

AAD ANNUAL MEETING

AEDV highlights

SAN DIEGO 
8-12 MARZO



#AEDVENAAD2024



ACADEMIA ESPAÑOLA
DE DERMATOLOGÍA
Y VENEREOLOGÍA

AAD ANNUAL MEETING

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highlights

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Psoriasis y otras enfermedades inflamatorias





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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. Fisiopatología y biomarcadores
2. Comorbilidades
3. Update tratamientos aprobados

2. Liquen plano y otras dermatosis liquenoides



Single cell and spatial sequencing define processes by which keratinocytes and fibroblasts amplify inflammatory responses in psoriasis

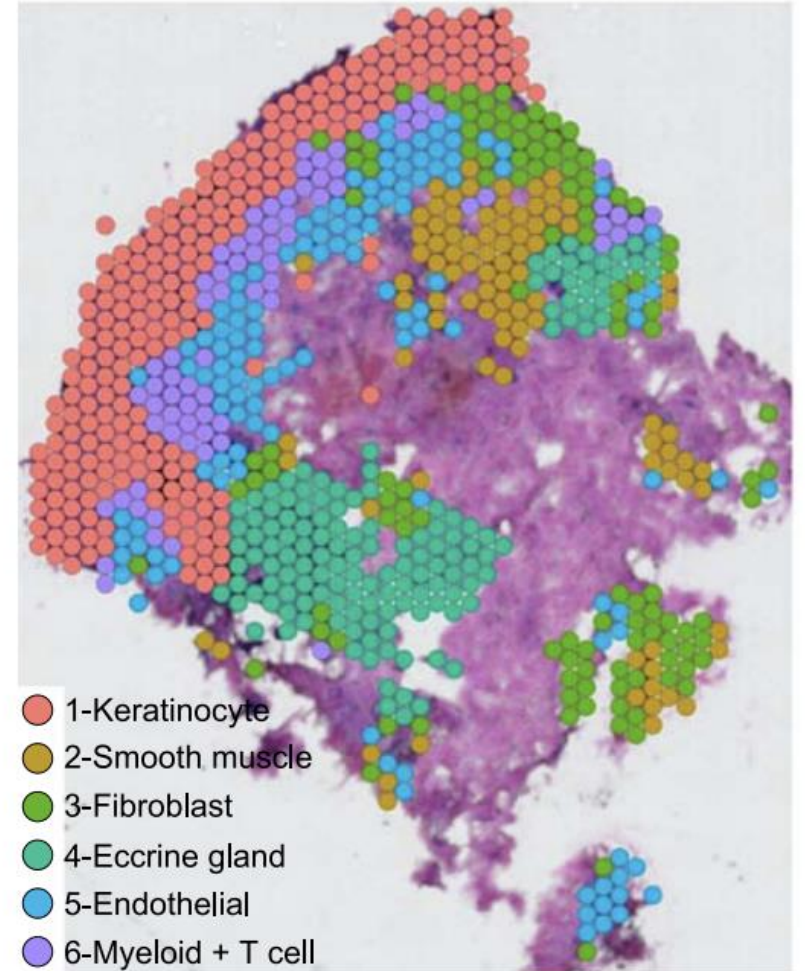
- Which cell types and cytokines are the main drivers of psoriatic inflammation?
- How do the numerous cell types and cytokines in psoriatic lesions interact with one another?

#1

REF: Ma et al, *Nat Commun*, 2023



d



Single cell and spatial sequencing define processes by which keratinocytes and fibroblasts amplify inflammatory responses in psoriasis

- **IL-36** amplifies IL-17A responses in the supraspinous epidermis of psoriatic skin
- **SFRP2+ fibroblasts** transition from pro-fibrotic state to pro-inflammatory state within psoriatic skin
- **CD8+ Tc17 cells** are a major source of IL-17A in psoriatic skin

REF: Ma et al, Nat Commun, 2023



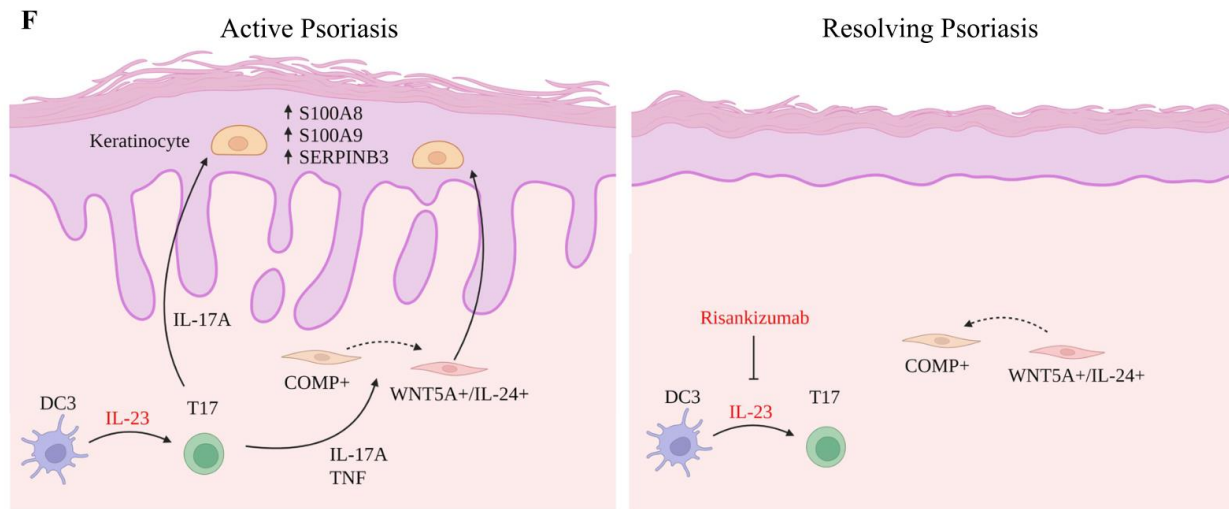
nature communications



Article

<https://doi.org/10.1038/s41467-024-44994-w>

Single-cell analysis of psoriasis resolution demonstrates an inflammatory fibroblast state targeted by IL-23 blockade



Gravedad

Genomic markers

- LCE3D
- IL23R
- IL23A
- NFKBIL1
- HLA-C*06:02

Proteomic markers

- IL-17A
- IgG aHDL – GlycA
- I-FABP
- kallikrein 8

Metabolic markers

- tyramine

Artritis psoriásica

Genomic markers

- HLA-C*06:02
- HLA-B*27
- HLA-B*38
- HLA-B*08 – IL23R
- IL13

Proteomic markers

- IL-17A
- CXCL10
- Mac-2 protein – integrin b5
- MMP-3
- M-CSF

Metabolic markers

- tyramine , mucic acid

Respuesta terapéutica

Genomic markers of TNF

- CARD14
- CDKAL1
- IL1B
- IL12B
- IL17RA

Cellular markers of adalimumab

- LPS-induced phosphorylation of NFκB in type 2 dendritic cells

Genomic marker of ustekinumab response

- HLA-C*06-02
- IL1B

Pharmacogenetic biomarkers for secukinumab response in psoriasis patients in real-life clinical practice

Effectiveness	Variable	Gene	Model	Risk phenotype %Resp/%Nonresp	Odds ratio	p	[95% Conf. Interval]
Absolute PASI ≤3 at 6 months	rs1051738	PDE4A	A	AC/AA (33.3/5.1)	0.03	0.006	0.003–0.36
	rs12191877	HLACw6	R	TT (2.3/15.0)	29.80	0.012	2.09–423.9
	rs1801274	FCGR2	O	AG (45.3/70.0)	3.3	0.024	1.17–9.59
Absolute PASI ≤1 at 6 months	rs2227322	CSF3	R	GG (16.4/1.7)	0.10	0.018	0.096–0.64
	rs645544	SLC9A8	R	GG (22.7/5.0)	0.21	0.017	0.05–0.75
Absolute PASI ≤3 at 12 months	rs26528	IL27	R	CC (21.5/2.4)	0.02	0.012	0.001–0.42
	rs12191877	HLACw6	R	TT (2.5/14.6)	27.38	0.005	2.75–254.0

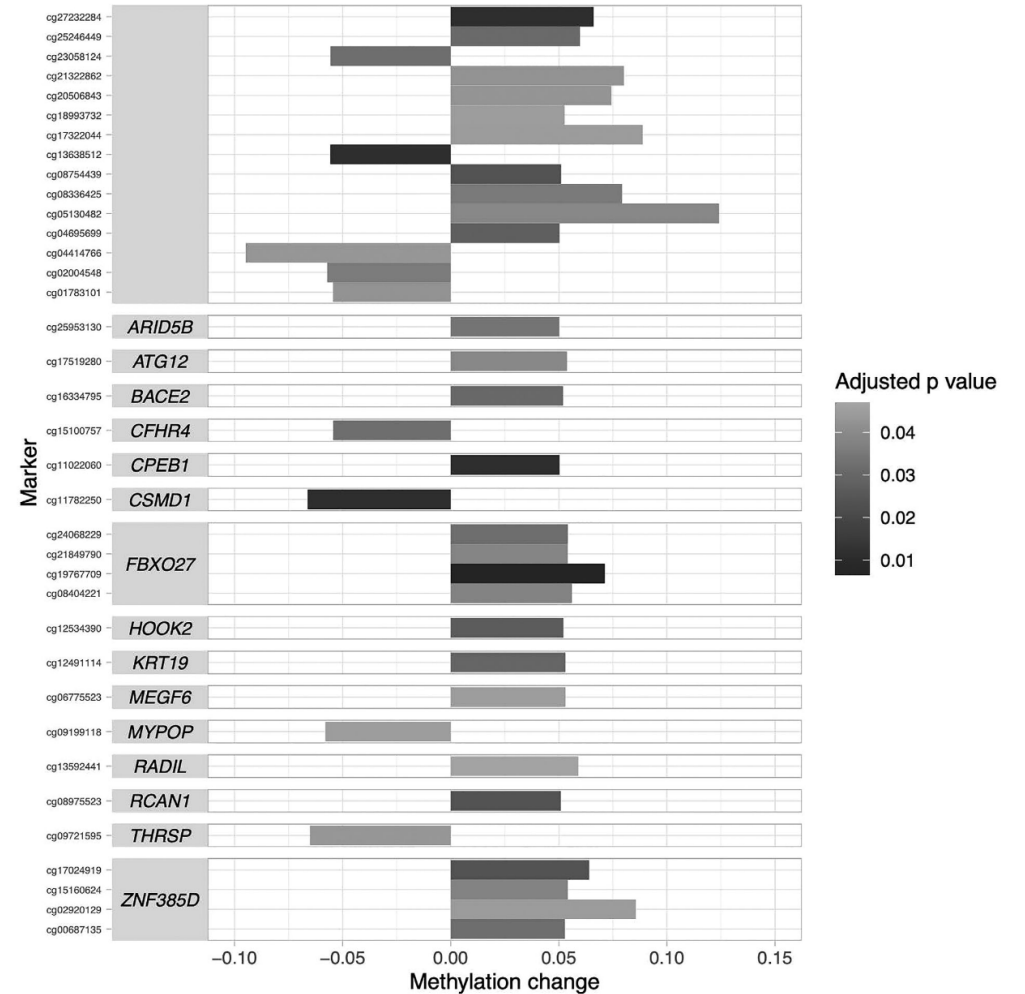
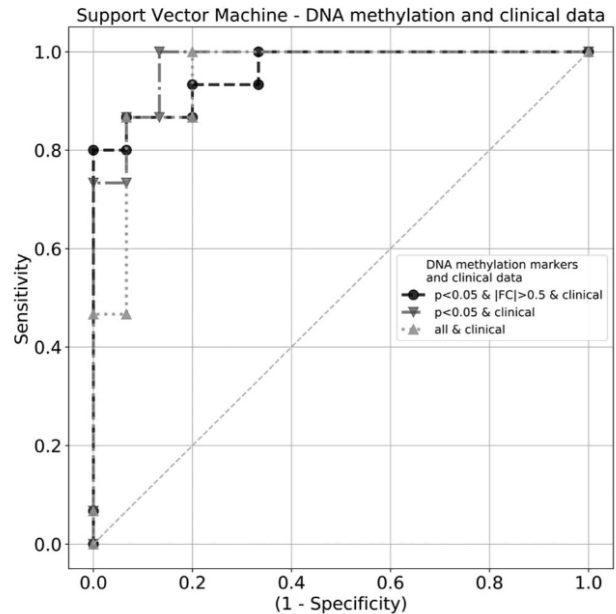
REF: Munoz-Aceituno et al, *J Eur Acad Dermatol Venereol*, 2024



Metilación DNA como predictor PsA

Prediction of Psoriatic Arthritis in Patients With Psoriasis Using DNA Methylation Profiles

- 60 pacientes con PsO que desarrollaron PsA – 60 PsO sin PsA
- Estudio de metilación del genoma completo
- 36 zonas de metilación relevantes en 15 genes y varias zonas intrónicas.



Artritis psoriásica

- PROM
- Valorar la intensidad de los síntomas musculoesqueléticos en pacientes con psoriasis (con o sin PsA)
- Desarrollado por IDEOM
- Faltan estudios de correlación

THE IDEOM MSK-Q

IDEOM MSK Questionnaire

Instructions: Please complete this questionnaire about the musculoskeletal (MSK) symptoms (pain at or around your joints or in your back, joint swelling, and/or joint stiffness) and fatigue you have experienced **over the last 7 days**.

MSK Symptoms

1. Pain

Select the number that best describes the pain you felt at or around your joint/s or in your back over the last 7 days (for example, heel pain, back pain, joint pain in your fingers and/or toes, or any other joint pain):

None=0 1 2 3 4 5 6 7 8 9 10=Extreme

2. Joint Swelling

Select the number that best describes the joint swelling you experienced over the last 7 days:

None=0 1 2 3 4 5 6 7 8 9 10=Extreme

3. Joint stiffness

For how many **minutes per day** have you felt joint stiffness and/or difficulty moving after you woke up in the morning or after a period of inactivity over the last 7 days:

None=0 1-10 11-20 21-30 31-40 41-50 51-60 61-70 71-80 81-90 90(+)minutes per day

Impact of MSK Symptoms (pain at or around your joints or in your back, joint swelling, or joint stiffness)

If you selected "None=0" for Questions 1, 2, AND 3, please check the box "Does not apply to me" and skip to Question 9.

Does not apply to me

4. Work and/or school activities

Select the number that best describes the difficulties you experienced to participate fully in work (including household work) and/or school activities **due to your MSK symptoms** over the last 7 days:

No difficulty=0 1 2 3 4 5 6 7 8 9 10=Extreme difficulty

5. Family, social, and/or leisure activities

Select the number that best describes the difficulties you experienced to participate fully in family, social, and/or leisure activities (for example, meeting friends and relatives, or hobbies) **due to your MSK symptoms** over the last 7 days:

No difficulty=0 1 2 3 4 5 6 7 8 9 10=Extreme difficulty

6. Physical activities

Select the number that best describes the difficulties you experienced in doing daily physical activities (for example, getting in and out of bed, lifting groceries, or taking a bath or shower) **due to your MSK symptoms** over the last 7 days:

No difficulty=0 1 2 3 4 5 6 7 8 9 10=Extreme difficulty

7. Sleep

Select the number that best describes the sleep difficulties (for example, resting at night) you experienced **due to your MSK symptoms** over the last 7 days:

No difficulty=0 1 2 3 4 5 6 7 8 9 10=Extreme difficulty

8. Emotional State

Select the number that best describes the negative feelings (for example, feeling depressed, sad, or anxious) you experienced **due to your MSK symptoms** over the last 7 days:

None=0 1 2 3 4 5 6 7 8 9 10=Extreme

Fatigue

9. Fatigue

Select the number that best describes the fatigue (for example, persistent feeling of tiredness, lack of energy, or feeling worn out) you experienced over the last 7 days:

No fatigue=0 1 2 3 4 5 6 7 8 9 10=Totally exhausted

51651
Impact of Risankizumab on Enthesitis and Dactylitis Over 148 Weeks: Integrated Analysis of the Phase 3, Randomized, Double-Blind KEEPSAKE 1 and 2 Trials

Figure 2. Proportion of Patients Achieving Resolution of Dactylitis Over 148 Weeks

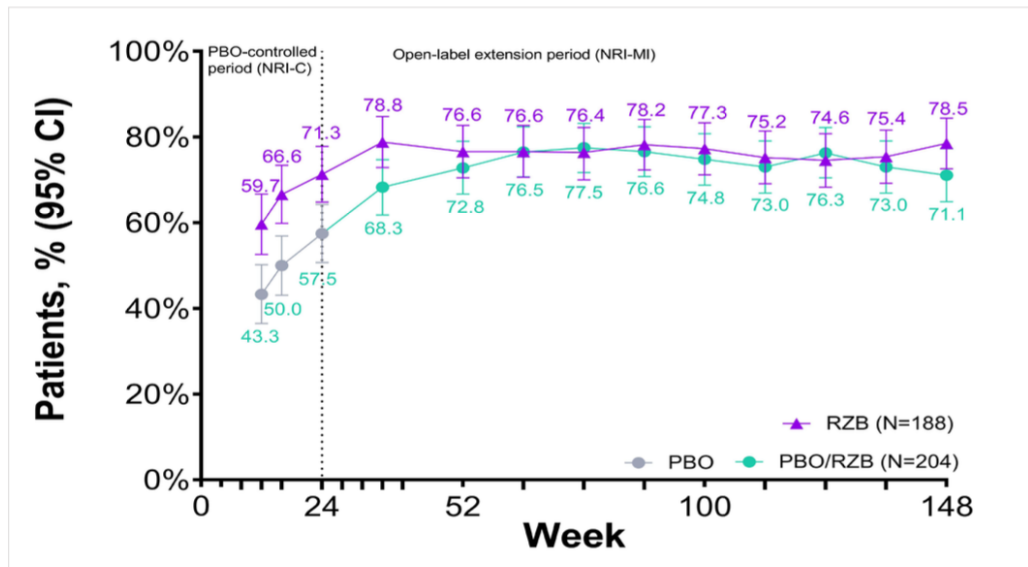
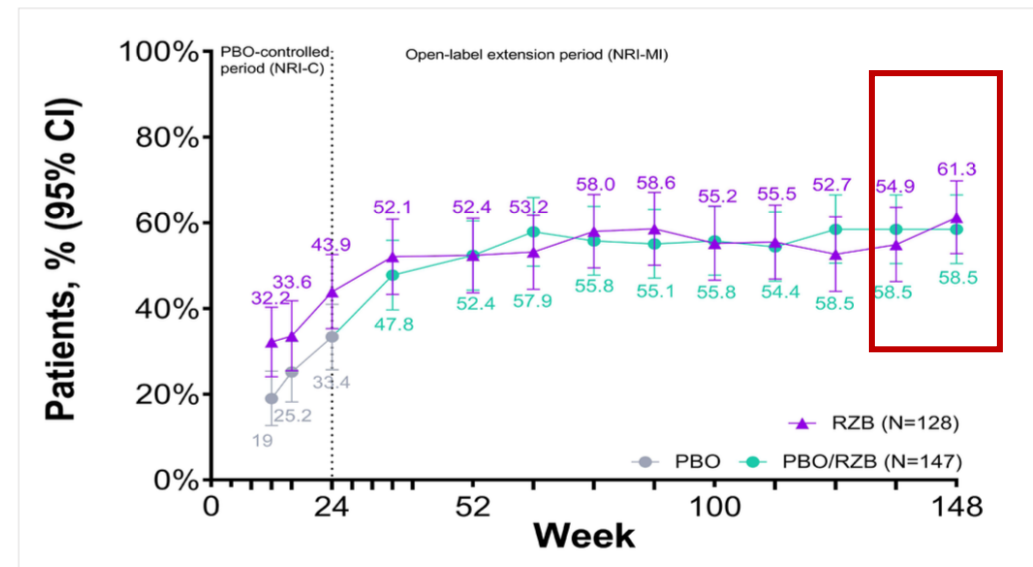


Figure 3. Proportion of Patients Achieving Resolution of Enthesitis and Dactylitis Over 148 Weeks

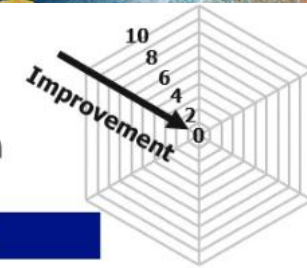


NRI, nonresponder imputation; NRI-C, nonresponder imputation incorporating multiple imputation to handle missing data resulting from COVID-19; NRI-MI, as observed with missing data imputed as non-responders except those missing due to COVID-19 or geo-political conflict in Ukraine and Russia, which are imputed by multiple imputation; PBO, placebo; RZB, risankizumab.

NRI, nonresponder imputation; NRI-C, nonresponder imputation incorporating multiple imputation to handle missing data resulting from COVID-19; NRI-MI, as observed with missing data imputed as non-responders except those missing due to COVID-19 or geo-political conflict in Ukraine and Russia, which are imputed by multiple imputation; PBO, placebo; RZB, risankizumab.

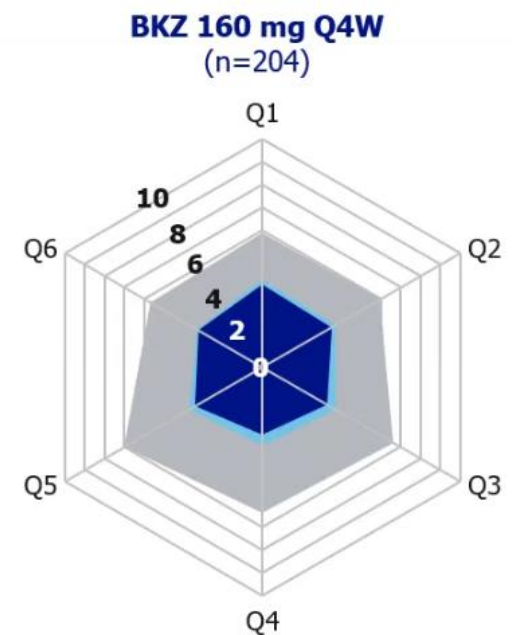
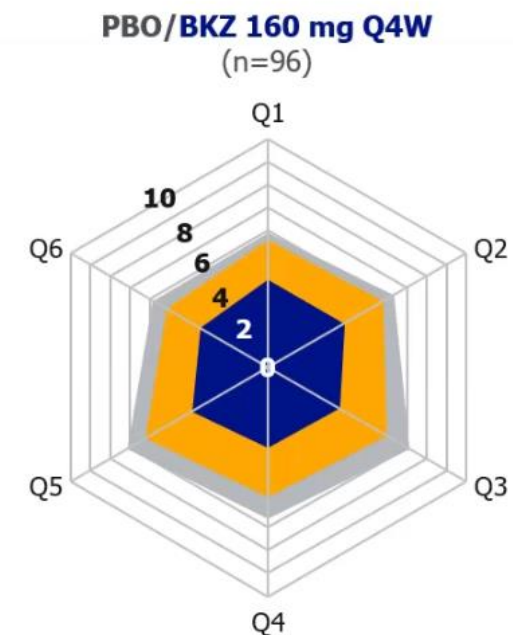
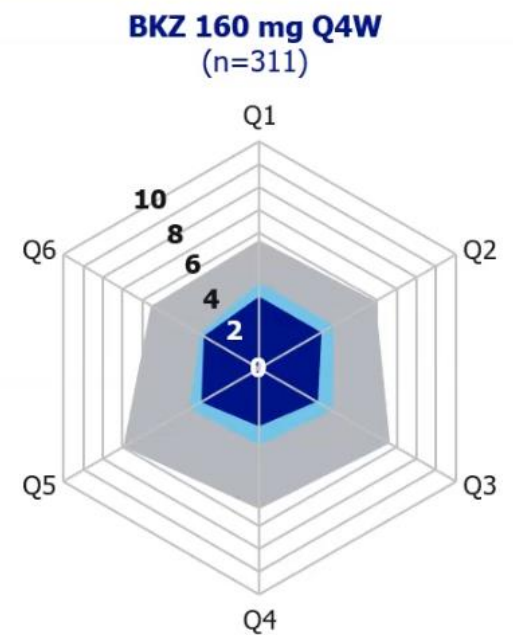
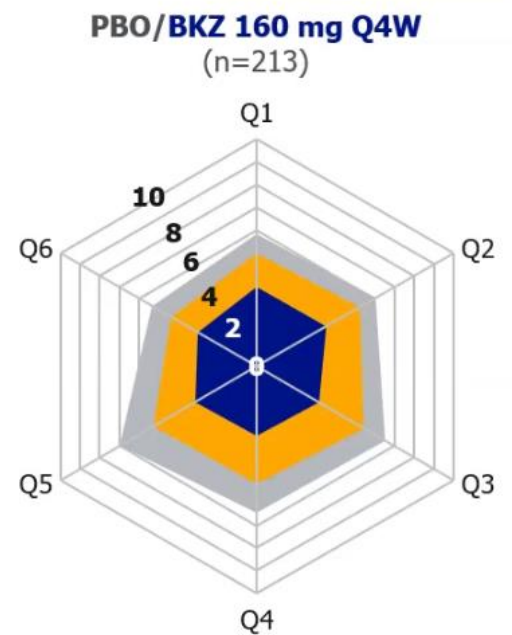
Mean BASDAI Component Scores for Patients through Week 52 (MI)

BKZ-treated patients demonstrated improvement in all BASDAI domains, including in neck/back/hip pain



BE OPTIMAL (bDMARD-naïve)

BE COMPLETE (TNFi-IR)



■ Baseline ■ Week 16 PBO ■ Week 16 BKZ 160 mg Q4W ■ Week 52 BKZ 160 mg Q4W

Q1: Fatigue; Q2: Neck/back/hip pain; Q3: Peripheral arthritis; Q4: Enthesitis; Q5: Intensity of morning stiffness; Q6: Duration of morning stiffness

Mean (SE) Cfb in BASDAI Q2 score:

	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
BL mean:	6.05	5.91
Week 16	-0.8 (0.2)	-2.1 (0.2)
Week 52	-2.5 (0.2)	-2.7 (0.2)

Mean (SE) Cfb in BASDAI Q2 score:

	PBO/BKZ 160 mg Q4W	BKZ 160 mg Q4W
BL mean:	6.36	5.94
Week 16	-0.6 (0.3)	-2.3 (0.2)
Week 52	-2.5 (0.3)	-2.5 (0.2)

Comorbilidades - Neoplasias

- Recogida de datos de TriNext Research Network, con acceso a historia clínica de aprox 110 millones de pacientes de 78 centros/organizaciones
- Objetivo: determinar el riesgo de malignidad

Results

- 21,718 patients on IL-12/23i or IL-23i, 42,792 on TNFi, and 19,425 on IL-17i met criteria.
- Propensity score matching for demographics, social history, and past medical history resulted in cohorts of 19,308 IL-17i patients and 19,715 IL-12/23i or IL-23i, both matched to equal numbers in the TNFi-cohort.
- In the IL-17i-cohort there were 384 new malignancies, 549 in the IL-12/23i or IL-23i-cohort, and 1547 in the TNFi cohort prior to matching.

A comparative assessment for risk of malignancy following initiation of biologic therapy among psoriasis patients: A retrospective cohort study

Chunghwan Ro¹, BS, Clinton Enos¹, MD

¹Department of Dermatology, Eastern Virginia Medical School, Norfolk, VA

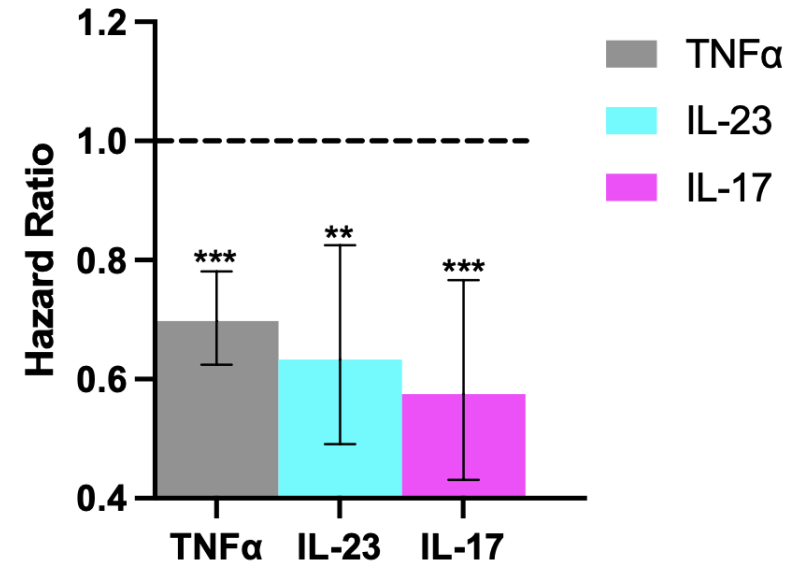
Cohort	Patients in Cohort prior to matching	Patients in Cohort after matching	Patients with Outcome prior to matching	Patients with Outcome after matching	Hazard Ratio (95% CI)	
Analysis 1 TNFi	IL 12/23i or IL-23i	21718	19715	549	525	1.004 (0.89, 1.133)
	TNFi	42792	19715	1547	527	
Analysis 2 TNFi	IL-17i	19425	19308	384	384	0.92 (0.8, 1.058)
	TNFi	42792	19308	1547	405	
Analysis 3 IL 12/23i or IL-23i	IL-17i	19425	15024	384	305	0.861 (0.738, 1.004)
	IL 12/23i or IL-23i	21718	15024	549	351	

Conclusions:

- Consistent with previous results through 2.5 years,¹ during a median follow-up period of ~8 years, malignancy rates were ~5-fold higher in psoriasis patients with a history of malignancy (excluding NMSC) than in those without a history of malignancy

Neoplasias

- Retrospective cohort study of 2,103,979 patients with psoriasis using TriNetX.
- Patients grouped by biologic (IL-17 inhibitor, IL-23 inhibitor, TNF- α inhibitor) along with a no biologic control.
- Patients with IBD or a previous history of colorectal cancer were excluded from the study.
- Patients were propensity matched by the demographic and disease categories on the right



Tratamiento biológico podría disminuir el riesgo de CCR

Outcomes		TNF α vs No Biologics		IL-23 vs No Biologics		IL-17 vs No Biologics	
Patients in Cohort (Patient with Outcome)	Experimental	146,800	(525)	38,879	(98)	37,485	(74)
	No Biologics	146,800	(743)	38,879	(153)	37,485	(126)
Hazard Ratio (95% CI)	Experimental	0.698	(0.624, 0.781)	0.633	(0.491, 0.815)	0.575	(0.431, 0.766)
	No Biologics						
Log-Rank Test P-value	Experimental	< 0.0001		0.0004		< 0.0001	

Eventos cardiovasculares

Question

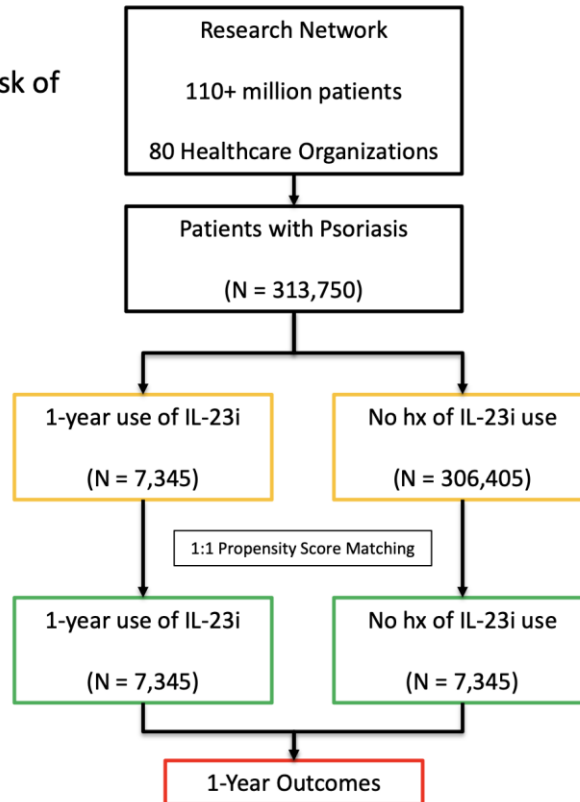
How do IL-23 inhibitors impact the risk of thromboembolic events in psoriasis?

Design

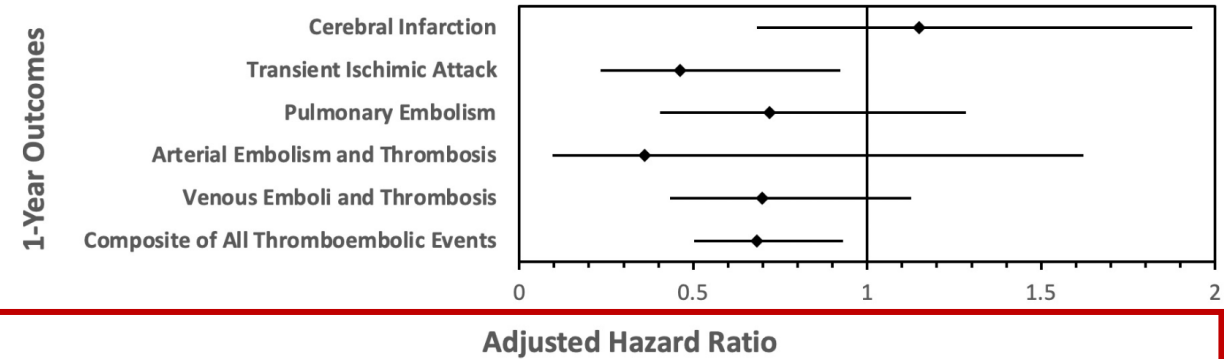
Step 1: Patient Identification

Step 2: Propensity Score Matching

Step 3: Outcome Analysis



Risk of Thromboembolic Events in Psoriasis Patients on IL-23 Inhibitors



- 54% reduced risk in TIA (aHR[95% CI]= 0.46 [0.23,0.92]).
- 32% reduced risk in any thromboembolic event 0.68 [0.5,0.93]).

Tratamiento tópico

1:50 PM

Debate #1: Will non-steroidal topical medications replace topical steroids in the treatment of psoriasis?

Kenneth B. Gordon, MD, FAAD; Bruce Elliot Strober, MD, PhD, FAAD

Statements never made when prescribing nonsteroidal topicals

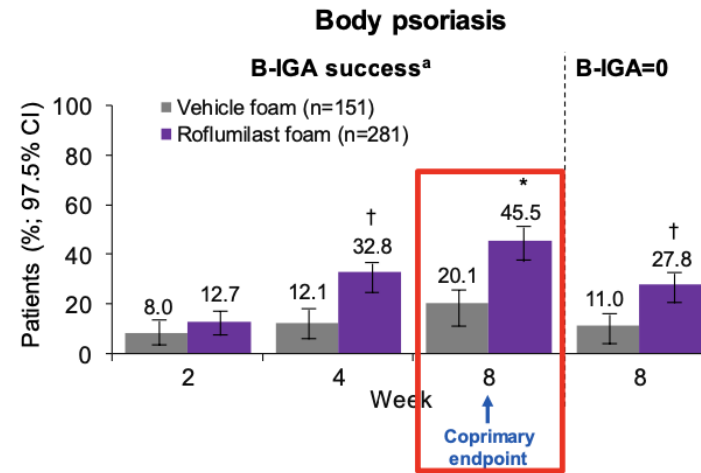
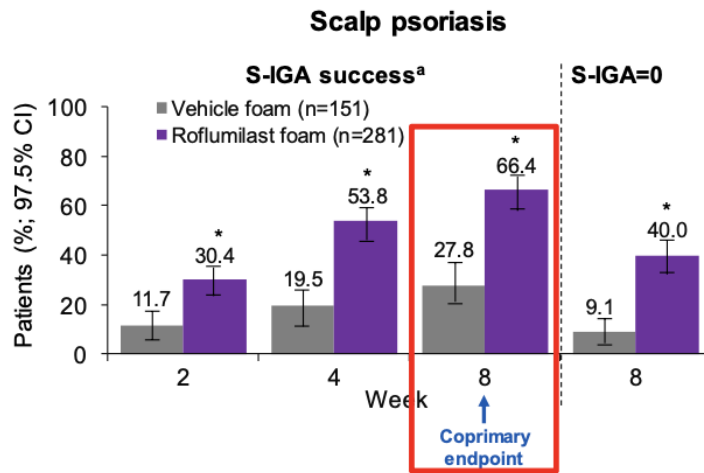
- “Don’t use this on your face.”
- “Don’t use this in your private area.”
- “Don’t use this in your armpits.”
- “Only use for up to 2 weeks.”
- “Use this cream on your face, and this ointment on your elbows, this cream in your private area and this solution in your scalp.”
- “If you keep using this topical it might eventually lose its effectiveness.”
- “If you overuse this topical you might thin your skin, cause stretch marks, very prominent blood vessels and bruising.”

Nonsteroidal Topicals: Multiple MOAs and Indications

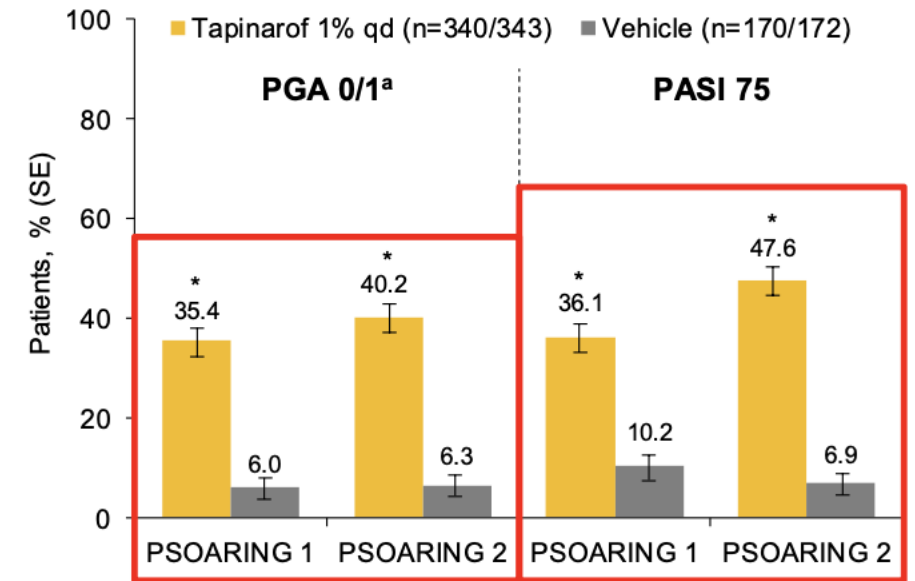
- TCIs: [pimecrolimus](#) and [tacrolimus](#)
 - atopic dermatitis
 - intertrigous and facial psoriasis (off label)
- PDE4 inhibitors: [crisaborole](#) and [roflumilast](#)
 - atopic dermatitis (off label for roflumilast)
 - psoriasis (off label for crisaborole)
- Aryl hydrocarbon receptor (AHR) agonist: [tapinarof](#)
 - atopic dermatitis (off label)
 - psoriasis
- All of the above have or will have pediatric indications.

Roflumilast & topinarof

ARRECTOR: Improvement in scalp and body psoriasis with roflumilast foam 0.3% for 8 weeks



PGA 0/1 (primary endpoint) and PASI 75 responses at Week 12 (ITT MI)



*P<0.0001 vs vehicle; †P<0.0001 vs vehicle [nominal]; ^aS-IGA Success or B-IGA Success: Clear or almost clear with ≥2-grade improvement from baseline

Gooderham M, et al. WCD 2023. Late-breaking poster. Sponsored by Arcutis Biotherapeutics, Inc

^aPGA of 0 or 1 and ≥2-grade improvement at Week 12

*P<0.0001 vs vehicle; based upon Cochran-Mantel-Haenszel analysis stratified by baseline

Lebwohl M, et al. EADV 2020, Late breaking news D3T03.3D. Sponsored by Dermavant

Corticoides y combinaciones

COST

- Triamcinalone ointment – 1 lb jar - \$13.04
- Fluocinonide cream – 60 g – \$21.16
- Clobetasol solution – 50 ml - \$17.53
- Roflumilast cream – 60 g - \$885.75
- Tapinorof cream – 60 g - \$1,337.80

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 knowledge changing life

TOPICAL CORTICOSTEROIDS ARE STILL THE CHAMPIONS OF TOPICAL THERAPY

- Highly effective
 - Safe
 - Fast
 - Convenient – come in many formulations
 - Affordable
 - New topical are good but they will never replace our old friends
-
- **Risk of skin atrophy**
 - 13 studies with topical steroid evaluating treatment durations from 4 weeks to 1 year were analyzed
 - The frequency of skin atrophy was low (0% to 5% of patients)

Halobetasol + tazaroteno

Figure 1. Rates of IGA×BSA-75 in participants with baseline moderate-to-severe scaling.

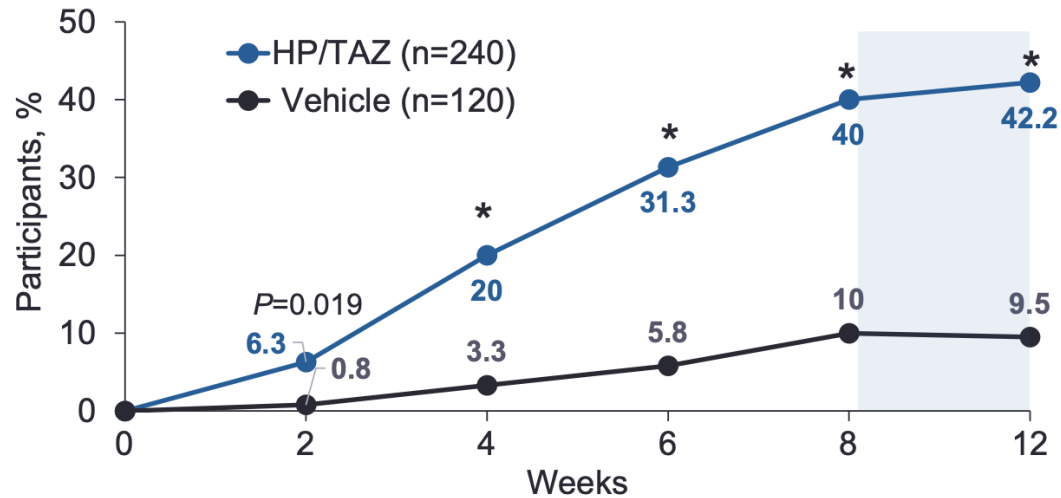
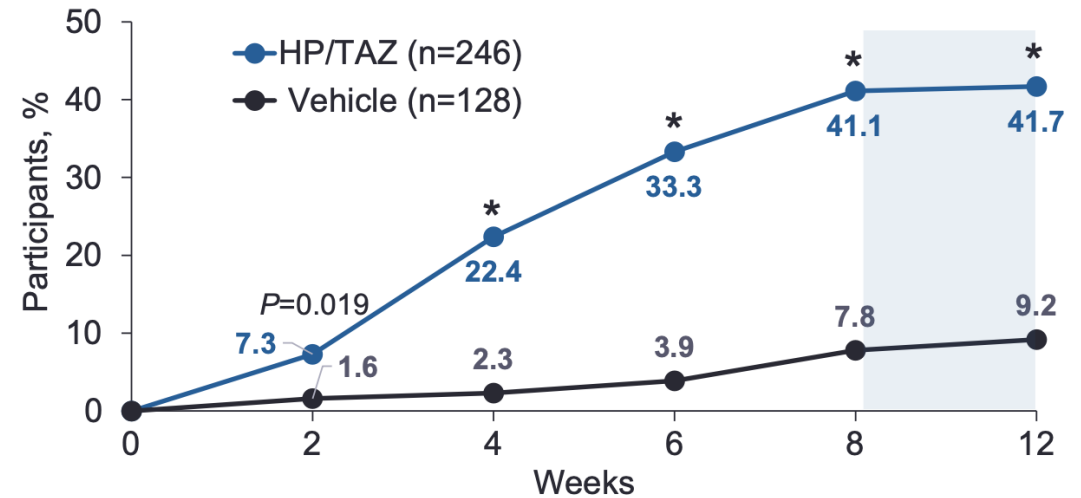


Figure 2. Rates of IGA×BSA-75 in participants with baseline moderate-to-severe plaque elevation.

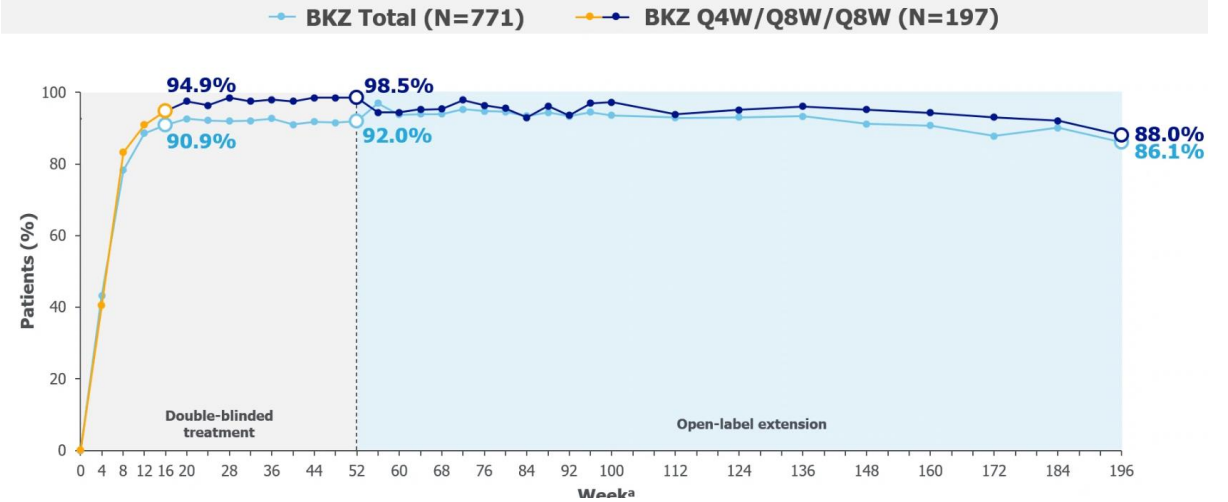


- Significantly greater rates of IGA×BSA-75 were observed at week 2 and maintained through week 12 in participants with baseline moderate-to-severe scaling or plaque elevation receiving HP/TAZ than in participants receiving vehicle (Figures 1 and 2, respectively)
- Additionally, compared with vehicle, HP/TAZ was associated with significantly greater rates of IGA×BSA-90 at week 4 ($P=0.026$) through week 12 ($P<0.001$) in participants with baseline moderate-to-severe plaque elevation and at weeks 6 through 12 ($P<0.001$) in participants with baseline moderate-to-severe scaling (data not shown)

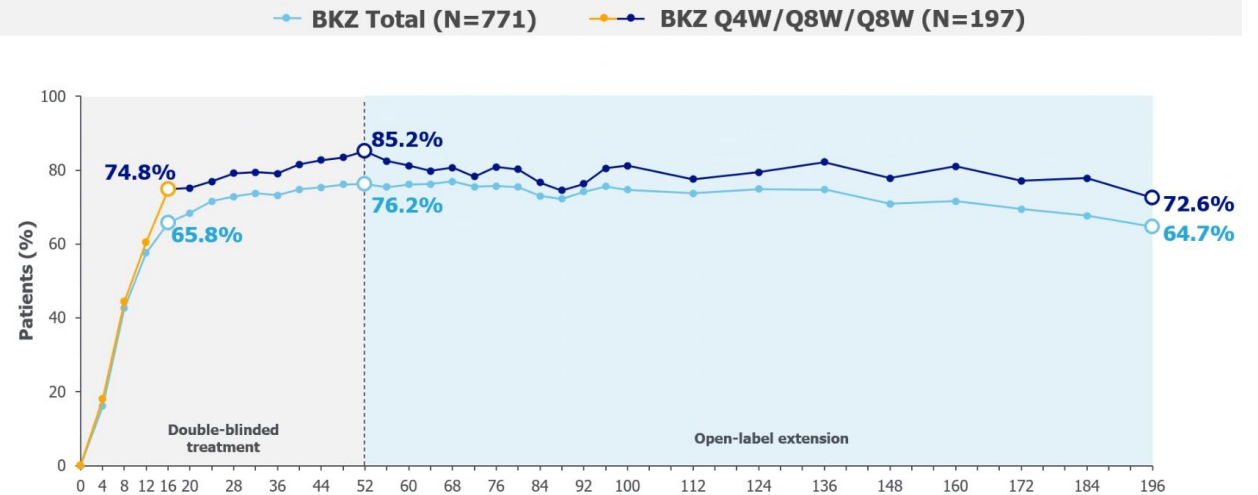
Bimekizumab 4 años

Bimekizumab demuestra altas tasas de blanqueamiento de la piel persistentes a lo largo de 4 años, así como en la mejoría de la calidad de vida.

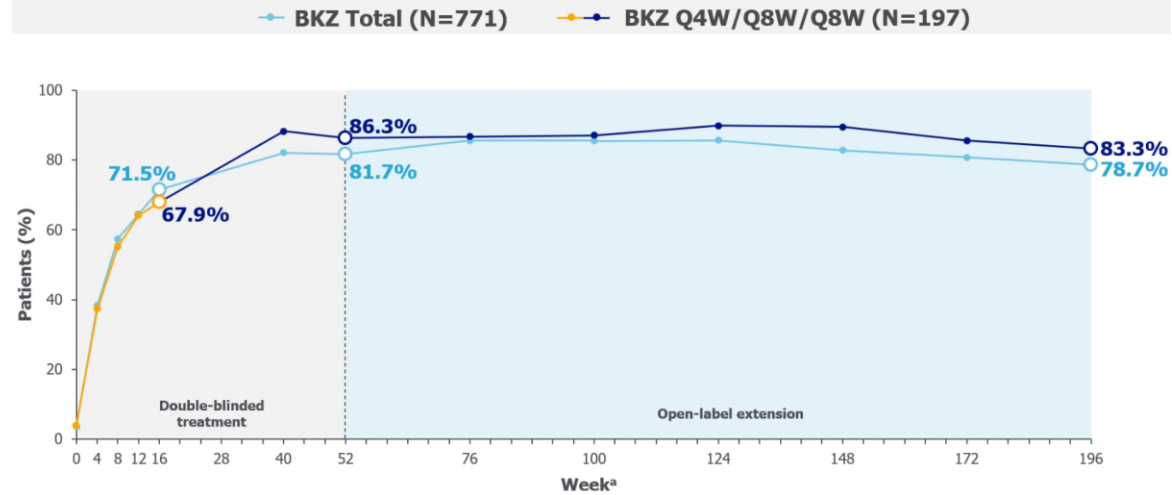
PASI 90 responses over 4 years (mNRI)



PASI 100 responses over 4 years (mNRI)



DLQI 0/1 responses over 4 years (mNRI)



Deucravactinib

Figure 1. Mechanism of action of deucravactinib

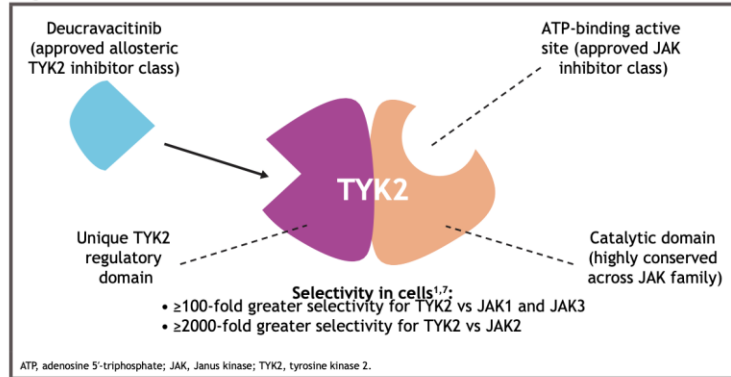


Figure 2. POETYK PSO-1, PSO-2, and LTE analysis populations^a

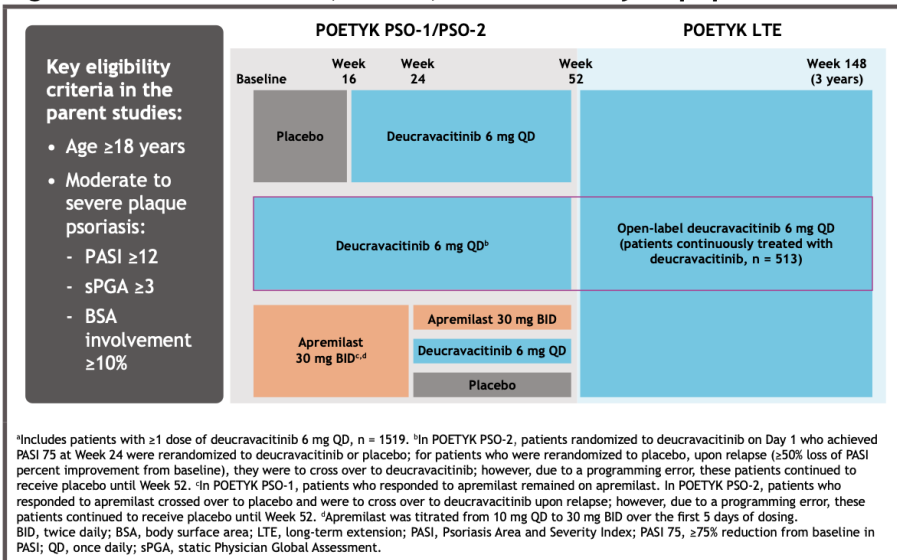
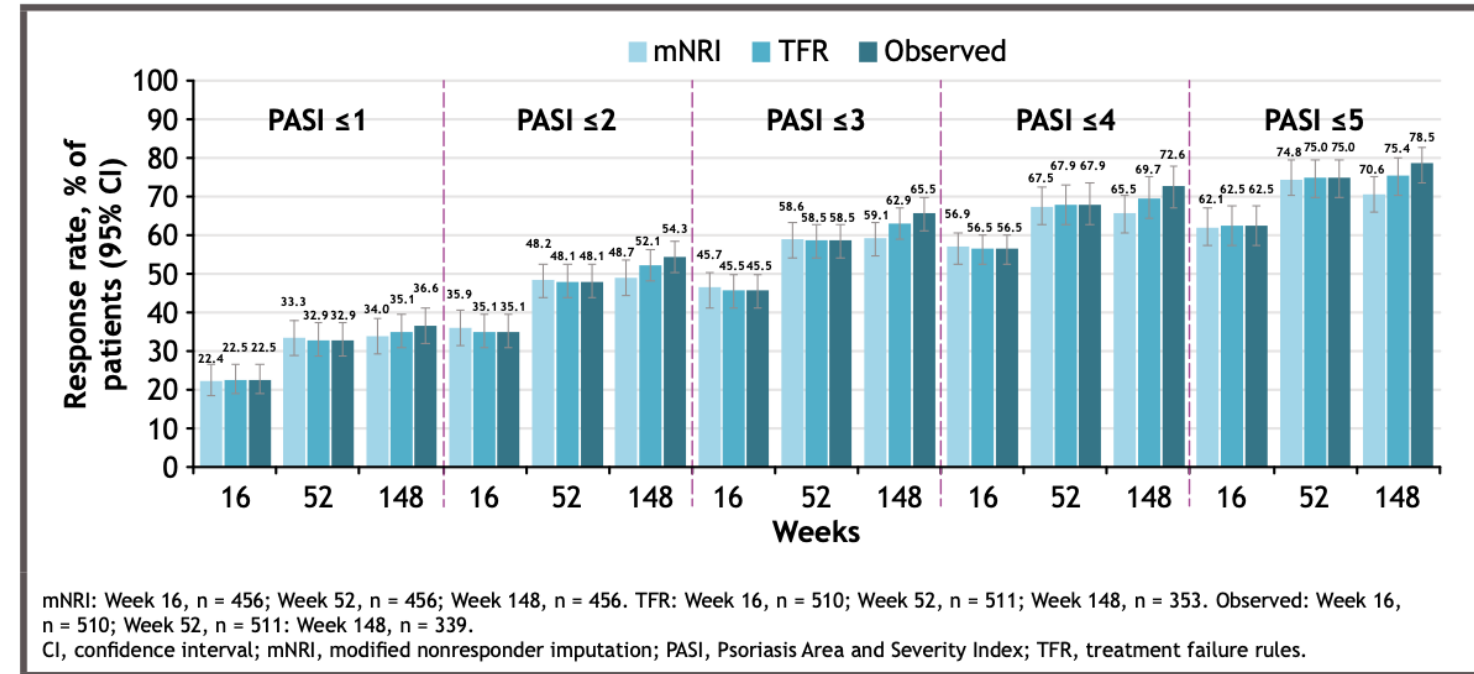
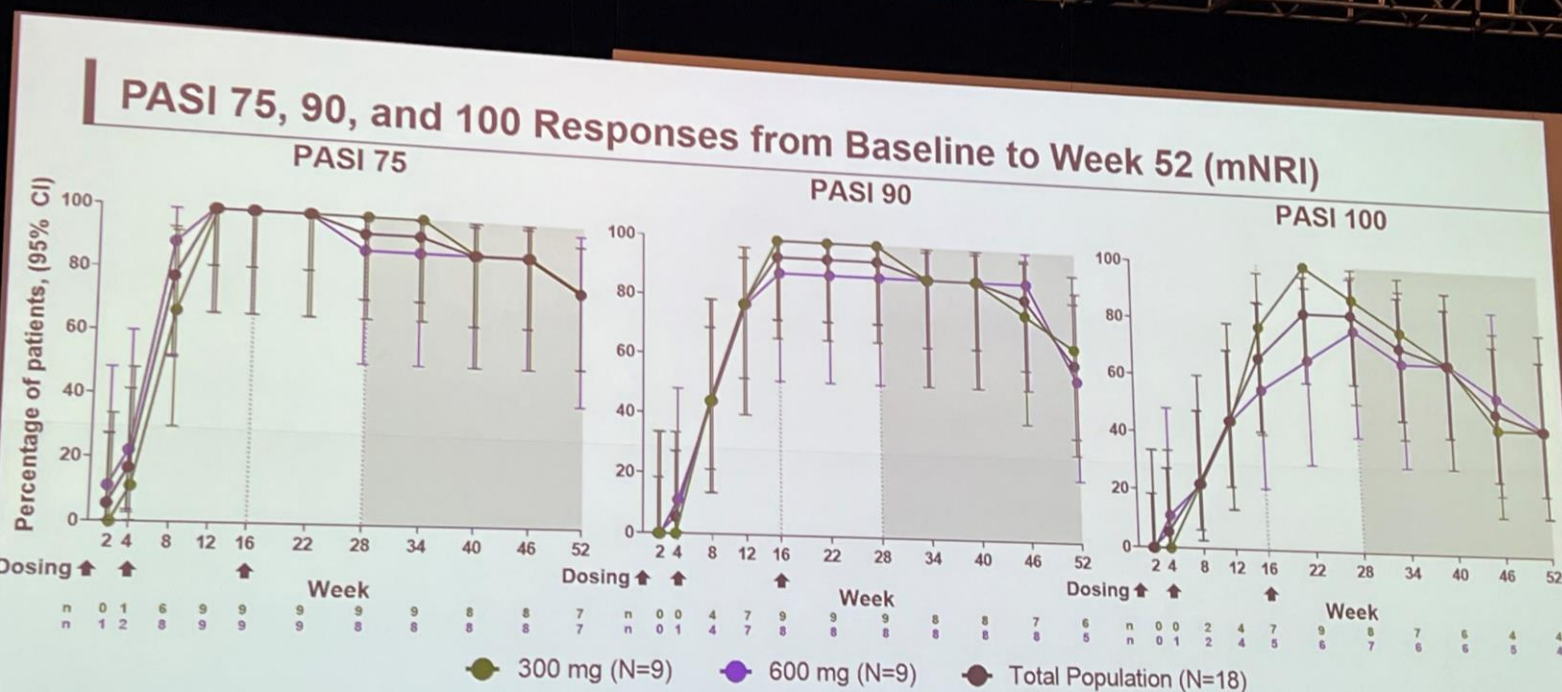


Figure 5. Proportions of patients achieving absolute PASI thresholds over time

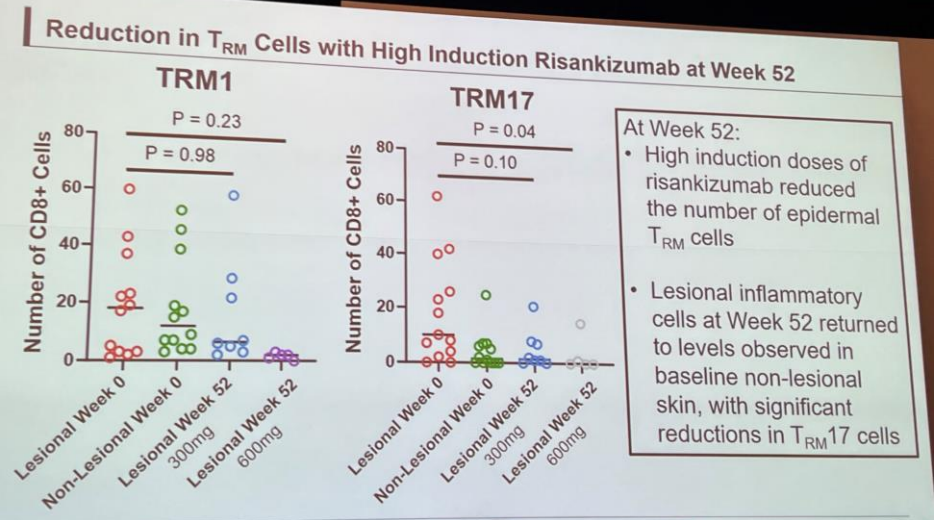
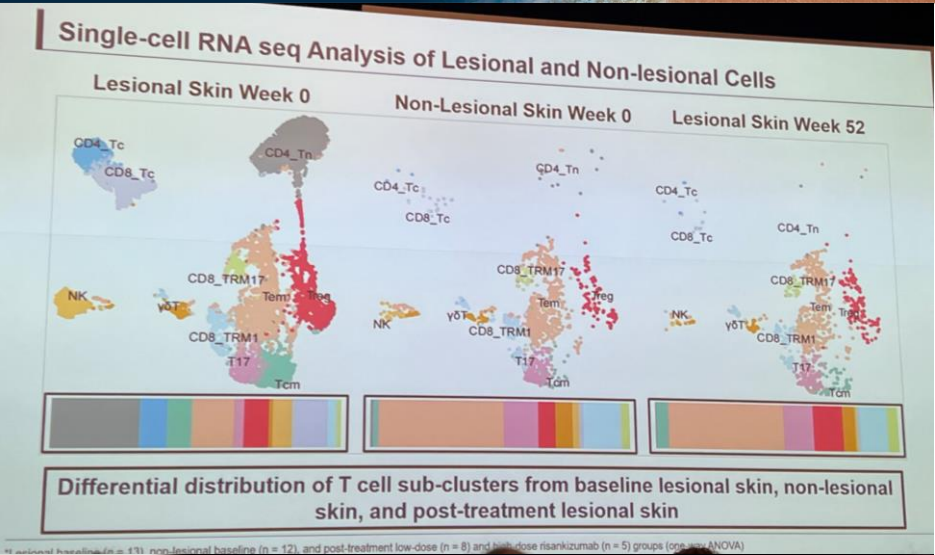


Knockout study



• Rapid and high improvements in skin responses were observed with high doses of risankizumab induction

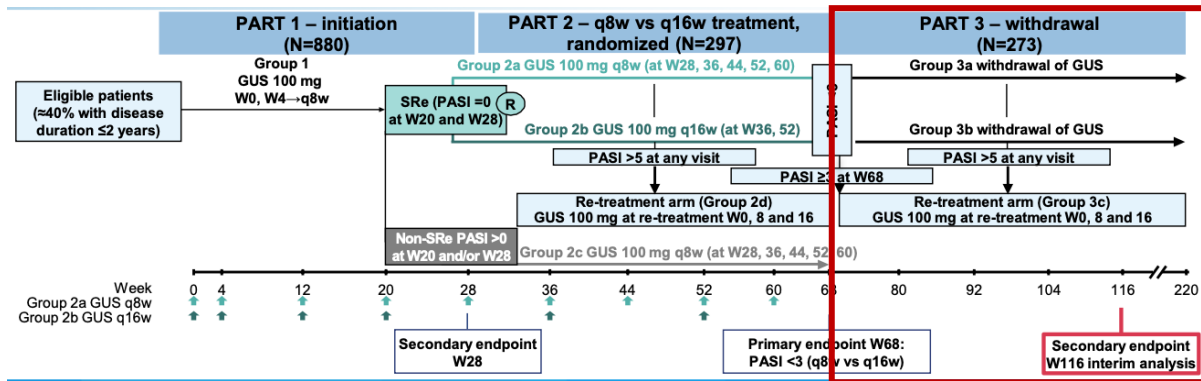
mNRI, modified non-responder imputation; PASI, Psoriasis Area Severity Index; RZB, risankizumab
The mNRI analysis excluded patients who discontinued risankizumab for reasons other than lack of efficacy or intolerance; 95% CI for response rate was calculated based on Clopper-Pearson interval.



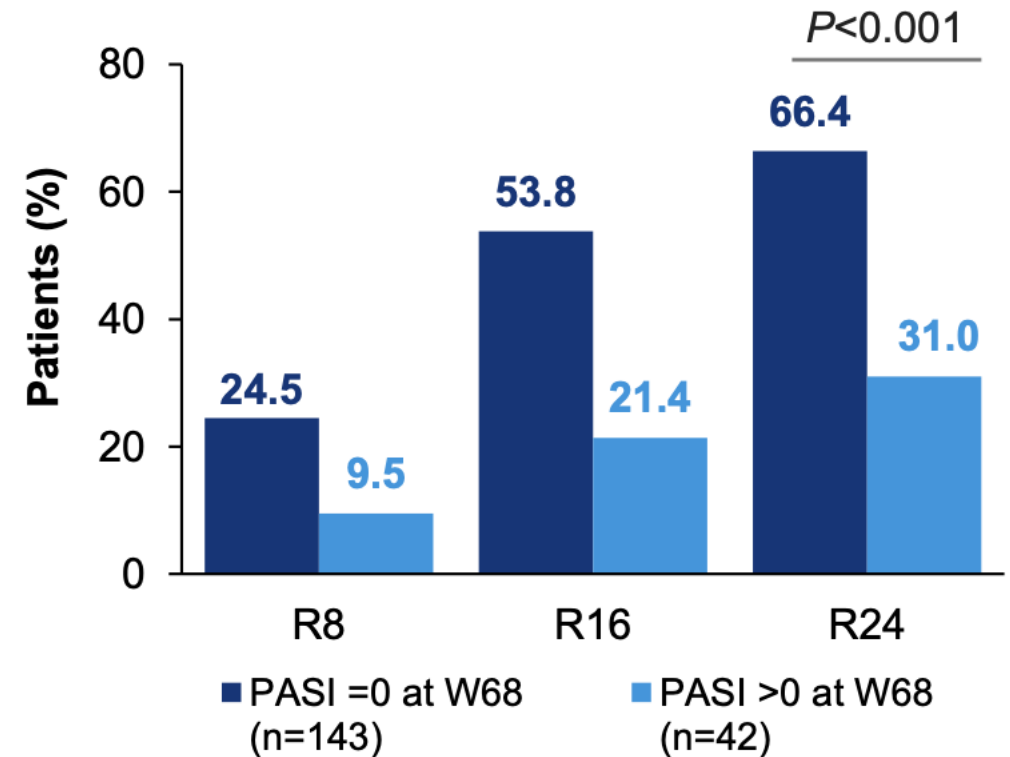
At Week 52:

- High induction doses of risankizumab reduced the number of epidermal T_{RM} cells
- Lesional inflammatory cells at Week 52 returned to levels observed in baseline non-lesional skin, with significant reductions in T_{RM}17 cells

Re-treatment response was greater in those with vs without PASI =0 at time of guselkumab withdrawal



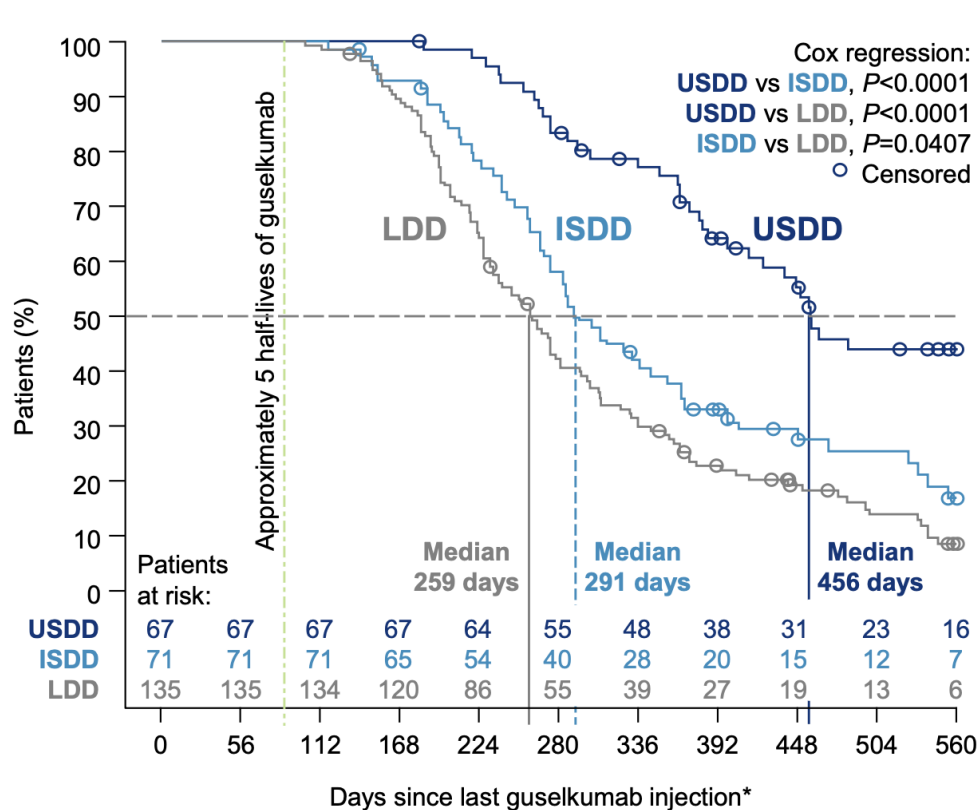
b) PASI =0 after initiating re-treatment (NRI)



K. Schäkel et al. GUIDE part 3: USDD

Patients with disease duration <15 months (USDD) remained treatment free significantly longer than those with disease duration >15 months (ISDD and LDD)

Figure 3. Treatment-free period (N=273)



Disease duration	Months since symptom onset
Long disease duration (LDD)	>24
Intermediate-short disease duration (ISDD)	≥15–≤24
Ultra-short disease duration (USDD)	<15

Median treatment-free period

- USDD patients: **456 days**
 - ISDD patients: **291 days**
 - LDD patients: **259 days**
- USDD vs ISDD: ↑ 165 days (57%)
 HR = 0.41, 95% CI 0.27–0.62
 $P < 0.0001$
- USDD vs LDD: ↑ 197 days (76%)
 HR = 0.30, 95% CI 0.21–0.44
 $P < 0.0001$

The treatment-free observation period is ongoing (to W220)

Loss of maintenance of response was defined as PASI >5, at which point treatment was re-initiated. Time to end of the treatment-free period was calculated from time of last guselkumab injection in study part 2 to the date of the first re-treatment visit (irrespective of PASI assessments). If no re-treatment was started, time was censored to the date of the W116 visit or the date of study termination, whichever came first

How to Combine?

NM: No monitoring

*: LFTs, anemia

*: Lipids

IL 12/23 and IL-23

Reliable
Rapid
Durable
NM



Apremilast (NM)
Methotrexate (*)
Acitretin (*)
JAKI (*)
TYK 2(NM) ?

IL-17

Reliable
Rapid
Durable
PMN monitoring
GI sx



Apremilast
Methotrexate (*)
Acitretin (*)
JAKI (*, Candidiasis)
TYK 2(NM)

TNFi

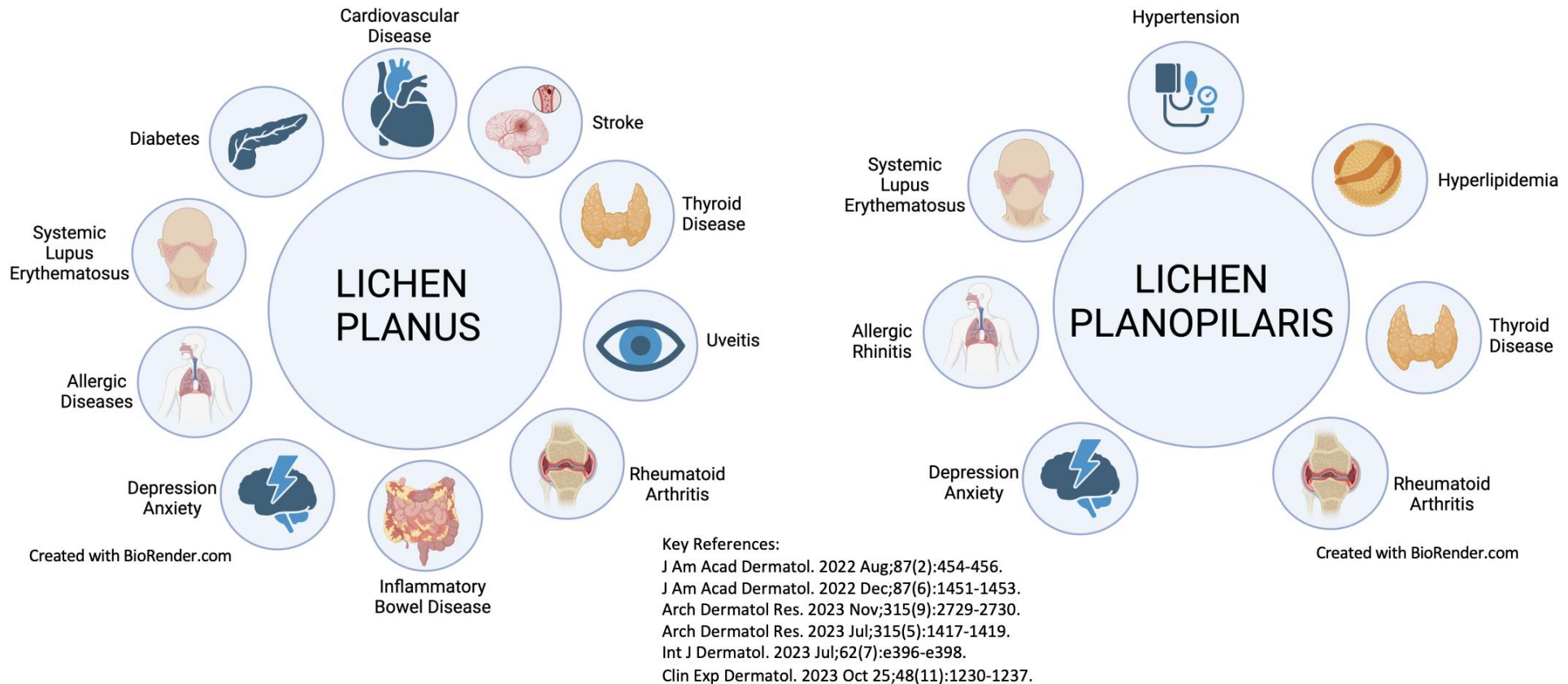
Most Data
PSA
Monitoring



Apremilast (NM)
Methotrexate (*)
Acitretin (*)
TYK 2(NM)

Liquen plano y dermatosis liquenoides

LICHEN PLANUS AND LICHEN PLANOPILARIS AS SYSTEMIC DISEASES: NEW AND EMERGING COMORBIDITIES



*Not intended to be an exhaustive review of comorbidities of LP and LPP, but rather a summary of new and emerging comorbidities.

March 8, 2024

Jeffrey M. Cohen, M.D.; Department of Dermatology, Yale School of Medicine



Recommended Screening for Multi-Site LP

◆ ROS

- **GI:** Problems swallowing? Food sticking? Need liquid to get food down?
- **Otic:** Ear pain? Recurrent ear infections? Hearing loss? EAC stenosis?
- **Ocular:** Pain? Dryness? Lacrimal duct stenosis?
- **Genital:** Pain with intercourse or urination? Itch?
- **Hair:** loss, scalp pain/itch/redness?
- **Skin** rashes? **Nail** issues?
- **New Meds?**
 - new meds 3-6 months prior? 2 years? NSAIDs or herbals?
- **Recent vaccinations or infections?**
- **Family history** autoimmunity or LP of any subtype?
- Age-appropriate malignancy screening up-to-date?

PE

- **FBSE:** Skin, Scalp, nails, mouth, **genitals**, eyes



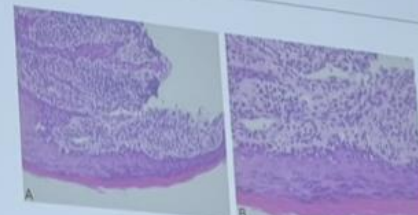
Esophageal LP

- ◆ Underreported
- ◆ Can be asymptomatic, predate or follow onset of other LP subtypes
 - One review in derm literature 2011 by L Fox et al of all Pubmed through 2009 (< 100 patients)
 - 12 cases (17%) with asymptomatic disease
 - Two studies looking prospectively for esophageal involvement – 25-50% patients found to have eLP
- ◆ F >> M
- ◆ Most common with other mucosal LP
- ◆ Complications:
 - esophageal strictures, food sticking/problems swallowing/choking
 - SCC



Otic LP

- ◆ Rare, underreported
 - 10-yr institutional review (Mayo), 19 cases found (Sattori. JAAD 2013)
 - Can have isolated otic LP 5/19 (26%)
 - Avg 3 anatomic LP sites
 - 43% unilateral
 - Mean from sx to dx = 4 years
- ◆ F > M
- ◆ Symptoms
 - Hearing loss and/or ear pain > EAC plugging >> pruritus
- ◆ Complications:
 - Recurrent infections, pain, conductive hearing loss, perforated tympanic membrane



Guo et al. JAAD Case Rep 2021



Sattori et al. JAAD 2013

Liquen plano

- Uso de inhJak en case reports (24 tofacitinib) y upadacitinib (7 casos con respuesta rápida y sostenida)
- Fase 2 baricitinib en LP cutáneo
 - 12 pacientes 2mg baricitinib
 - Reducción >3 PGA a semana 16
 - At week 16, **10 of 12 (83.3%; 95% CI: 51.6% - 97.9%)**
 - **Five** of the 10 treatment-responsive patients had **PGA of 0**, and **five** had **PGA of 1 (almost clear)**.

FIGURE 1



Week 0



Week 16

Example image of cutaneous LP response to baricitinib

Topical Ruxolitinib for LPPigmentosus

- ▶ 63 year old male with recalcitrant LPPigmentosus associated with intractable itch
- ▶ Nonresponsive to topical steroids, topical tacrolimus
- ▶ Treated with topical 1.5% ruxolitinib cream daily for nine months with improvement in itch and discoloration



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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GRACIAS