#WCD2019

AEDV HIGHLIGHTS

24th World Congress of Dermatology (WCD)

10-15 JUNIO 2019

Milàn

Patrocina:

janssen Immunology
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Organiza:

ACADEMIA ESPAÑOLA DE DERMATOLOGÍA Y VENEREOLOGÍA
AEDV 1909

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24th World Congress of Dermatology (WCD)

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Milán

Psoriasis

Dr. Pablo de la Cueva

Hospital Universitario Infanta Leonor

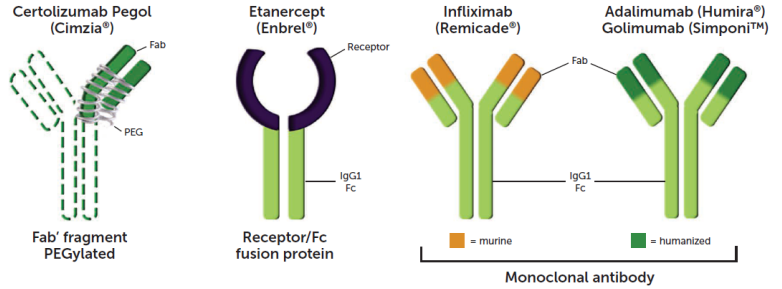
Patrocina: Janssen Immunology, Pharmaceutical Companies of Johnson & Johnson

Organiza: Academia Española de Dermatología y Venereología AEDV 1909

Psoriasis. Treatment. Biologics.

- **CERTOLIZUMAB**

Figure 1. Structure of TNF-Blocking Agents



Fab, antigen-binding fragment; Fc, fragment crystallizable; IgG, immunoglobulin G; PEG, polyethylene glycol

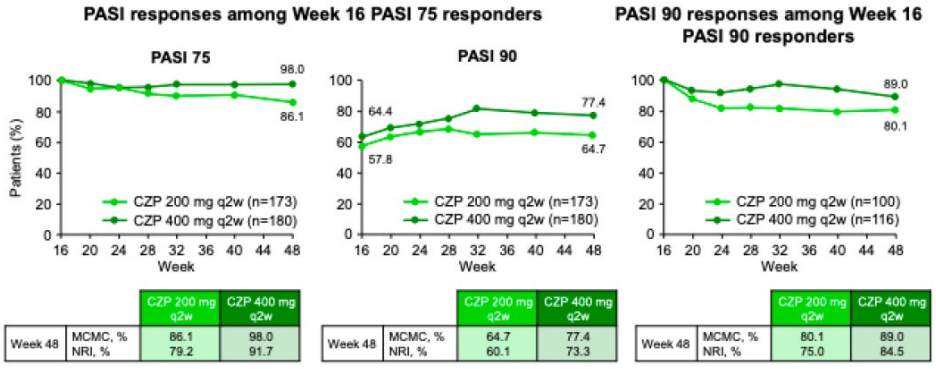
Table 2. Responder Rates in the Overall Population at Week 16 (Randomized Set)

	Placebo (N=157)	CZP 200 mg Q2W[a] (N=351)	CZP 400 mg Q2W (N=342)
Study Endpoint	Responder Rate (%)		
PASI 75	7.5	74.5*	80.1*
PGA 0/1	2.8	54.6*	63.7*
PASI 90	1.6	44.5*	52.2*

Randomized Set includes all randomized patients
*p<0.0001 vs placebo (not adjusted for multiplicity)
[a]CZP 200 mg Q2W patients received loading dose of CZP 400 mg at Weeks 0, 2, and 4
CZP indicates certolizumab pegol; PASI, psoriasis area and severity index; PGA 0/1, 'clear'/'almost clear' with ≥2-category improvement in physician's global assessment; Q2W, every 2 weeks

- CZP does not bind the Fc receptor and consequently shows minimal placental transfer from mothers to infants[9]

CIMPASI-1, CIMPASI-2, and CIMPACT: Durability of response with certolizumab pegol over 48 weeks



		CZP 200 mg q2w	CZP 400 mg q2w
Week 48	MCMC, %	86.1	98.0
	NRI, %	79.2	91.7

		CZP 200 mg q2w	CZP 400 mg q2w
Week 48	MCMC, %	64.7	77.4
	NRI, %	60.1	73.3

		CZP 200 mg q2w	CZP 400 mg q2w
Week 48	MCMC, %	80.1	89.0
	NRI, %	75.0	84.5

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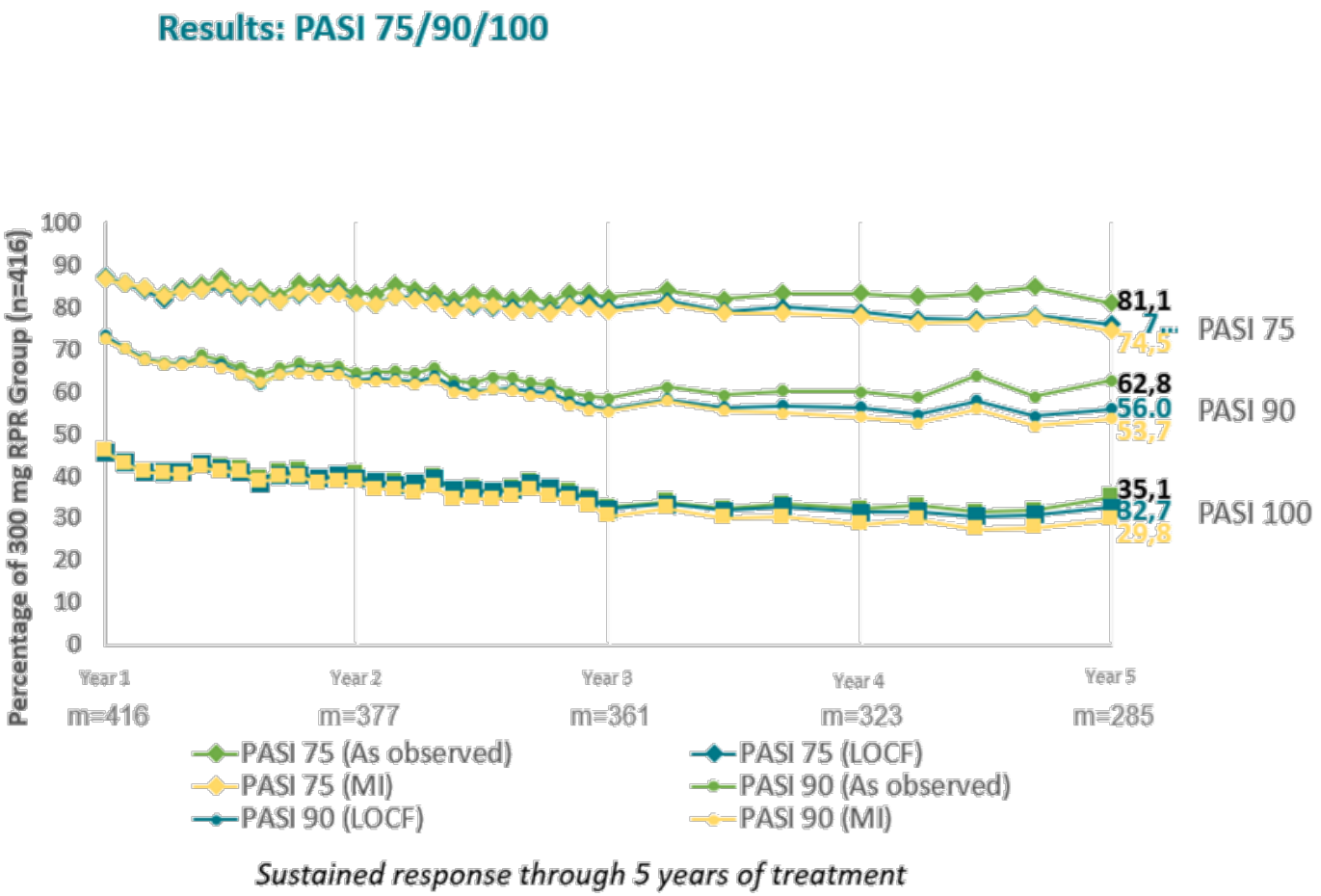
- **SECUKINUMAB**



Sustained response through 5 years of treatment

Group RPR

m, number of patients as observed; PASI 75/90/100, 75/90/100 percent improvement in Psoriasis Area and Severity Index; MI, multiple imputation; LOCF, last observation carried forward

Psoriasis. Treatment. Biologics.

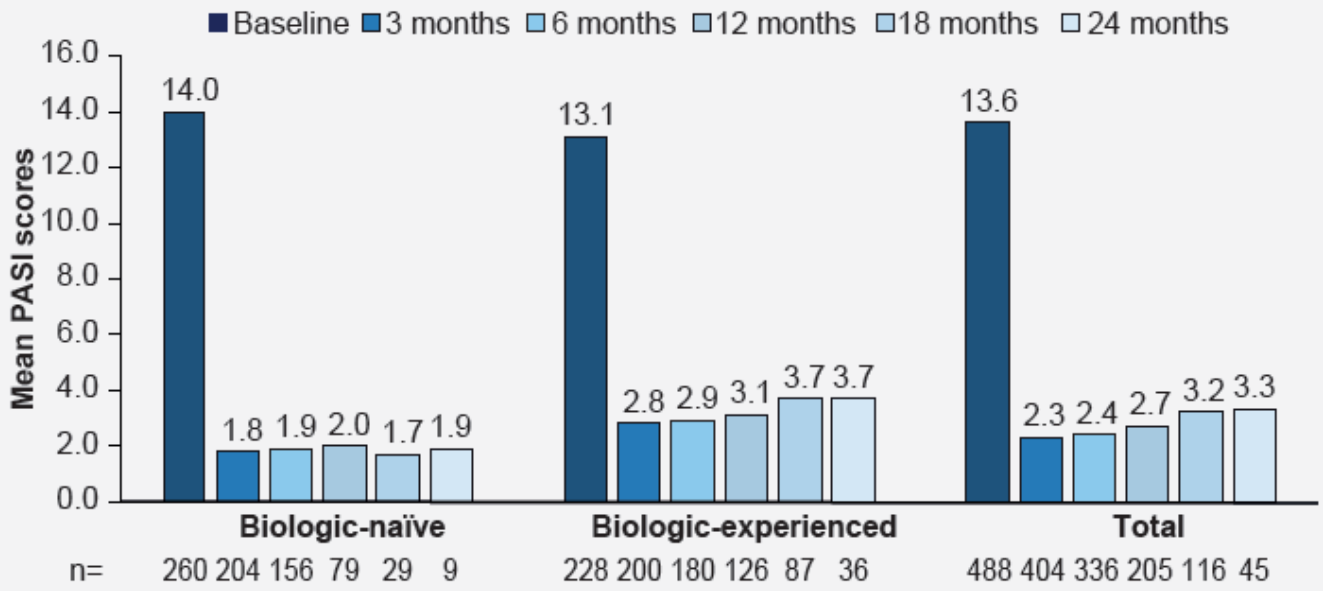
- **SECUKINUMAB**

Secukinumab Treatment Results in Improvement of Disease Characteristics in Patients with Moderate to Severe Psoriasis: 24 Month Follow-up Data from the PURE Registry

Kim A. Papp[1], Melinda Gooderham[2], Afsaneh Alavi[3], Danielle Brassard[4], Norman Wasel[5], Jaggi Rao[6], Wei-Jing Loo[7], Emmanouil Rampakakis[8], Antonio Vieira[9] and Lenka Rihakova[9]

[1]K Papp Clinical Research and Probity Medical Research, Waterloo, ON, Canada; [2]SKIN Center for Dermatology and Probity Medical Research, Peterborough, and Queen's, Kingston, ON, Canada; [3]York dermatology center and Probity Medical Research, Richmond Hill , ON, Canada; [4]Clinique D, Laval, QC, Canada; [5]Stratica Medical Inc. and Probity Medical Research , Edmonton, AB, Canada; [6]Alberta Dermasurgery Centre and Probity Medical Research, United Health Centre, Edmonton, AB, Canada; [7]DermEffects and Probity Medical Research, London, ON, Canada; [8]JSS Medical Research, Saint-Laurent, QC, Canada; [9]Novartis Pharmaceuticals Canada Inc., Dorval, QC, Canada

Figure 3. Mean PASI over time by prior biologic exposure in secukinumab-treated patients



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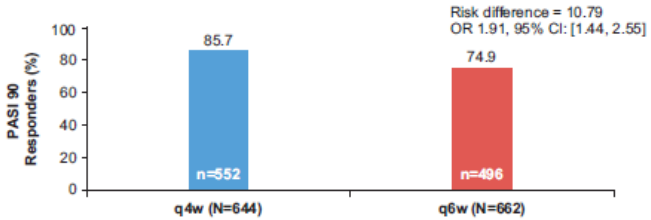
Maintenance regimen of Secukinumab in subjects with moderate to severe plaque psoriasis: Results from the OPTIMISE study

Kristian Reich[1], Luis Puig[2], Jacek C.Szepietowski[3], Carle Paul[4], Jean Philippe Lacour[5], Athanasios Tsianakas[6], Christian Sieder[7], Michael Rissler[8], Piotr Jagiello[8], Roberto Orsenigo[9]

[1]Dermatologikum Berlin and SCIderm Research Institute, Hamburg, Germany; [2]Department of Dermatology, Hospital de la Santa Creu i Sant Pau, Universitat Autònoma de Barcelona, Spain; [3]Department of Dermatology, Venereology and Allergology, Wroclaw Medical University, Wroclaw, Poland; [4]Department of Dermatology, Toulouse University and Larrey Hospital, Toulouse, France; [5]Hôpital Archet, CHU de Nice, Nice, France; [6]University of Münster, Münster, Germany; [7]Novartis Pharma GmbH, Nuremberg, Germany; [8]Novartis Pharma AG, Basel, Switzerland; [9]Novartis Farma S.p.A, Origgio, Italy

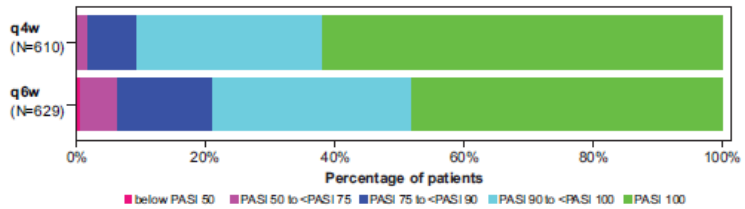
Figure 2. Proportion of PASI 90 responders at Week 24 who maintained a PASI 90 response at Week 52



q4w: Secukinumab 300 mg s.c. every 4 weeks (Group 1)
q6w: Secukinumab 300 mg s.c. every 6 weeks (Group 2)
Non-responder imputation

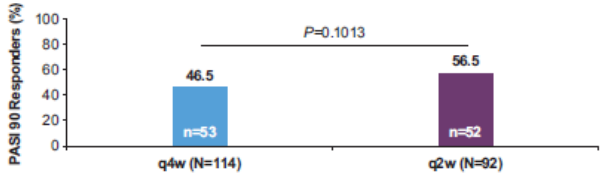
CI, confidence interval; N, total number of patients; n, number of patients available for assessment; OR, odds ratio; PASI, Psoriasis Area and Severity Index;
q4w, every 4 weeks; q6w, every 6 weeks; s.c., subcutaneous

Figure 3. PASI response distribution at Week 52



PASI, Psoriasis Area and Severity Index; q4w, every 4 weeks; q6w, every 6 weeks

Figure 4. Proportion of PASI ≥75 to <90 responders at Week 24 who gained PASI 90 response at Week 52



q4w: Secukinumab 300 mg s.c. every 4 weeks (Group 3)
q2w: Secukinumab 300 mg s.c. every 2 weeks (Group 4)
Non-responder imputation

CI, confidence interval; N, total number of patients; n, number of patients available for assessment; PASI, Psoriasis Area and Severity Index; q2w, every 2 weeks; q4w, every 4 weeks; s.c., subcutaneous

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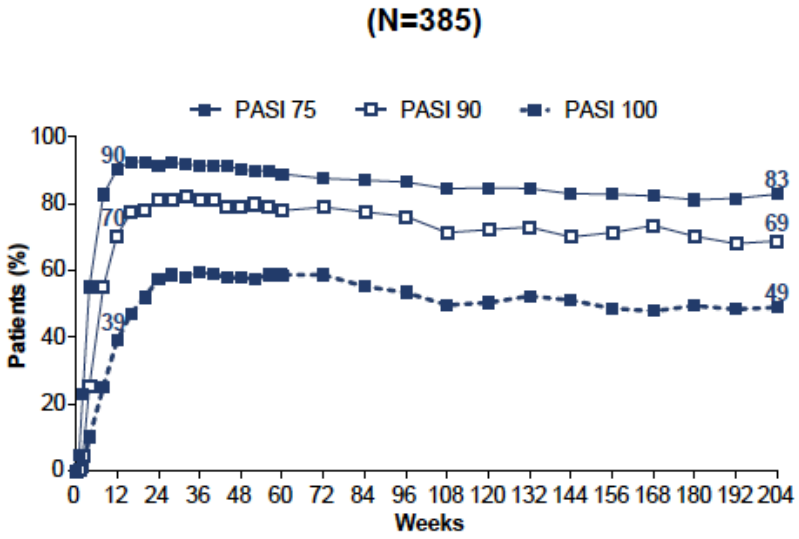
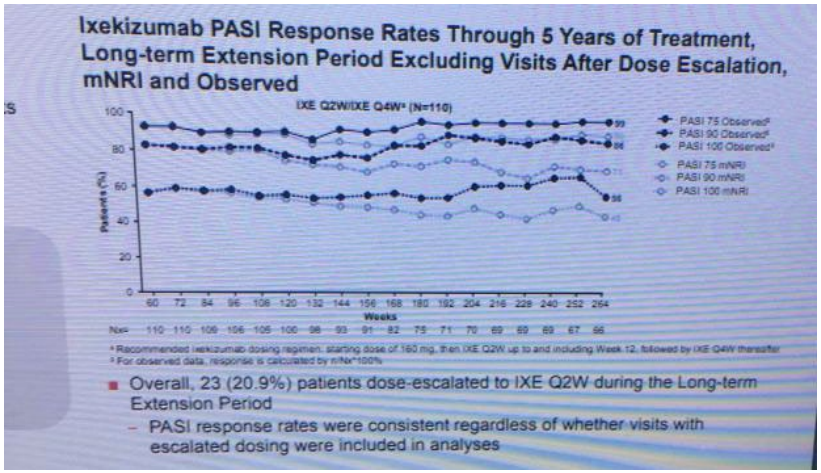
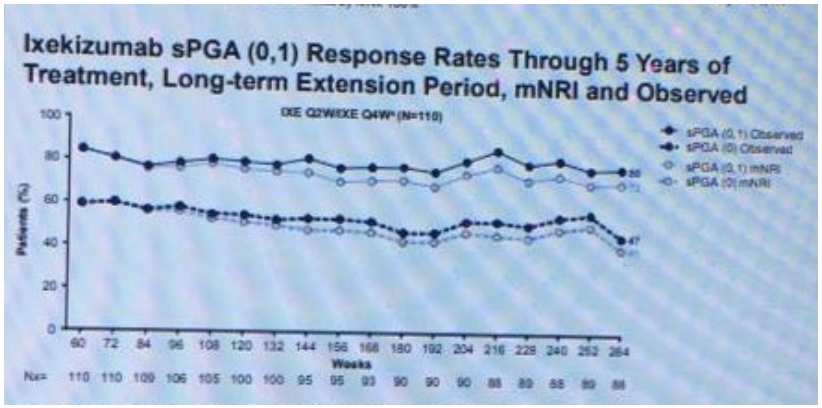
- **IXEKIZUMAB**

Ixekizumab[a] PASI Response Rates Through 4 Years of Treatment



Following Week 60, 254 (19.9%) patients increased ixekizumab dosage to 80 mg every 2 weeks; of these patients, 89.8% were PASI 50 responders and 59.8% were PASI 75 responders
* Recommended ixekizumab dosing regimen: starting dose of 160 mg, then 80 mg every 2 weeks up to and including Week 12, followed by 80 mg every 4 weeks thereafter





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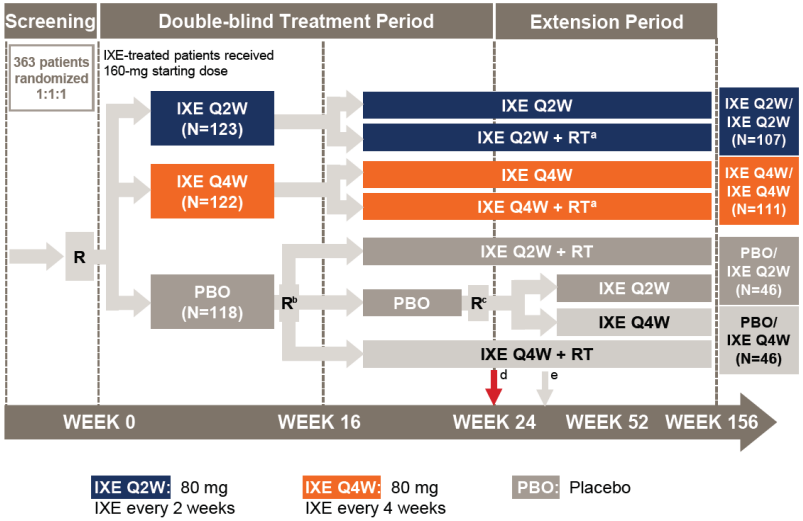
- **IXEKIZUMAB**

METHODS

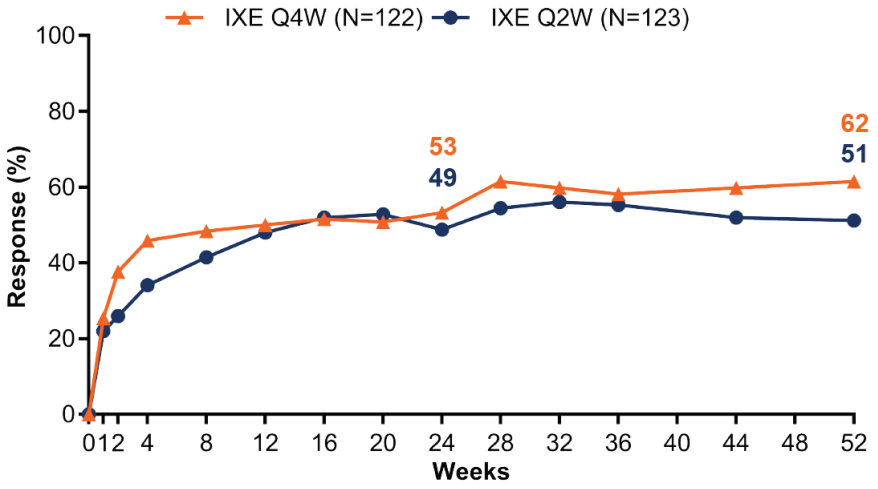
Figure 1. Study Design, SPIRIT-P2



[a] IRs in IXE arms at Week 16 maintained their IXE dose, but received RT (modifications to the patient's background therapy); [b] IRs in the PBO arm at Week 16 were randomized to IXE Q2W + RT or IXE Q4W + RT after a 160-mg starting dose. Responders continued on PBO until Week 24; [c] Patients receiving PBO until Week 24 were randomized to IXE Q2W or IXE Q4W after a 160-mg starting dose; [d] Primary endpoint; [e] Patients failing to demonstrate at least 20% improvement from baseline in both TJC and SJC at Week 32 or any subsequent visit were discontinued

IR=inadequate responder; IXE=ixekizumab; R=randomization; SJC=swollen joint count; TJC=tender joint count; RT=rescue therapy

Figure 3. Patients Achieving ACR 20, NRI, ITT Population



ACR 20=at least 20% improvement in the American College of Rheumatology response; ITT=Intent-to-Treat; IXE Q2W=80 mg ixekizumab every 2 weeks; IXE Q4W=80 mg ixekizumab every 4 weeks; NRI=non-responder imputation

- Ixekizumab provided persistent efficacy in ACR 20 response rates through 52 weeks of treatment

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- **BRODALUMAB**

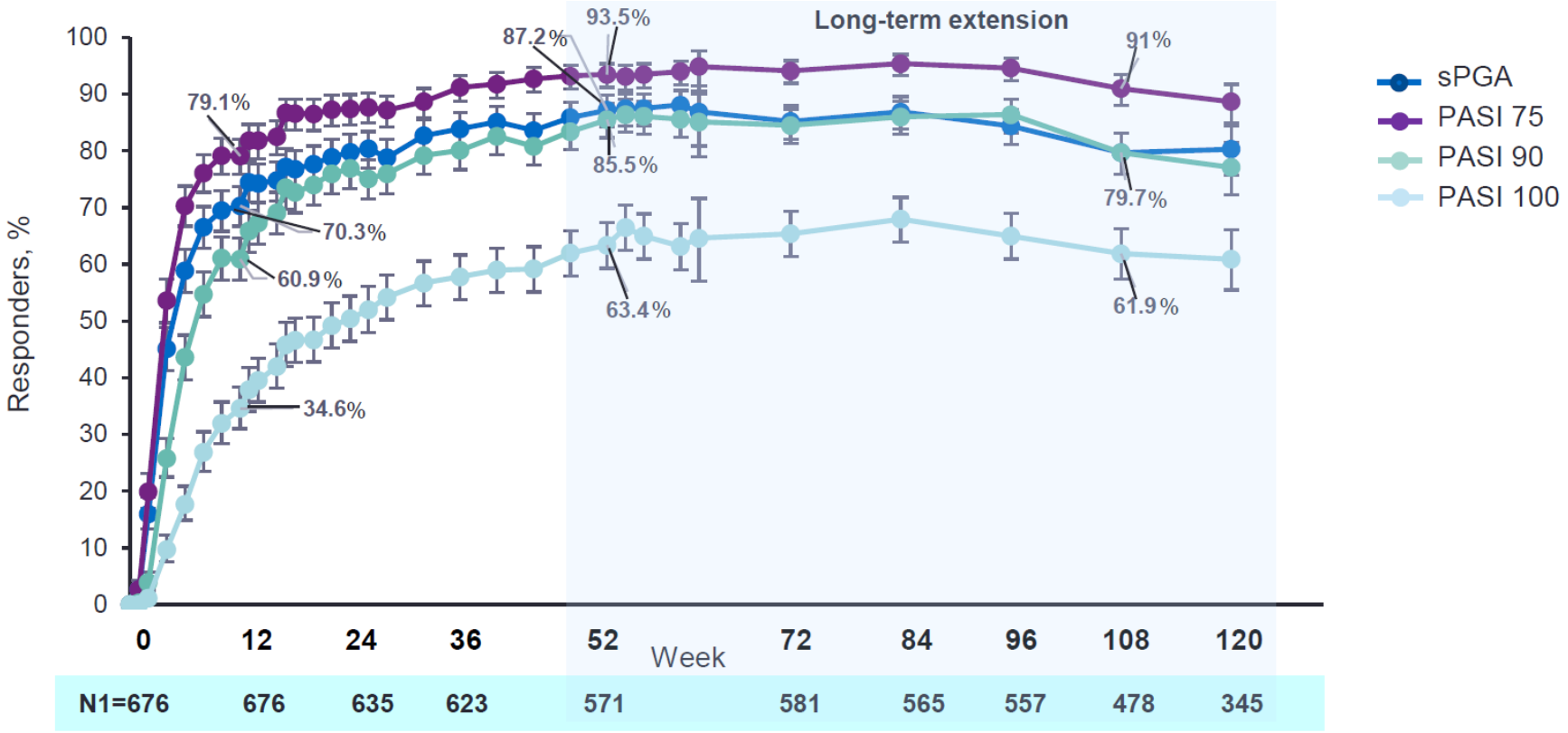

Figure 2. PASI and sPGA rates in patients who received any dose of brodalumab in the induction phase and brodalumab 210 mg Q2W (the US FDA–approved dose) during the maintenance and long-term extension phases (n=676).

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- **BRODALUMAB**

Icahn School of Medicine at Mount Sinai

Brodalumab in the treatment of moderate-to-severe psoriasis in patients who have previously failed treatment with anti-interleukin-17A therapies.

Grace Kimmel MD, Margot Chima MD, Hee Jin Kim MD, Christopher Yao MPH, Giselle Singer BS, and Mark Lebwohl MD.
Icahn School of Medicine at Mount Sinai

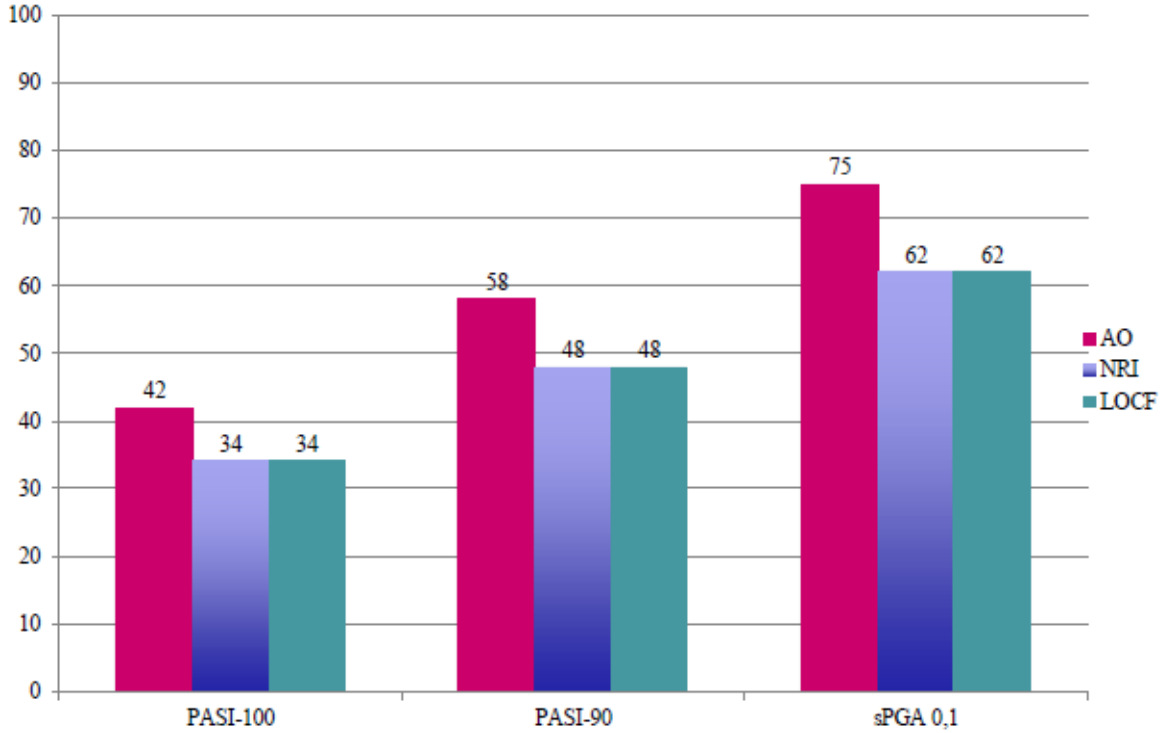

Figure 1. Week 16 results showing the percentage of patients achieving PASI-100, PASI-90, and sPGA scores of 0 or 1. AO= As-observed; NRI= Non-responder imputation, LOCF= Last observation carried forward.

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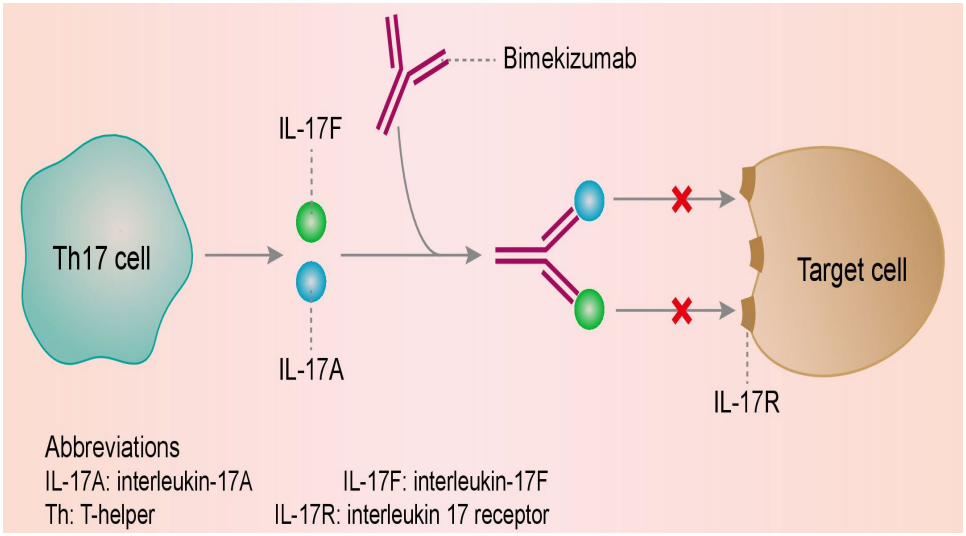
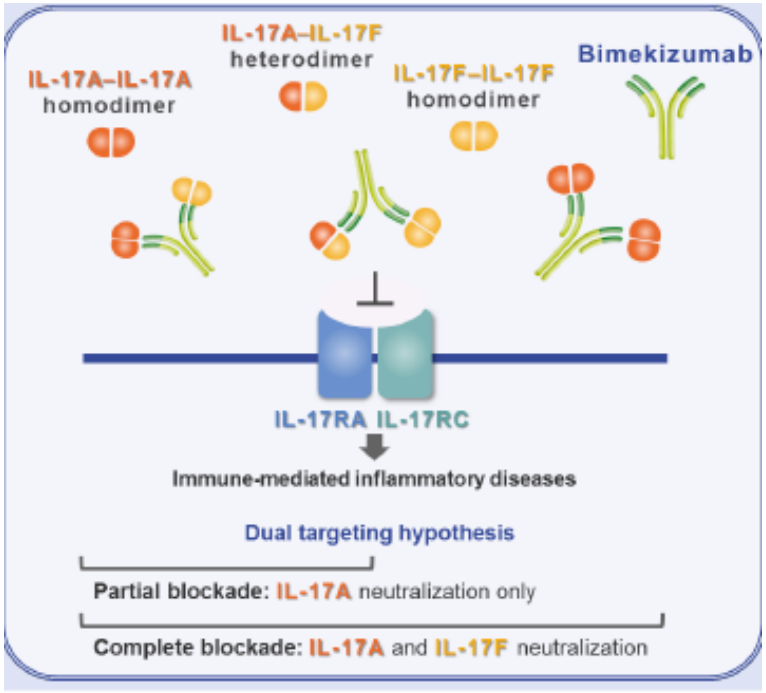
- **BIMEKIZUMAB**





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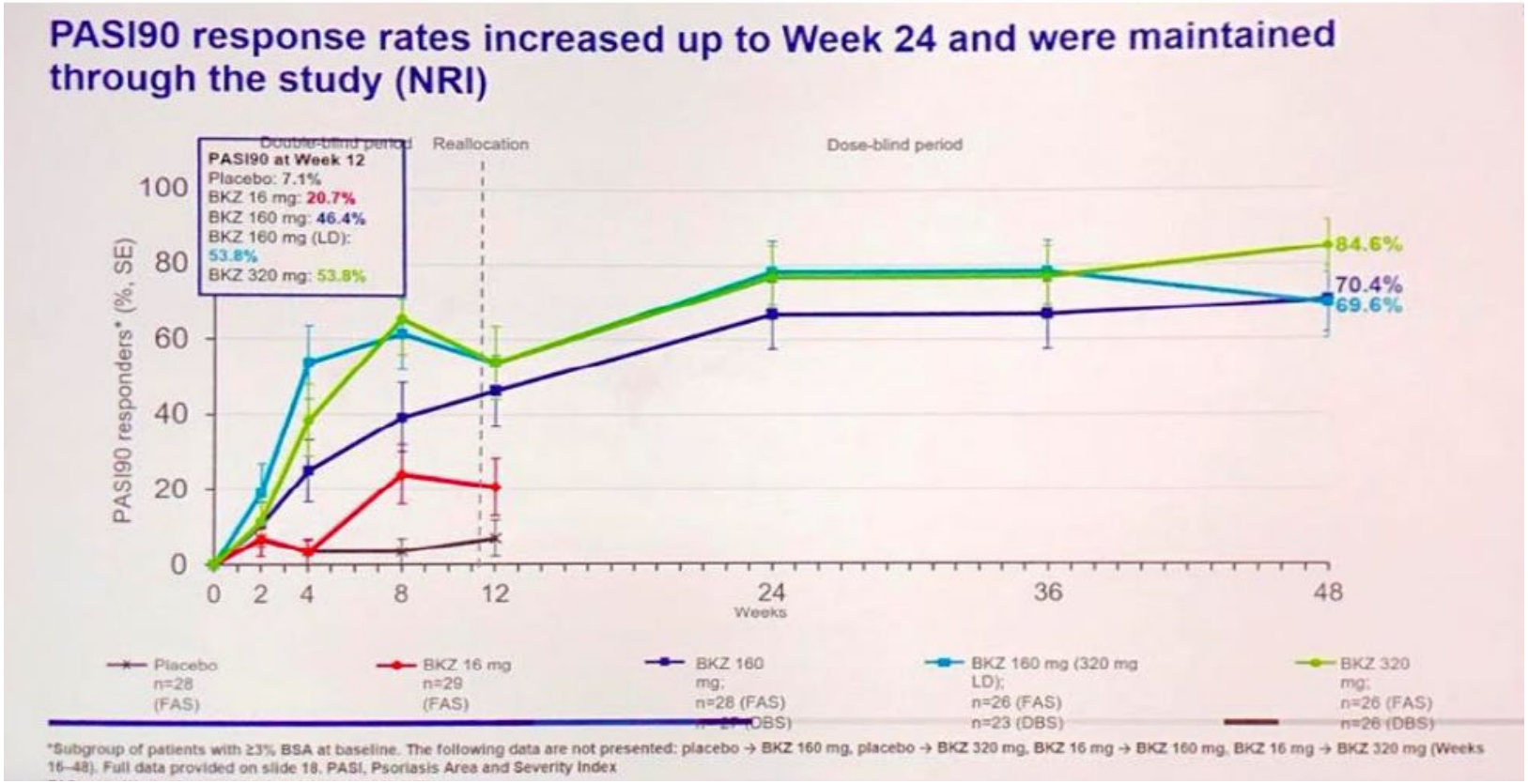
- **BIMEKIZUMAB**



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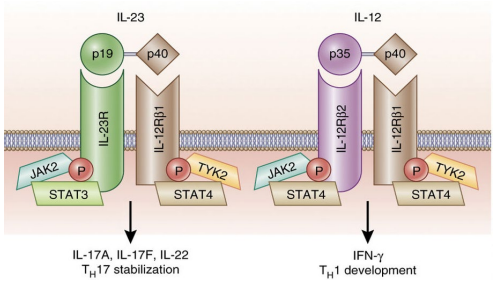
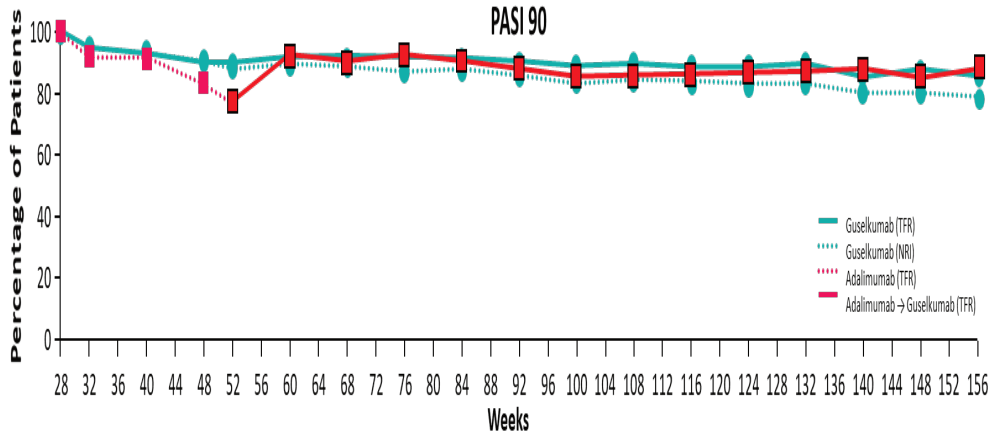
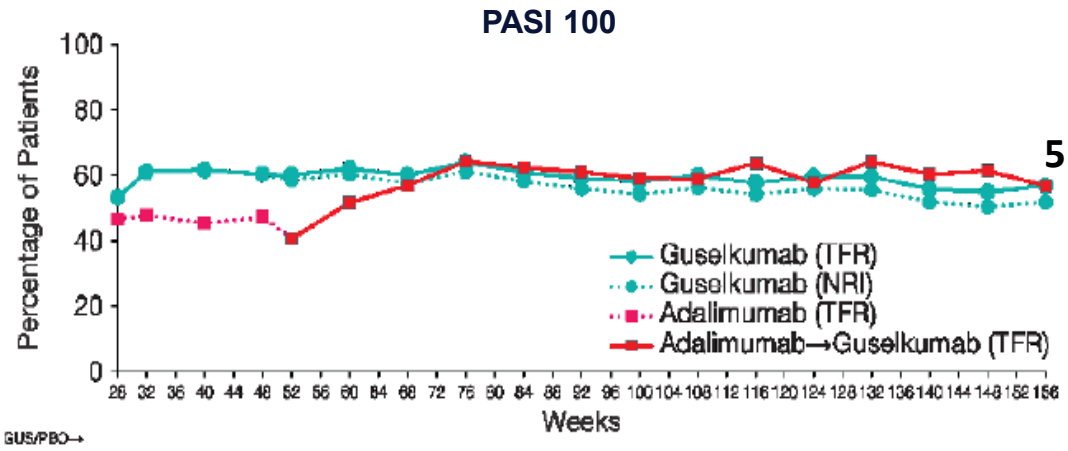
- **GUSELKUMAB**





79,5%



51,8%

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- **GUSELKUMAB**

Figure 5. Proportions of Patients Achieving DLQI Score of 0 or 1 From Weeks 76 Through 156 Among All Patients Treated With Guselkumab During the Open-label Phase (VOYAGE 1)

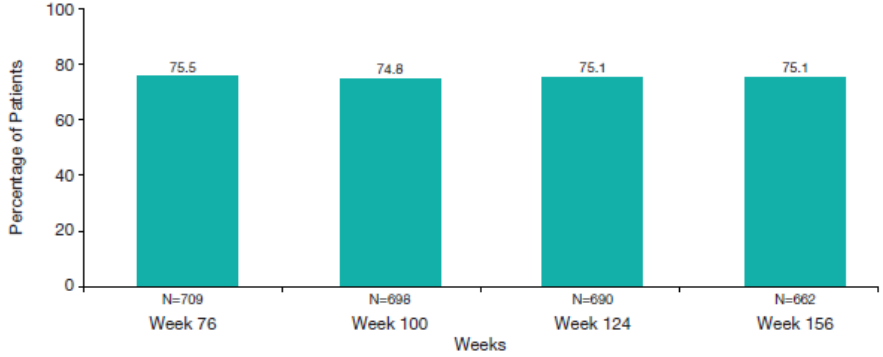
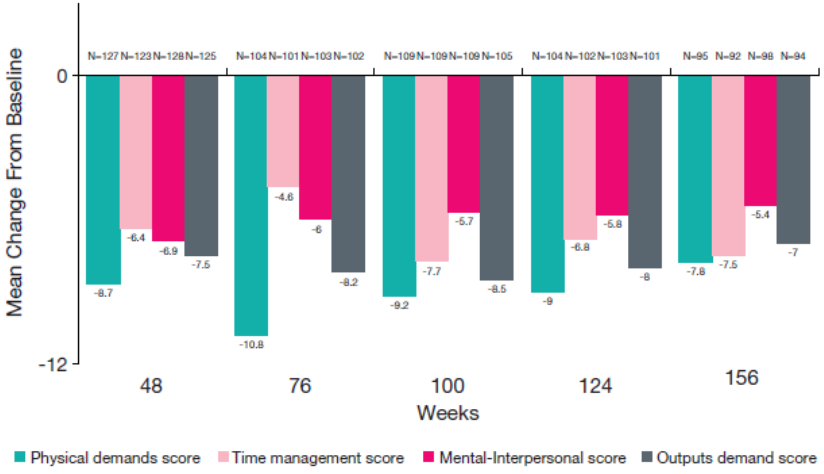


Figure 4A. Mean Change From Baseline Through 3 Years in WLQ Domain Scores Among Patients Re-randomized to GUS at Wk 28



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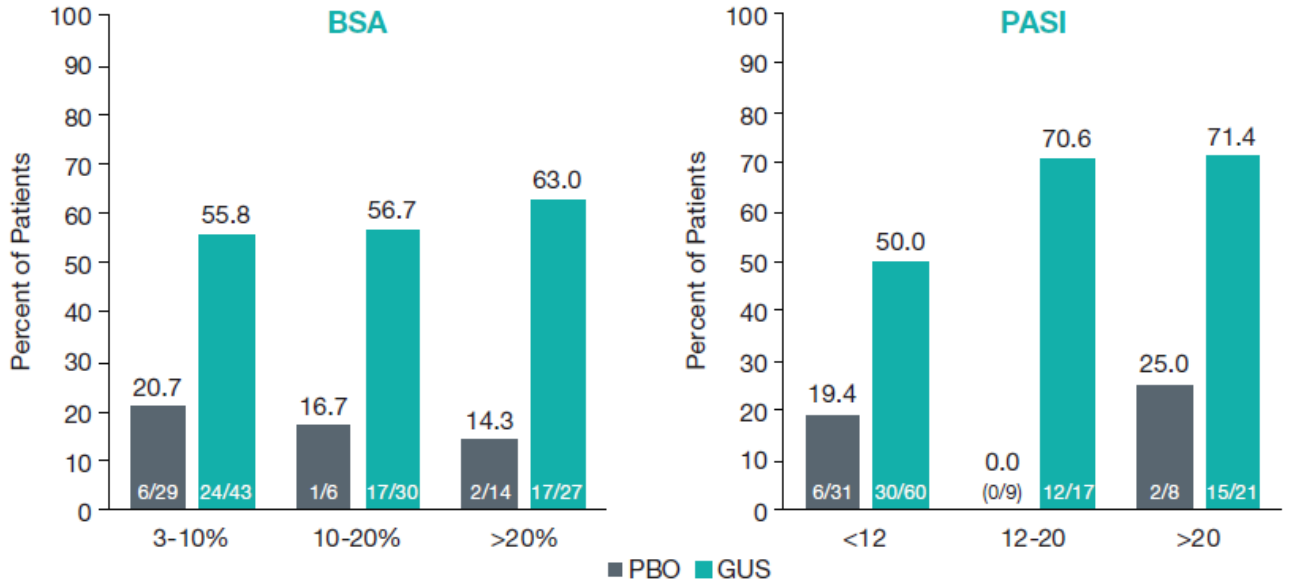
- **GUSELKUMAB**

The Effect of Guselkumab on Psoriasis in Patients With Active Psoriatic Arthritis: Results from a Phase 2 Study

A.B. Gottlieb,[1] W-H. Boehncke,[2] P. Helliwell,[3] A. Deodhar,[4] X.L. Xu,[5] S. Xu,[5] Y. Wang,[5] Y. Zhuang,[5] E.C. Hsia[5]

Figure 2. ACR 20 Response Rates at Week 24 by Baseline BSA or PASI Score



BSA=Body Surface Area; PASI=Psoriasis Area and Severity Index

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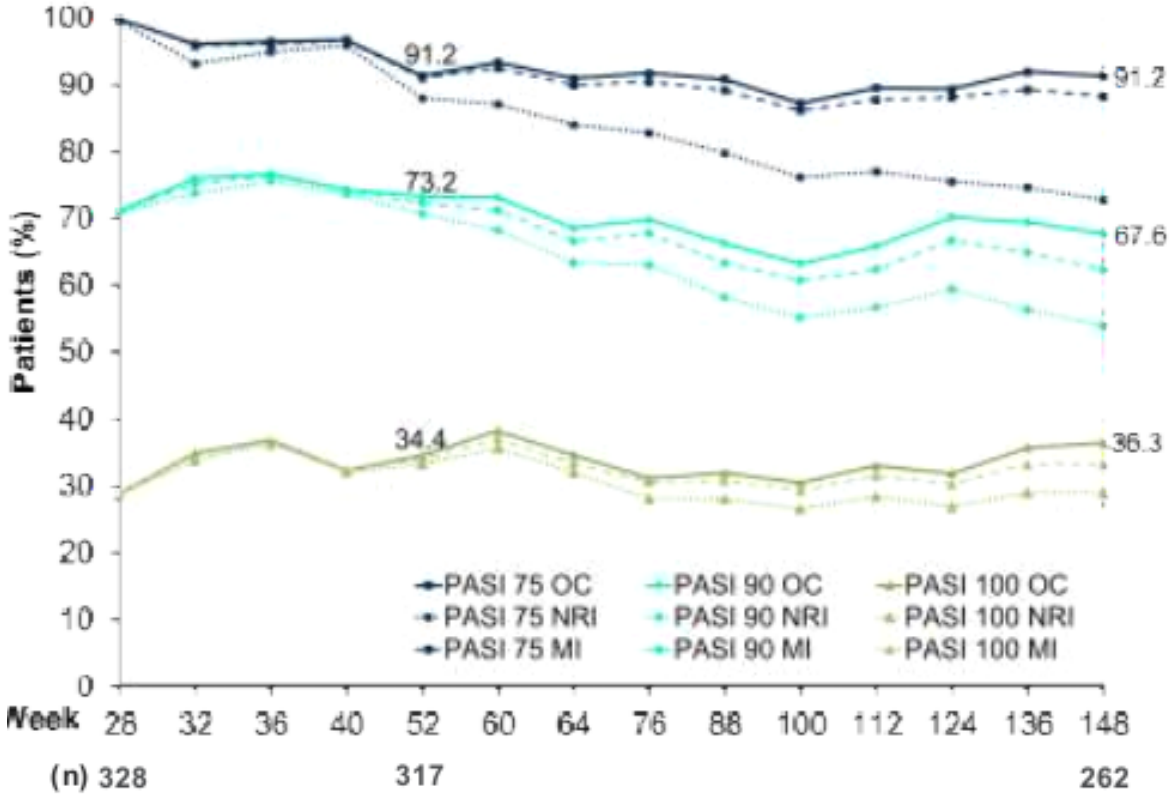
- **TILDRAKIZUMAB**

Figure 2. PASI 75/90/100 responses in patients treated with tildrakizumab 100 mg through week 148



MI, multiple imputation; NRI, non-responder imputation; OC, observed cases.

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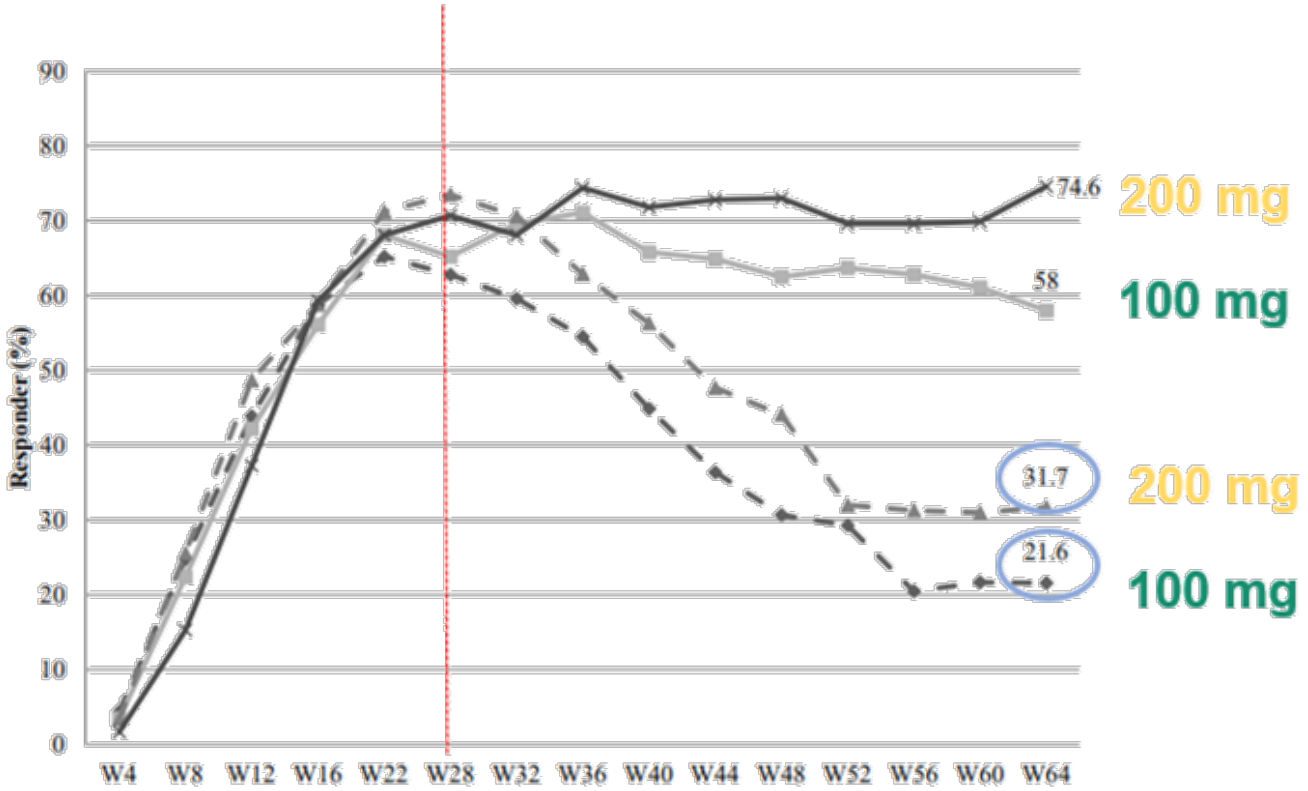
- **TILDRAKIZUMAB**

PASI 90



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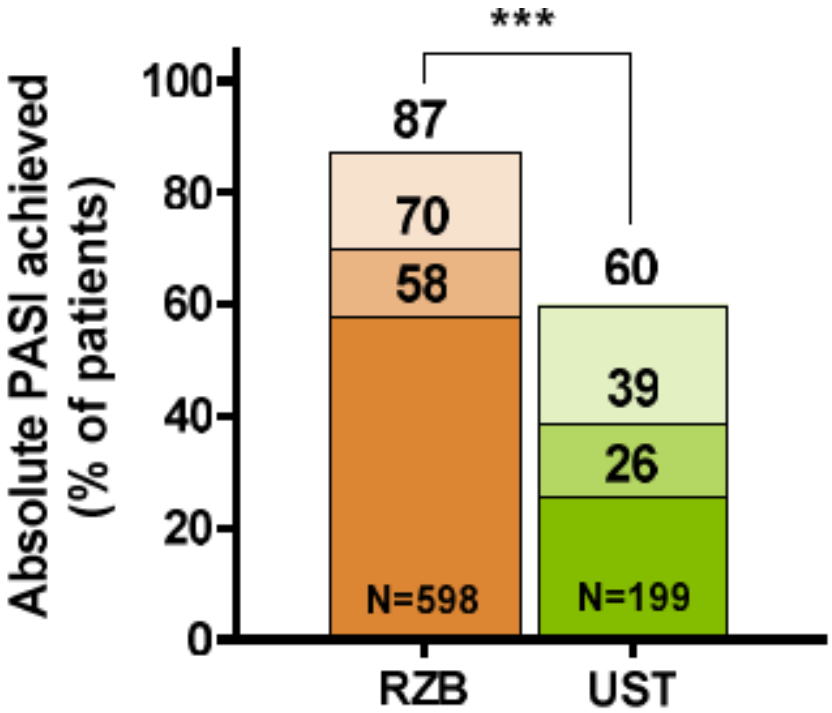
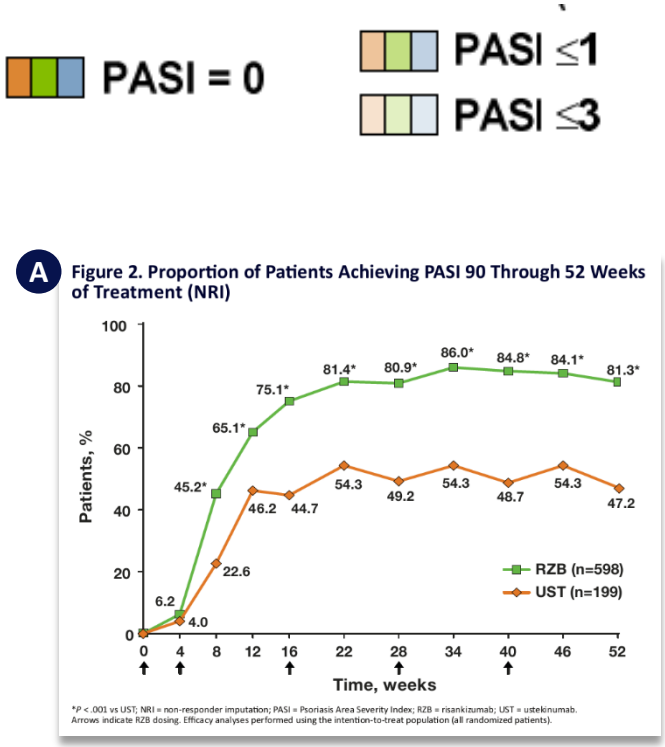
- **RISANKIZUMAB**





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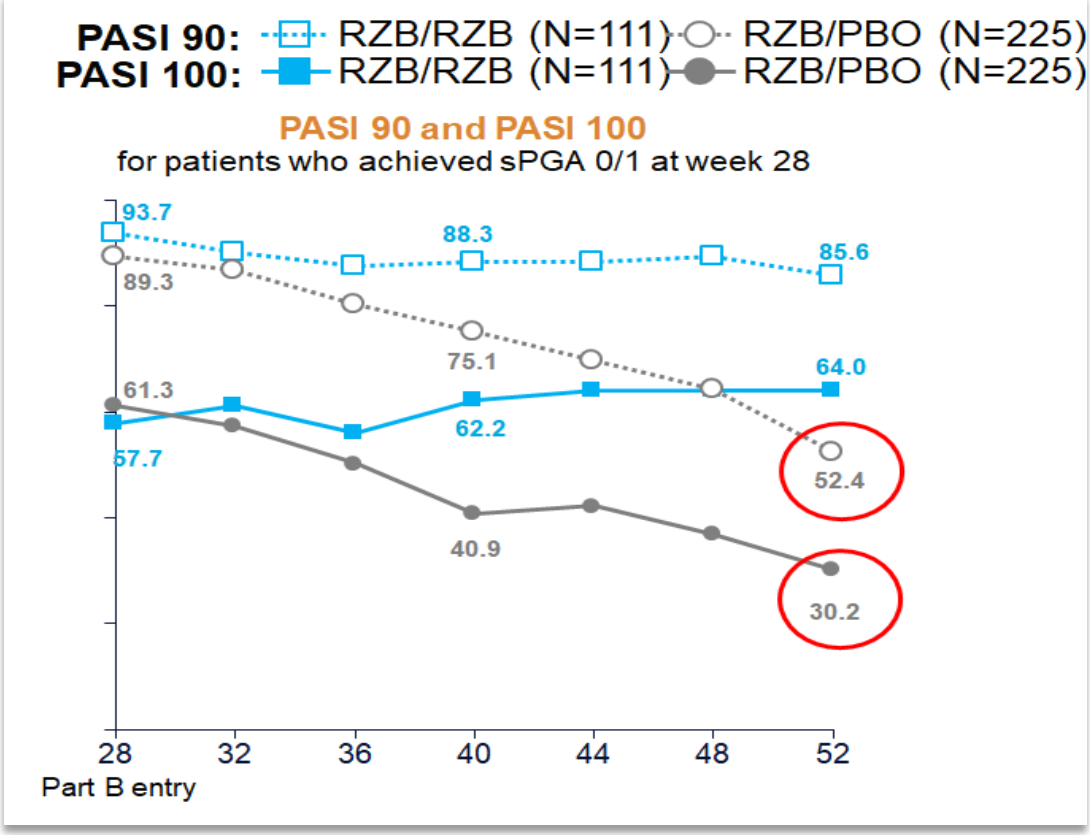
- **RISANKIZUMAB**



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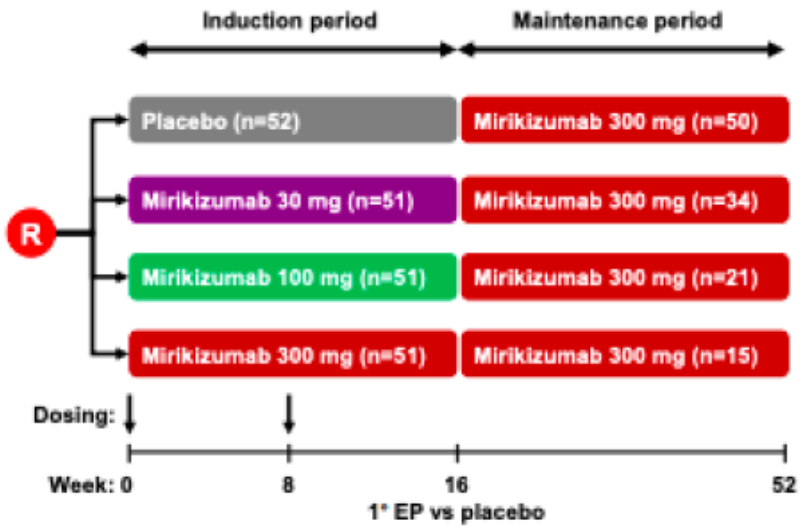
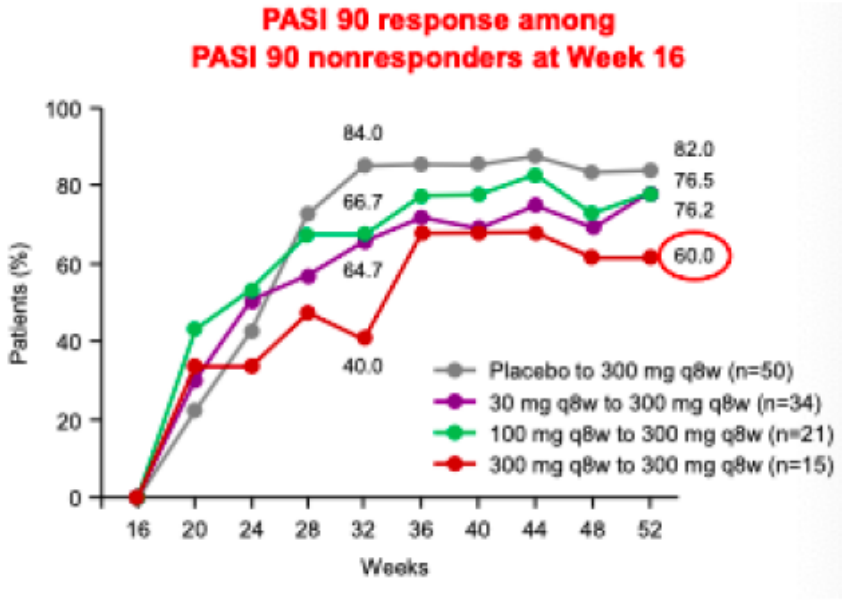
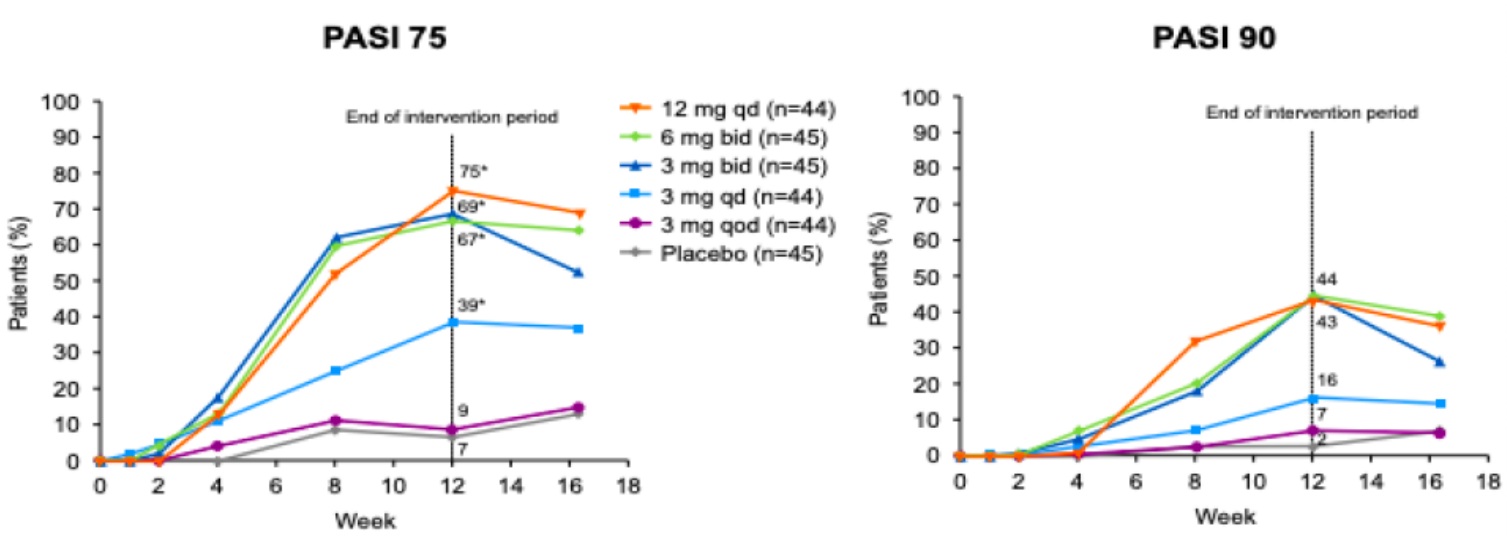
- **MIRIKIZUMAB**





Milàn

ANTI TYK-2. BMS-986165



	Placebo (n=45)	BMS-986165				
		3 mg qod (n=44)	3 mg qd (n=44)	3 mg bid (n=45)	6 mg bid (n=45)	12 mg qd (n=44)
Serious AEs	1 (2)	1 (2)	1 (2)	1 (2)	0	0
AEs	23 (51)	26 (59)	24 (55)	29 (64)	36 (80)	34 (77)
Drug-related AEs	7 (16)	6 (14)	7 (16)	13 (29)	12 (27)	10 (23)
Discontinuations due to AEs	2 (4)	1 (2)	2 (5)	1 (2)	3 (7)	1 (2)
Most frequently reported AEs						
Nasopharyngitis	2 (4)	1 (2)	4 (9)	5 (11)	7 (16)	2 (5)
Headache	2 (4)	4 (9)	4 (9)	3 (7)	3 (7)	2 (5)
Diarrhea	2 (4)	1 (2)	1 (2)	2 (4)	2 (4)	4 (9)
Nausea	2 (4)	4 (9)	0	1 (2)	1 (2)	2 (5)
URTI	0	1 (2)	3 (7)	1 (2)	4 (9)	1 (2)
Acne	0	1 (2)	0	1 (2)	2 (4)	4 (9)

Data are n (%)

- Preliminary but reassuring safety data suggest that TYK2 inhibition with BMS-986165 is selective and well tolerated

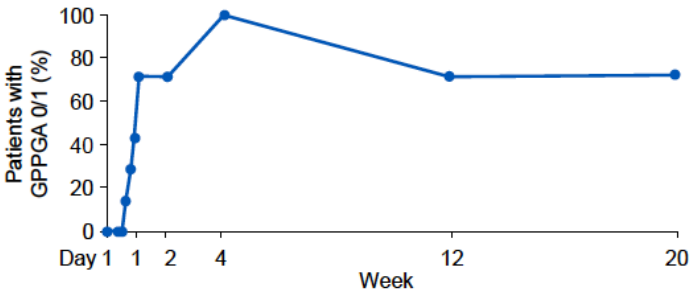
Generalized pustular psoriasis. Anti IL-36R

Phase 1 study: Safety and efficacy of BI 655130 for acute generalized pustular psoriasis

Summary of AEs through Week 20

AEs	BI 655130 10 mg/kg (n=7)
Any AE	7 (100)
Severe AE	0
Drug-related AE	
Eosinophilia	4 (57.1)
Vomiting	2 (28.6)
Chills	1 (14.3)
Pain[a]	1 (14.3)
URTI	2 (28.6)
UTI	1 (14.3)
Infusion-related reaction	1 (14.3)
Arthralgia	1 (14.3)
AEs leading to discontinuation	0
Serious drug-related AEs	0

GPPGA total score of 0/1



GPPGA score 0/1 achieved in 5 patients (71.4%) by Week 1, and in all patients by Week 4

- Preliminary evidence in support of safety and efficacy of IL-36R inhibition to treat GPP flares

Milàn

Clinical Efficacy of Thalidomide combined with Avermectin A in the treatment of Generalized Pustular Psoriasis. Li, et al (China)

Therapeutic regimen	cases	Temperature drops to normal (d)	Hospitalization time (d)	Side effects	Therapeutic effect (cases)			
					Recovery	apparent effect	improvement	invalid
acitretin + thalidomide	38	4.4±0.6*	10.3±0.8*	Almost none	26	12	0	0
acitretin	41	10.8±2.2	21.0±2.2	abnormal liver function; Itchy skin	9	11	19	2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