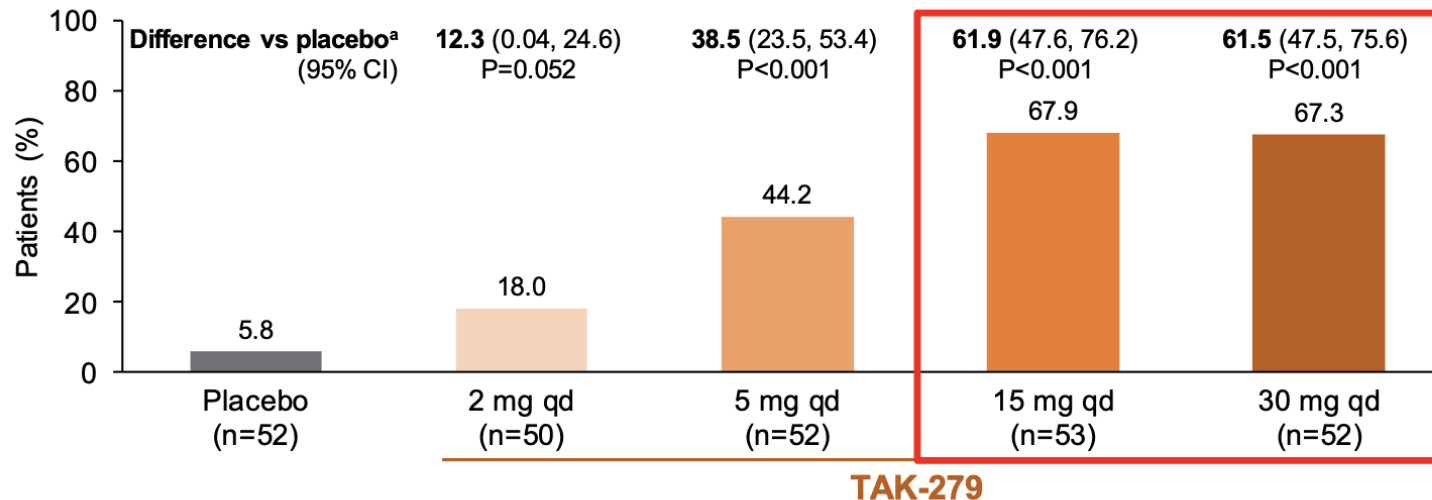
## Randomized, double-blind, placebo-controlled Phase 2b trial of the oral TYK2 inhibitor NDI-034858 (TAK-279) for moderate to severe psoriasis

- Allosteric inhibitor of TYK2 with significant selectivity over JAK1

TAK-279 is excluded from the allosteric binding pocket of JAK1 (JH2) owing to a single amino acid difference from TYK2

TYK2-JH2 binding $K_d$	0.034 nM
JAK1-JH2 binding $K_d$	5000 nM
Biochemical selectivity (fold)	1,470,588

### Primary endpoint: PASI 75 at Week 12 (mITT, NRI)



Deucravacitinib 53-58%  
semana 16

P-value: Cochran-Mantel-Haenszel test, with prior biologic treatment as stratification factor, comparing treatment group vs placebo

mITT analysis set: All patients who were randomized and received at least one dose of study treatment

<sup>a</sup>Disparity in values for differences may be due to rounding of source data.  $K_d$ , dissociation constant

Armstrong A, et al. AAD 2023, Late-breaking abstract. Sponsored by Nimbus

## CLINICAL EFFICACY OF TAK-279, A HIGHLY SELECTIVE ORAL TYROSINE KINASE 2 (TYK2) INHIBITOR, IS ASSOCIATED WITH MODULATION OF DISEASE AND TYK2 PATHWAY BIOMARKERS IN PATIENTS WITH MODERATE-TO-SEVERE PSORIASIS

James G Krueger,<sup>1</sup> Sandra Garcet,<sup>1</sup> Jie Cheng,<sup>2</sup> Sachin Kumar,<sup>3</sup> Jessamyn Blau,<sup>2</sup> Yiwei Zhao,<sup>2</sup> Wenwen Zhang,<sup>2</sup> Vinayagam Arunachalam,<sup>3</sup> Graham A Heap,<sup>2</sup> Paresh Thakker,<sup>2</sup> Amit Choudhury<sup>2</sup>

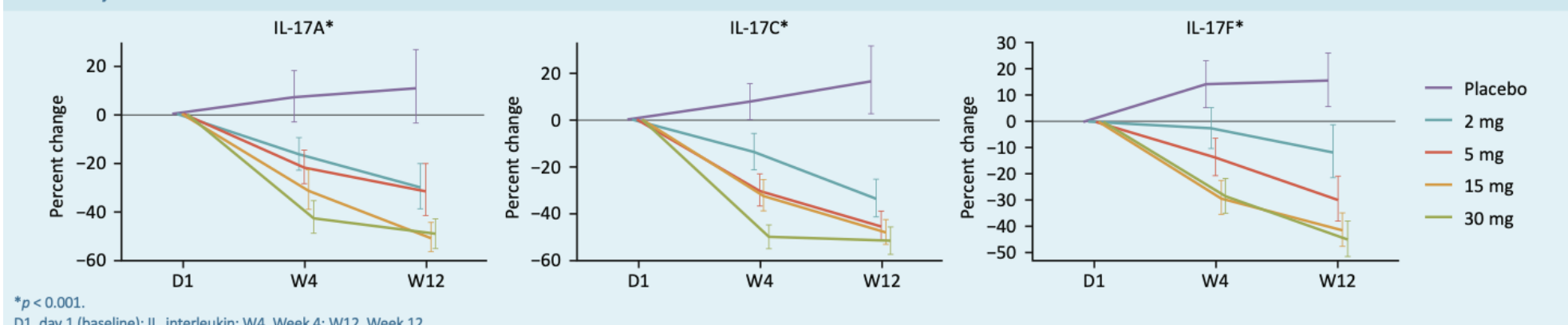
<sup>1</sup>Laboratory for Investigative Dermatology, The Rockefeller University, New York, NY, USA; <sup>2</sup>Gastrointestinal and Inflammation Therapeutic Unit, Takeda Pharmaceuticals International Co., Cambridge, MA, USA; <sup>3</sup>Gastrointestinal and Inflammation Therapeutic Unit, Takeda Pharmaceuticals International Co., San Diego, CA, USA

Presenting author: James G Krueger

- 256 patients included

- Of patients who received TAK-279 30 mg, 67%, 46% and 33% achieved Psoriasis Area and Severity Index (PASI) 75, PASI 90 and PASI 100 at Week 12, respectively, compared with 6%, 0% and 0% in the placebo arm.

**FIGURE 4. TAK-279 TREATMENT WAS ASSOCIATED WITH DOSE- AND TIME-DEPENDENT REDUCTIONS IN SERUM IL-17A, IL-17C AND IL-17F.**



## ESK-001: A Selective Oral Allosteric TYK2i Achieves Maximal TYK2 Inhibition for 24 hours at 40 mg BID dose



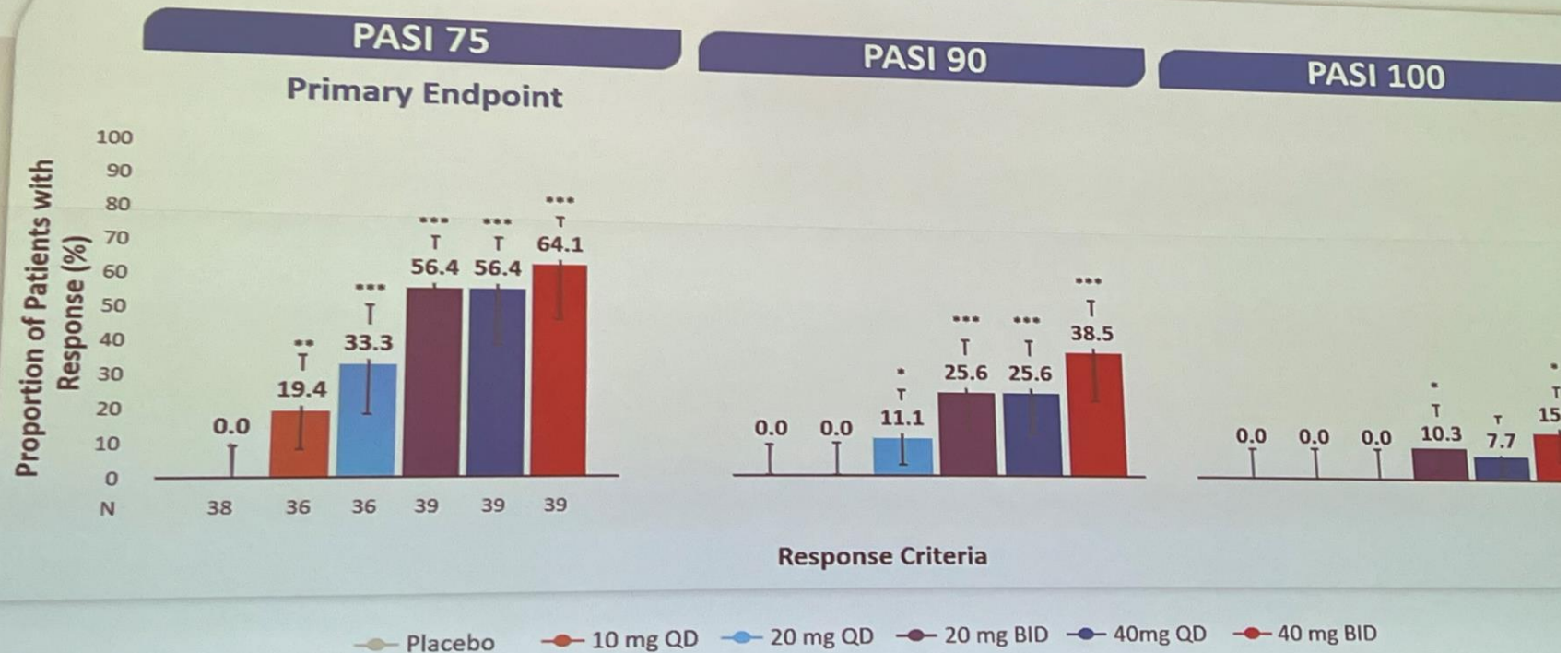
### ESK-001, a highly selective allosteric TYK2 inhibitor

- High intrinsic TYK2 selectivity, avoids classic JAKi liabilities

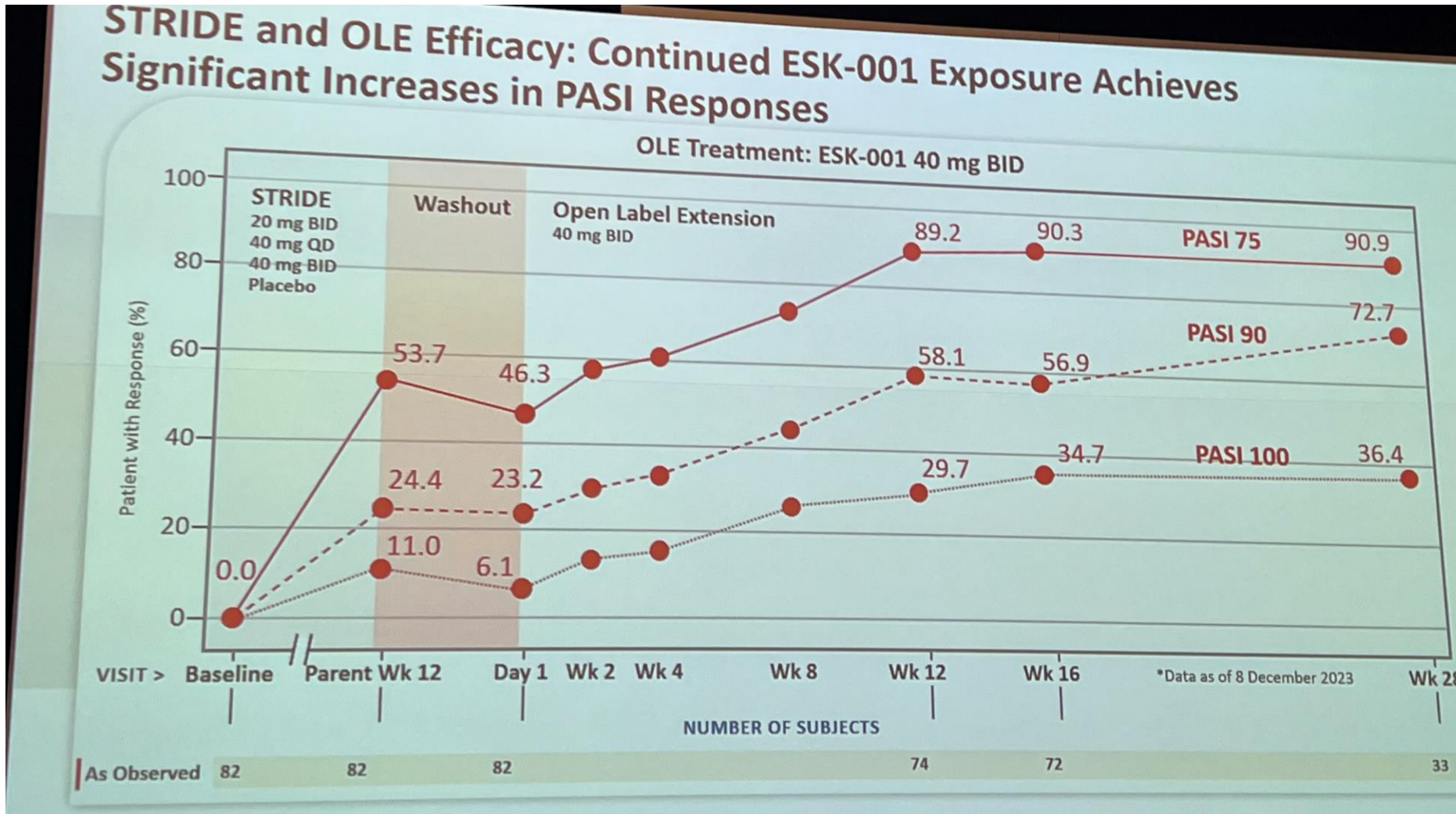
### Robust PK/PD correlation

- Maximal target inhibition of Type 1 IFN gene signature achieved at highest clinical dose
- Maintained across 24 hour-dosing period
- PK/PD dose-dependence reflected in clinical outcomes
- Aligns with Phase 1 PK/PD, AAD abstract #53968

## STRIDE: Primary and Secondary PASI Endpoints Achieved at Week 12 with Dose-Dependent Increase in Efficacy



\*p<0.05; \*\*p<0.005; \*\*\*p<0.001. P-value is comparing proportion in each active arm vs placebo using the Cochran-Mantel-Haenszel test adjusted for stratification factors (prior use of biologics and geographic region (North American vs. ROW)). NRI imputation was applied for subjects who discontinued study.

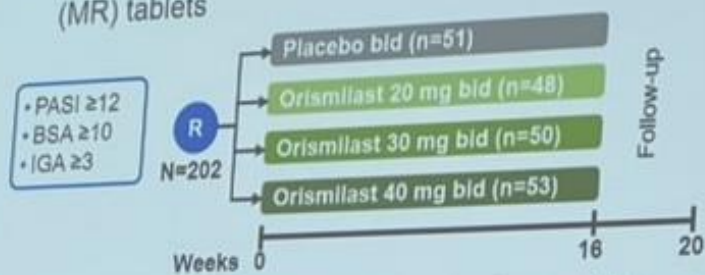


Adverse events: mild-to-moderate

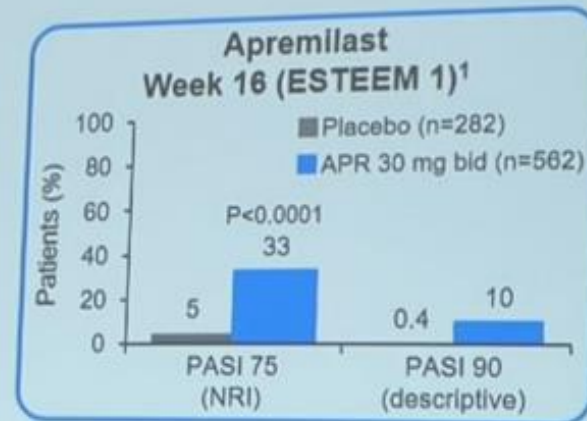
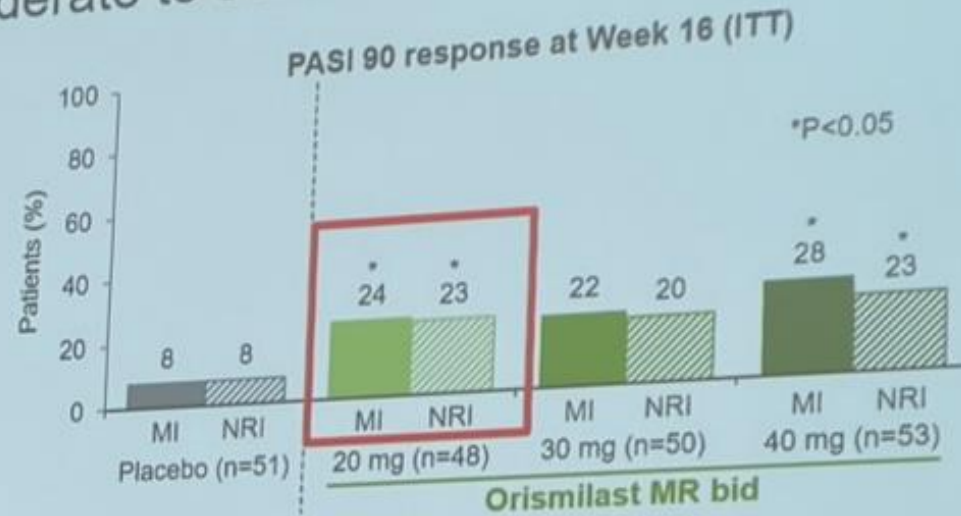
# Orismilast

## IASOS: Randomized, double-blind, placebo-controlled Phase 2b trial of the oral PDE4 inhibitor orismilast for moderate to severe psoriasis

- Second oral PDE4i to enter the psoriasis space
  - PDE4B and -D inhibitor: 2-5-fold more potent than apremilast
- Phase 2b dose-finding trial of **orismilast modified-release (MR) tablets**



- **Safety:** No new safety signals. Infection and depression rates similar to placebo, with no suicidal ideation, malignancy or death reported. Tolerability was dose dependent; the most frequent AEs were diarrhea, nausea, and headache



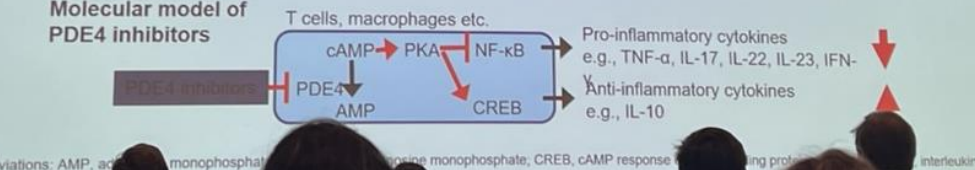
# ME3183

## Novel PDE4 Inhibitor in Development: ME3183

In an in vitro non-clinical study, the oral selective PDE4 inhibitor **ME3183 inhibited PDE4B more strongly than existing marketed PDE4 inhibitors.**

In vitro inhibitory activity against PDE4B1				
Compound	ME3183	Apremilast	Roflumilast	Crisaborole
IC <sub>50</sub> nM	2.3	42	4.3	237

### Molecular model of PDE4 inhibitors

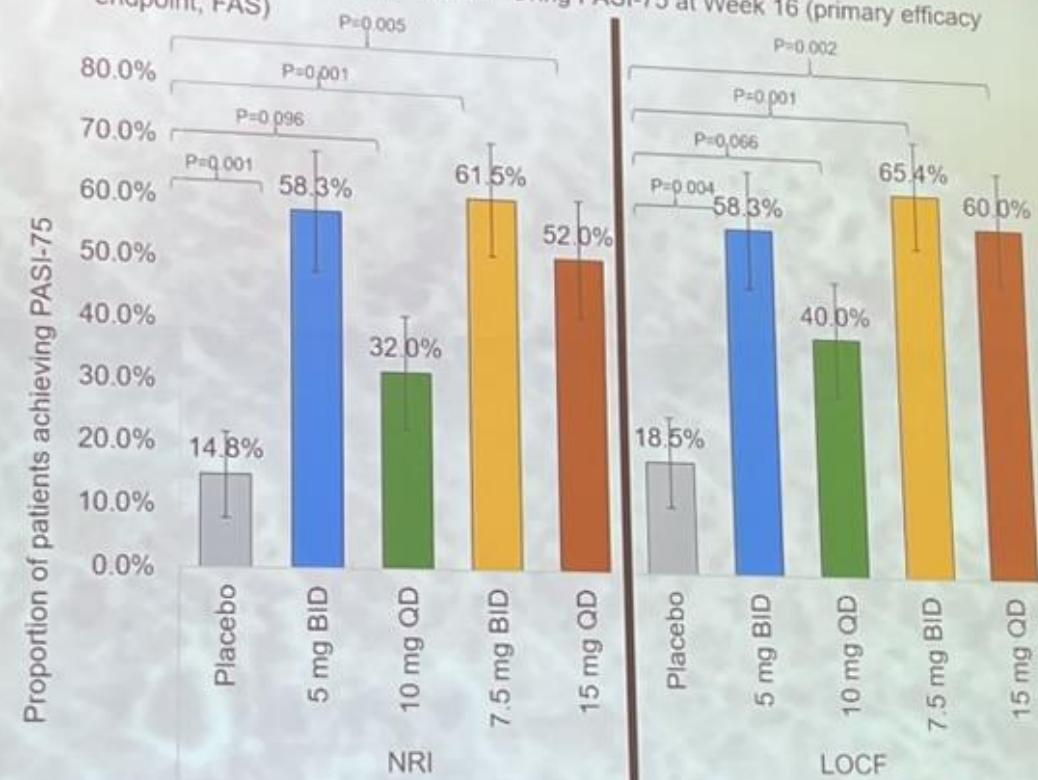


## ME3183 Efficacy: PASI-75, primary endpoint

- A significantly greater proportion of patients on ME3183 active doses (ME3183 5 mg BID, 7.5 mg BID, and 15 mg QD groups) achieved PASI-75 at Week 16 vs placebo.

At approximately Week 4, there was a 50% reduction from baseline in PASI score.

Figure 2. Proportion of patients achieving PASI-75 at Week 16 (primary efficacy endpoint, FAS)



or bars: standard

Abbreviations: BID, twice daily; FAS, full analysis set; LOCF, last observation carried forward; NRI, non-responder imputation; PASI, Psoriasis Area and Severity Index; QD, once daily.

# Vitiligo



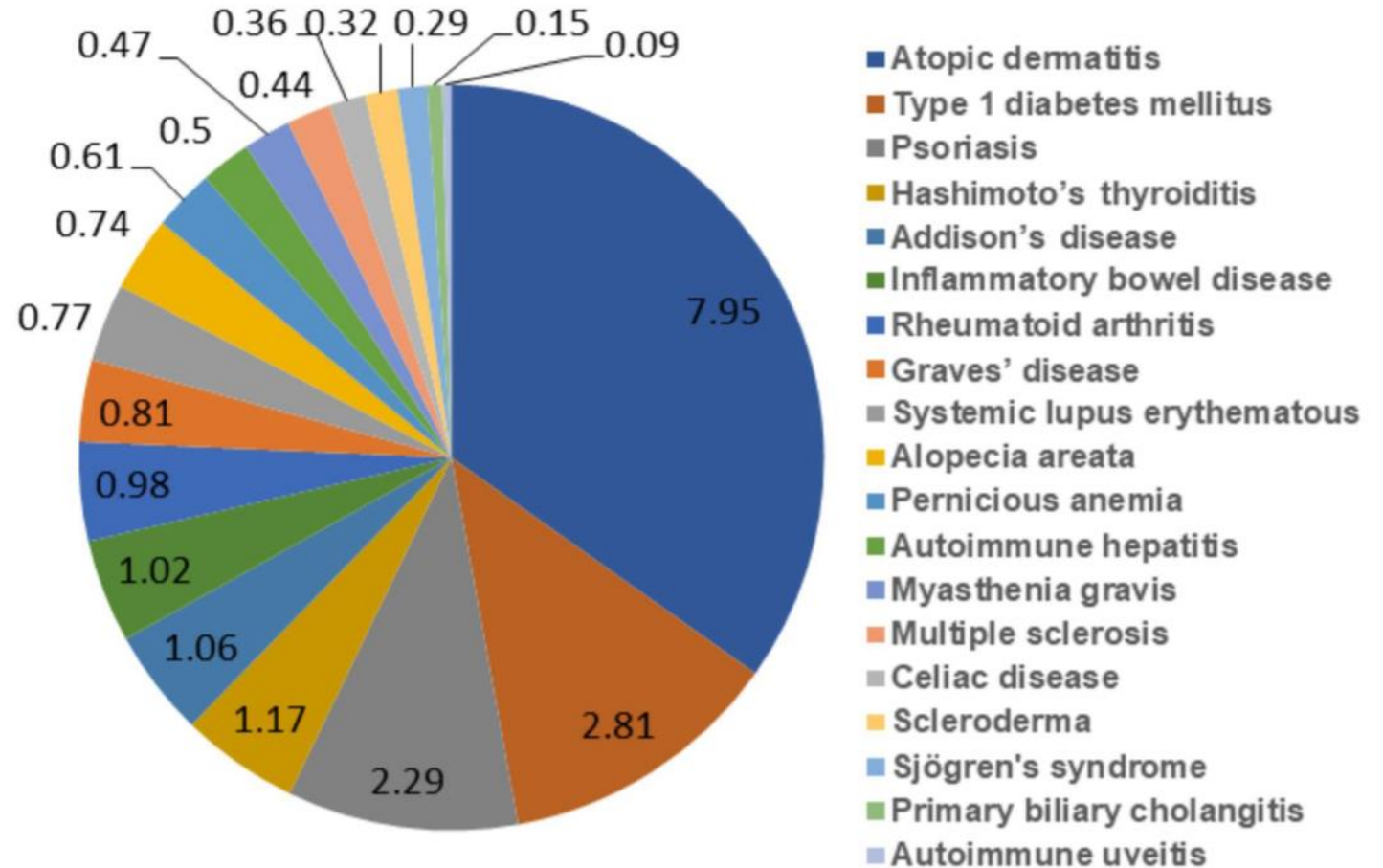
## Global prevalence of autoimmune diseases in patients with vitiligo: a systematic review


Michael J. Diaz, BS<sup>1</sup>, Deepak Lakshmi pathy, BS<sup>2</sup>, Shaliz Aflatooni, BS<sup>3</sup>, Isabella M. Mark, BS<sup>1</sup>, Jasmine T. Tran, BS<sup>4</sup>, Aria Wei, BS<sup>5</sup>, Parsa Abdi, BS<sup>6</sup>, Mahtab Forouzandeh, MD<sup>7</sup>

1. College of Medicine, University of Florida, Gainesville, FL; 2. Carle Illinois College of Medicine, University of Illinois Urbana-Champaign, Urbana, IL; 3. Morsani College of Medicine, University of South Florida, Tampa, Florida; 4. School of Medicine, Indiana University, IN; 5. University of Texas Southwestern Medical School, UT Southwestern Medical Center, Dallas, TX; 6. Faculty of Medicine, Memorial University, St. John's, NL; 7. Department of Dermatology, University of Florida College of Medicine, Gainesville, FL

Disclosures: The authors declare there are no conflicts of interest or disclosures in relation to this poster presentation.

- 23 studies were selected for analysis, from 16 countries.
- A total of 231,791 vitiligo patients were included (57.4% female, mean age: 36.6y [standard deviation: 11.4y]).
- Unspecified hypothyroidism and hyperthyroidism were prevalent in 3.18% (342/10,763) and 0.99% (106/10,724) of vitiligo cases, respectively



 Evaluating the Impact of Vitiligo Perception and Noticeability Across Different Skin Tones 

Priya Manjaly BA<sup>1</sup>, Ahana Gaurav BA<sup>1</sup>, Sophia Ly BA<sup>1</sup>, Kanika Kamal BA<sup>1</sup>, Nidhi Shah MD<sup>1</sup>, Kristina Liu MD<sup>2</sup>, Nicholas Theodosakis MD PhD<sup>3</sup>, Arash Mostaghimi MD MPH MPA<sup>1</sup>  
<sup>1</sup>Department of Dermatology, Brigham and Women's Hospital, Boston, MA; <sup>2</sup>Department of Dermatology, Kaiser Permanente, San Francisco, CA; <sup>3</sup>Department of Dermatology, Massachusetts General Hospital, Boston, MA  
Financial and Conflict of Interest Disclosures: None

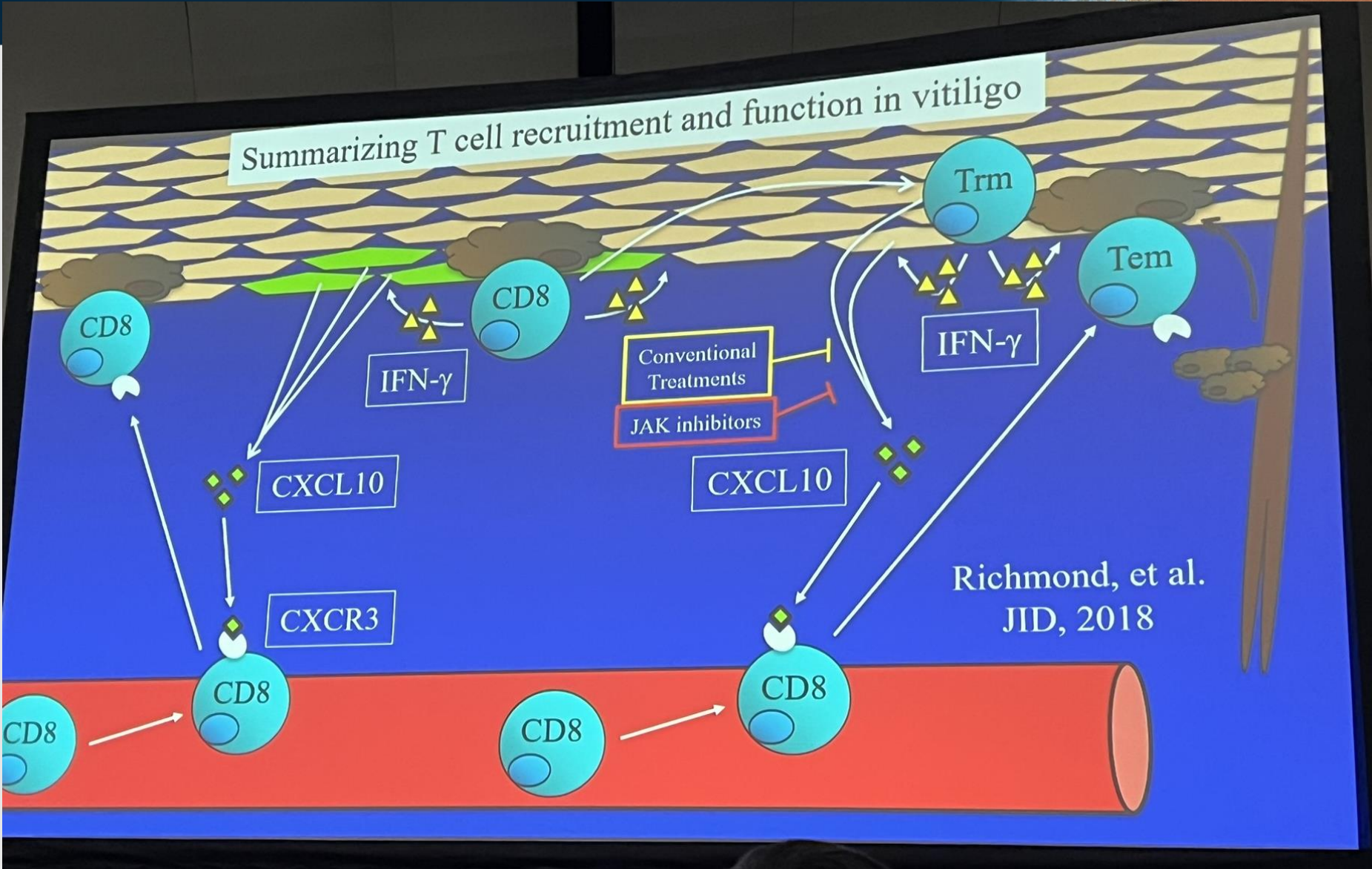
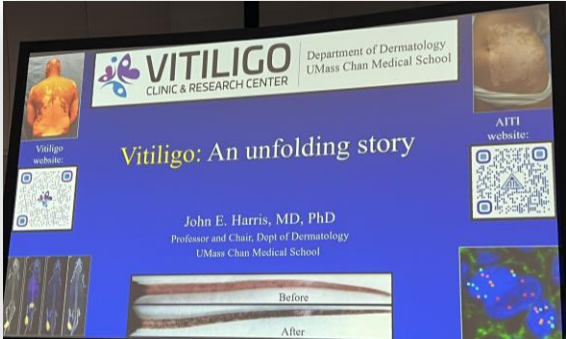
**Figure 1. Sample portrait images of low and high severity facial vitiligo**



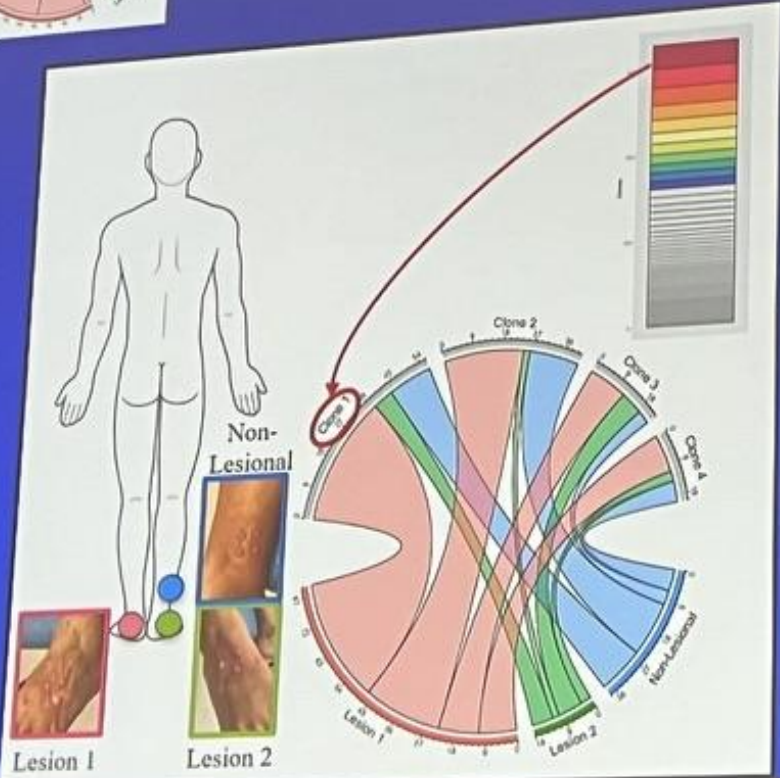
- **Baseline skin tone was not associated with increased disease noticeability of vitiligo ( $p>0.05$ ) or vitiligo-associated stigma ( $p>0.05$ ).**
- This may potentially suggest stigma associated with vitiligo varies across the individual, even within populations of similar skin tones



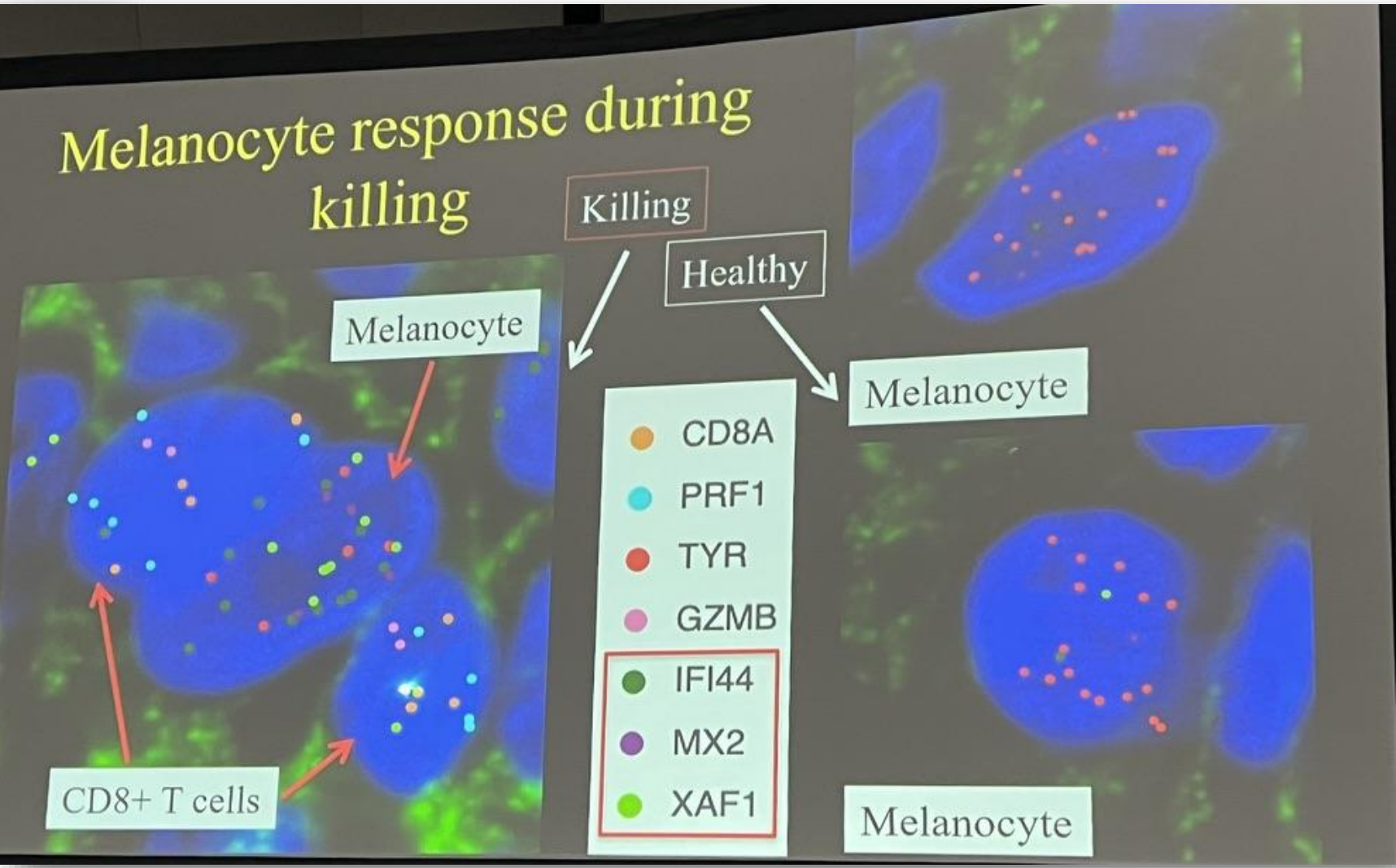
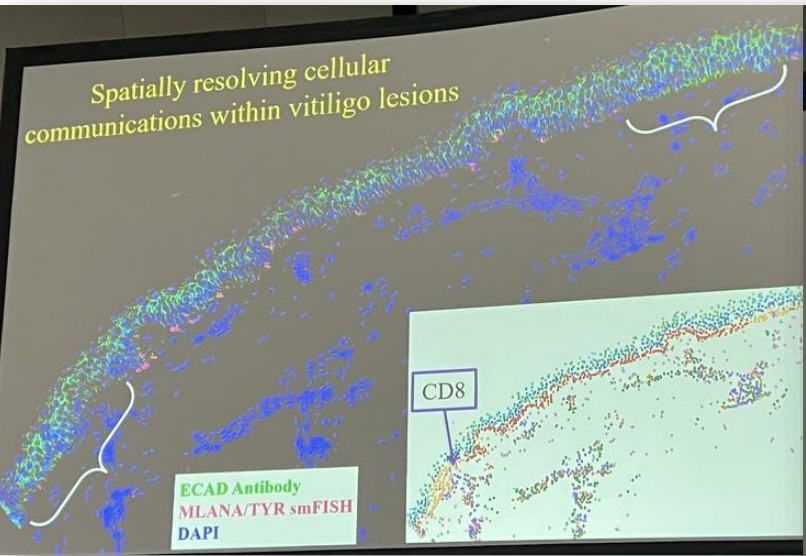
# Fisiopatología



## Tracking CD8+ T cell clones across the body



# Vitiligo



# Tratamiento

- Ruxolitinib tópico
- Sistémicos Fase 3

## Oral JAK inhibitors

AAD **JAAD** Journal of the American Academy of Dermatology

Published online ahead of print

Efficacy and safety of the oral Janus kinase 3 (JAK3)/TEC inhibitor **ritlecitinib** (PF-06651600) in adults with active non-segmental vitiligo: results from a phase 2b, randomized, dose-ranging study with an extension period

Efficacy and Safety of **Povorocitinib** for Extensive Vitiligo: Results From a Double-Blinded, Placebo-Controlled, Dose-Ranging Phase 2b Study

Amit G. Pandya, MD,<sup>1,2</sup> Khaled Ezzedine, MD, PhD,<sup>3</sup> Thierry Passeron, MD, PhD,<sup>4,5</sup>  
Nanja van Geel, MD, PhD,<sup>6</sup> Kurt Brown, MD,<sup>7</sup> Leandro Santos, MSc,<sup>7</sup> Lois Erskine, PhD,<sup>7</sup>  
Kofi Wagya, PhD,<sup>7</sup> Andrew Blauvelt, MD, MBA<sup>8</sup>

Presented at the American Academy of Dermatology (AAD) Annual Meeting  
March 17–21, 2023; New Orleans, LA

Efficacy and Safety of **Upadacitinib** in a Phase 2 Randomized, Double-Blind, Dose-Ranging Study of Adults With Extensive Non-Segmental Vitiligo

Presented at the European Academy of Dermatology and Venereology Congress, 11–14 October 2023, Berlin, Germany

Thierry Passeron,<sup>1,2</sup> Khaled Ezzedine,<sup>3,4</sup> Iltefat Hamzavi,<sup>5</sup> Nanja van Geel,<sup>6</sup> Bethanee J Schlosser,<sup>7</sup>  
Xiaofei Hu,<sup>7</sup> Xiaohong Huang,<sup>7</sup> David Rosmarin,<sup>8</sup> John E Harris,<sup>9</sup> Heidi S Camp,<sup>7</sup> Amit G Pandya<sup>10,11</sup>

All are entering  
Phase 3 trials!

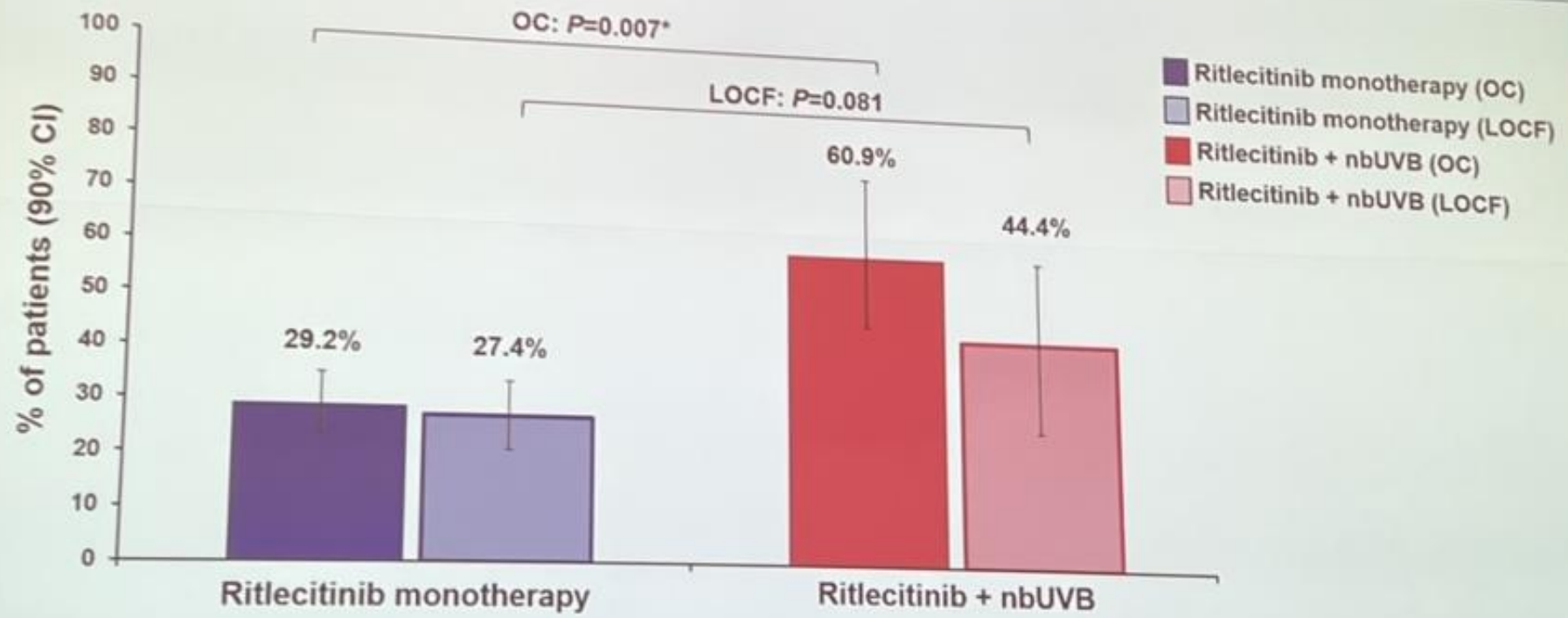
# Vitiligo



## Response to ritlecitinib with or without narrow band ultraviolet B (nbUVB) add-on therapy in patients with active non-segmental vitiligo (NSV)

Yuji Yamaguchi,<sup>1</sup> Elena Peeva,<sup>2</sup> Roni Adiri,<sup>3</sup> Pranab Ghosh,<sup>2</sup> Lynne Napatalung,<sup>4,5</sup> Iltefat Hamzavi,<sup>6</sup> Amit G. Pandya,<sup>7,8</sup> Ronald N. Shore,<sup>9</sup> Khaled Ezzedine,<sup>10</sup> Emma Guttman-Yassky<sup>5</sup>

### Proportion of patients meeting F-VASI75 at Week 24



Patients with response, n/N: 40/137      45/164      14/23      16/36

# Vitiligo

## Efficacy and Safety After 52 Weeks of Once-Daily Upadacitinib in Adults With Extensive Non-Segmental Vitiligo: Final Results From a Phase 2 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study

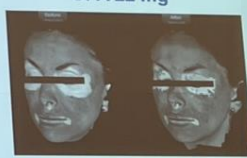
Thierry Passeron,<sup>1,2</sup> Khaled Ezzedine,<sup>3,4</sup> Iltefat Hamzavi,<sup>5</sup> Nanja van Geel,<sup>6</sup> Bethanee J Schlosser,<sup>7</sup> Yaofei Hu,<sup>7</sup> Ahmed M Soliman,<sup>7</sup> David Rosmarin,<sup>8</sup> John E Harris,<sup>9</sup> Heidi S Camp,<sup>7</sup> Amit G Pandya<sup>10,11</sup>

### Percent Change From Baseline in F-VASI at Week 24 in Representative Patients Randomized to PBO, UPA 11 mg, and UPA 22 mg

PBO<sup>a</sup>

UPA 11 mg<sup>a</sup>

UPA 22 mg<sup>a</sup>



Baseline Week 24

Baseline Week 24

Baseline Week 24

F-VASI

F-VASI

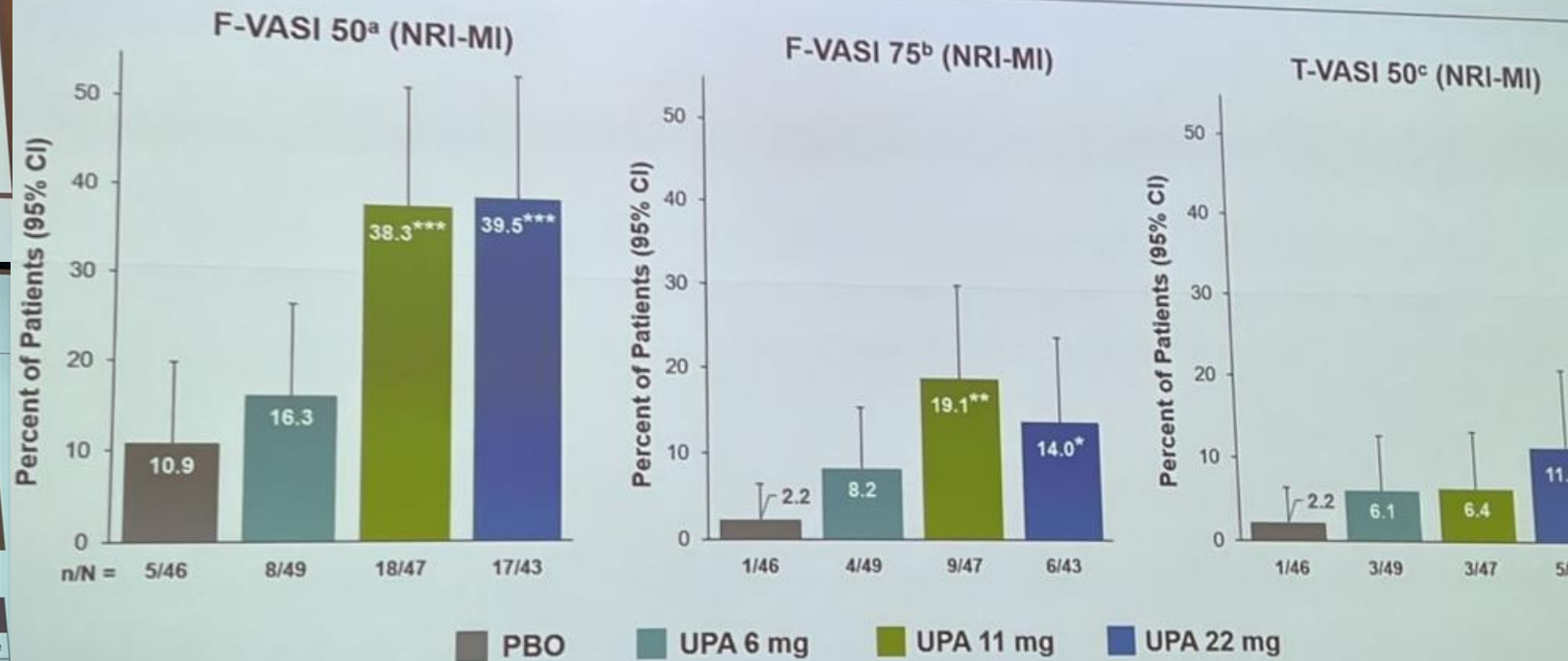
F-VASI

Baseline	Week 24	% Change
0.8	0.45	-43.75

Baseline	Week 24	% Change
0.5	0.03	-94.44

Baseline	Week 24	% Change
1.4	0.45	-67.86

## F-VASI 50, F-VASI 75, and T-VASI 50 Response Rates at Week 24



F-VASI, Facial Vitiligo Area Scoring Index; NRI-MI, nonresponder imputation while incorporating multiple imputation to handle missing data due to COVID-19 or any other missing data that can be reasonably assumed to be missing at random; PBO, placebo; T-VASI, Total Vitiligo Area Scoring Index; UPA, upadacitinib. \* $P \leq .05$ ; \*\* $P \leq .01$ ; \*\*\* $P \leq .001$  vs PBO based on Cochran-Mantel-Haenszel test adjusted for strata. All tests were 2-sided with an alpha of 0.1. No overall type I error control was applied; all  $P$  values for UPA vs PBO are nominal. There were no missing data due to COVID-19 at week 24. <sup>a</sup>Achievement of  $\geq 50\%$  improvement from baseline in F-VASI. <sup>b</sup>Achievement of  $\geq 75\%$  improvement from baseline in F-VASI. <sup>c</sup>Achievement of  $\geq 50\%$  improvement from baseline in T-VASI.

F-VASI, Facial Vitiligo Area Scoring Index; PBO, placebo; UPA, upadacitinib. Patient images are based on 3-dimensional digital imaging.<sup>1</sup> Passeron AK, et al. Poster presentation at: European Academy of Dermatology and Venereology, 11-14 October 2023, Berlin, Germany.

AAD ANNUAL MEETING

# AEDV highlights

SAN DIEGO   
8-12 MARZO



La Academia Española de Dermatología y Venereología expresa su agradecimiento al patrocinador UCB, por su especial apoyo y contribución con la actividad formativa Highlights 2024.

AAD ANNUAL MEETING

# AEDV highlights AEDV

SAN DIEGO   
8-12 MARZO



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Y VENEREOLOGÍA

# GRACIAS