EULAR REVIEW

#EULAREVIEW19

MADRID JUNIO 2019

Annual European Congress of Rheumatology

Con la colaboración de:

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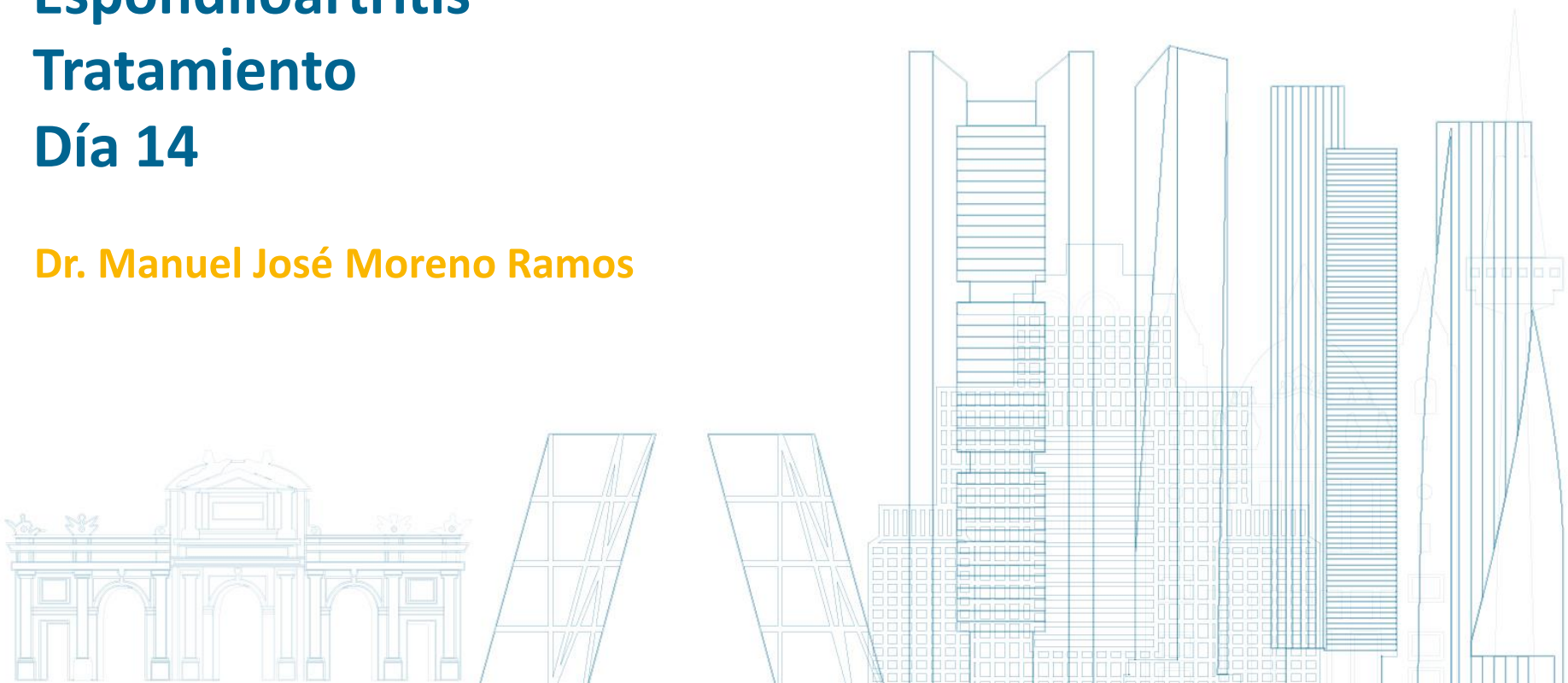
Espondiloartritis
Tratamiento
Día 14

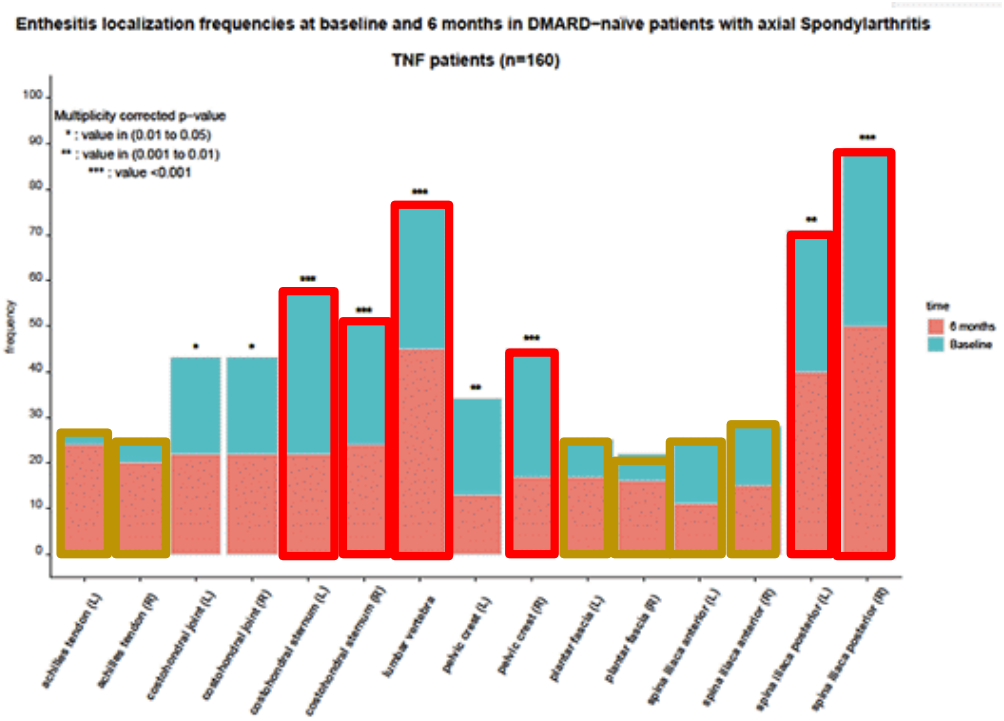
Dr. Manuel José Moreno Ramos



FRI0375

SITE-SPECIFIC EFFECTIVENESS OF TNF INHIBITORS FOR ENTHESITIS IN DMARD-NAÏVE PATIENTS WITH AXIAL SPONDYLOARTHRITIS

- Retrospectivo (cohorte suiza, SCQM).
- Eficacia TNFi en EspA-Ax (entesis); DMARD naïve (n=781).
- MASES basal (n= 160, entesis activas) y 6 meses (**45%** resolución completa).
- Entesis resueltas completamente: costocondral esternal y articulación costocondral, vertebra lumbar, cresta pélvica y espina ilíaca posterior.
- Entesis con parcial resolución: espina ilíaca anterior, fascia plantar y tendón de Aquiles.
- **> resolución entesis torácicas y columna y menos en miembros inferiores (factores mecánicos?).**

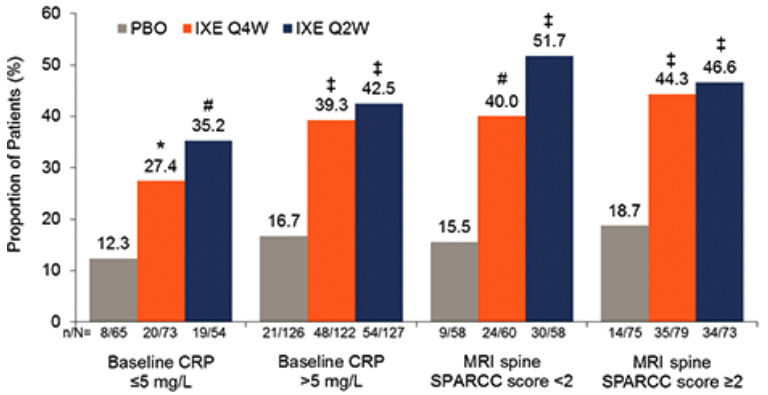


FRI0398

IXEKIZUMAB IS EFFECTIVE IN THE TREATMENT OF RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS REGARDLESS OF THE LEVEL OF C-REACTIVE PROTEIN OR MAGNETIC RESONANCE IMAGING SCORES: 16-WEEK DATA FROM COAST-V AND COAST-W

- PCR alta predice buena respuesta a TNFi pero no a Secukinumab.
- El papel de la RMN basal de columna como predictor de respuesta a los IL17i no ha sido estudiada.
- Objetivo 1º: ASAS40 a semana 16 según PCR < o > 5 mg/l o RMN de columna SPARCC <2 o > 2 (ECA fase 3: COAST-V-naïve a TB- Y COAST-W-TNFI previo).
- IXE>PBO para alcanzar ASAS40 sem 16, independientemente de los valores basales de la PCR o de la actividad axial por RMN (Figura 1).
- **IXE demuestra eficacia a las 16 sem en el manejo de EA/EspA axial, independientemente de PCR / RMN basales.**

Figure 1 **COAST-V/W Integrated Dataset, ITT ASAS40 Response at Week 16, NRI**



*p<.05, #p<.01, ‡p<.001 versus placebo. ASAS40=Assessment in SpondyloArthritis international Society 40% response rate; CRP=C-reactive protein; ITT=intent-to-treat; IXE=ixekizumab; n=number of patients in the specified category; N=number of patients in the analysis population; NRI=nonresponder imputation; PBO=placebo; Q2W=every 2 weeks; Q4W=every 4 weeks; SPARCC=Spondyloarthritis Research Consortium of Canada

FRI0412

SPINAL AND SACROILIAC JOINTS INFLAMMATION IN PATIENTS WITH RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS TREATED WITH NETAKIMAB-16-WEEKS RESULTS OF MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III ASTERA STUDY

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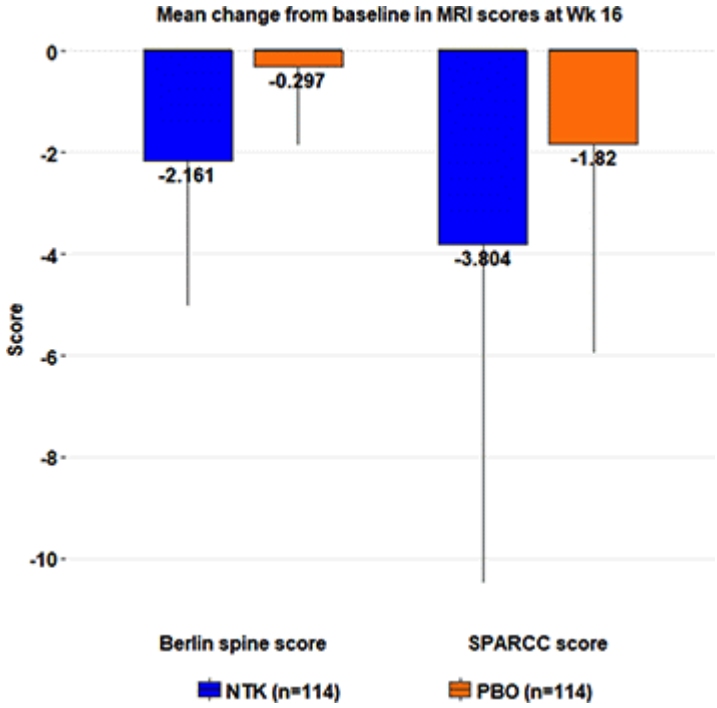
- NTK (IL17Ai), ASTERA (ECA fase 3, eficacia y seguridad en EspA-Ax-r; n= 228).
- Objetivo: eficacia en inflamación (RMN) columna y sacroiliacas semana 16.
- 2 brazos: NTK 120 mg vs PBO sc Wk 0, 1, 2 y cada 2 sem, hasta sem 16 (abierto con NTK hasta sem 52).
- RMN basal y sem 16 (Berlin spine score y SPARCC score).
- **NTK (120 mg sc) mejora EMO en CV/SI en EspA-Ax-r a la semana 16 vs PBO.**



FRI0452

TOFACITINIB IN PATIENTS WITH PSORIATIC ARTHRITIS: ANALYSIS OF DERMATOLOGIC ENDPOINTS FROM 2 PHASE 3 STUDIES

- Objetivo: eficacia TOFA en piel en Aps activa.
- 2 ECA fase 3 Aps activa csDMARD-IR (OPAL Broaden-TNFi naïve-; OPAL Beyond-TNFi-IR-).
- TOFA 5 mg BID, 10 mg BID, ADA 40 mg c2sem (OPAL Broaden), PBO (a 3º mes, pasa a Tofa 5-10 mg).
- Variables: PASI total, PASI 75 y PGJS-VAS Psoriasis (% cambio desde basal-mes 6-12).
- Resultados (Tabla): mejoría en todas las variables en los pacientes con Tofa, con dif. signif. con respecto a PBO.
- **En pacientes con Aps (TNFi naïve o TNFi-IR), Tofa mejora piel y la respuesta es mantenida.**

OPAL-broaden (TNFi naive) **OPAL-Beyond (TNFi-IR)**

Table. Dermatologic endpoints in OPAL Broaden and OPAL Beyond

Month	OPAL Broaden (up to M12; N=422) Tofacitinib 5 mg BID N=107	Tofacitinib 10 mg BID N=104	Adalimumab 40 mg SC Q2W N=186	PBO N=105	OPAL Beyond (up to M6; N=394) Tofacitinib 5 mg BID N=131	Tofacitinib 10 mg BID N=132	PBO N=131	
			S mean (SE) percentage chang[e] fro[m] baseline in PASI [to]tal score[a,b]					PASI TOTAL
	n=82	n=70	n=77	n=81	n=79	n=79	n=84	
1	-39.1 (5.0)***	-45.1 (5.3)***	-34.1 (5.1)**	-16.5 (5.4)	-25.9 (7.7)*	-33.6 (7.7)**	-4.0 (7.4)	
3	-58.4 (5.7)***	-67.0 (6.0)***	-55.1 (5.8)***	-27.6 (6.0)	-36.5 (7.9)	-47.4 (7.7)**	-17.6 (7.7)	
6	-61.7 (5.4)	-79.9 (5.8)	-71.3 (5.6)	-	-46.7 (7.2)	-53.1 (7.2)	-	
9	-72.8 (5.2)	-85.5 (5.6)	-75.0 (5.4)	-	-	-	-	
12	-80.2 (5.5)	-86.5 (5.9)	-75.0 (5.7)	-	-	-	-	
	Number of re[s]ponders achieving PASI75/pis e[va]luation at visit (%) with [b]aseline PA[SI] >0 to ≤10[b,c,d]							PASI75 (BL 0-10)
1	15/60 (25.0)	15/44 (34.1)	8/47 (17.0)	4/54 (7.4)	10/52 (19.2)	12/45 (26.7)	5/56 (8.9)	
3	29/57 (50.9)	22/44 (50.0)	14/46 (30.4)	9/54 (16.7)	11/45 (24.4)	23/46 (50.0)	12/48 (25.0)	
6	29/57 (50.9)	25/42 (59.5)	23/45 (51.1)	-	17/48 (35.4)	24/42 (57.1)	-	
9	28/57 (49.1)	28/41 (68.3)	22/43 (51.2)	-	-	-	-	
12	37/54 (68.5)	28/41 (68.3)	21/42 (50.0)	-	-	-	-	
	Number o[f] responders achieving PASI75/pi[s] evaluable at visit (%) w[ith] baseline [P]ASI >10[b,c,e]							PASI75 (BL>10)
1	4/21 (19.1)	4/25 (16.0)	3/28 (10.7)	0/26 (0.0)	2/27 (7.4)	3/33 (9.1)	0/28 (0.0)	
3	6/21 (28.6)	9/25 (36.0)	16/28 (57.1)	3/25 (12.0)	6/27 (22.2)	12/30 (40.0)	0/25 (0.0)	
6	9/20 (45.0)	17/25 (68.0)	19/28 (67.9)	-	10/27 (37.0)	13/29 (44.8)	-	
9	8/20 (40.0)	20/25 (80.0)	23/28 (82.1)	-	-	-	-	
12	9/19 (47.4)	19/24 (79.2)	22/28 (78.6)	-	-	-	-	
	S mean (SE) change from base[li]ne in PGJS-VAS Psoria[sis] question[b]							PGJS-VAS-PsO
	n=106	n=104	n=106	n=104	n=128	n=130	n=130	
1	-18.6 (2.3)***	-22.1 (2.3)***	-15.0 (2.3)**	-6.7 (2.5)	-21.4 (2.0)***	-23.3 (2.0)***	-7.4 (2.0)	
3	-25.3 (2.4)***	-29.7 (2.4)***	-23.4 (2.5)***	-10.6 (2.6)	-22.4 (2.3)***	-27.6 (2.3)***	-7.7 (2.3)	
6	-27.0 (2.4)	-30.8 (2.4)	-26.1 (2.4)	-	-21.7 (2.3)	-27.8 (2.3)	-	
9	-27.4 (2.4)	-32.3 (2.4)	-27.0 (2.5)	-	-	-	-	
12	-27.8 (2.5)	-30.4 (2.5)	-27.0 (2.5)	-	-	-	-	

[a]Measured in patients with baseline BSA ≥3% and PASI >0. [b]This analysis was pre-specified; the total number of patients by treatment group included in the longitudinal model is shown as n; [c]Post hoc analysis; [d]PASI >0 to ≤10 was considered 'mild'; [e]PASI >10 was considered 'moderate/severe'; [f]Patients answered the question "In all the ways your psoriasis affects you, how would you rate the way in which you felt over the past week?", and their response was recorded on a VAS of 0–100 mm (0 = excellent; 100 = poor)

N = number of patients in the full analysis set.

*Nominal p≤0.05; **p<0.01; ***p<0.001 vs PBO. No imputation was applied for missing values

For percentage change from baseline in PASI total score and change from baseline in PGJS-VAS, the data were analysed using a repeated-measures model with fixed effects for treatment group, visit, interaction of the treatment group by visit, geographic location and baseline value. The model used a common unstructured variance–covariance matrix, without imputation for missing data. Two models were used. In the analyses of results through the first 3 months, the two PBO-to-tofacitinib sequences were combined into a single PBO group (pooled PBO group); the results through M3 were from this model. In the analyses of results after M3 (including all post-baseline data through M6 for OPAL Beyond and M12 for OPAL Broaden), the PBO-to-tofacitinib sequences were kept separate; the results after M3 were from this model

BID, twice daily; BSA, body surface area; Q2W, once every 2 weeks; LS, least squares; M, month; PASI, Psoriasis Area and Severity Index; PASI75, >75% PASI improvement from baseline; PBO, placebo; PGJS-VAS Psoriasis, Patient's Global Joint and Skin Assessment-Visual Analogue Scale Psoriasis question: pts. patients; SC, subcutaneous; SE, standard error; VAS, visual analogue scale

OP0234

EFFICACY AND SAFETY OF BRODALUMAB, AN ANTI-INTERLEUKIN-17 RECEPTOR A MONOCLONAL ANTIBODY, IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: A 16-WEEK RESULTS OF A PHASE 3, MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

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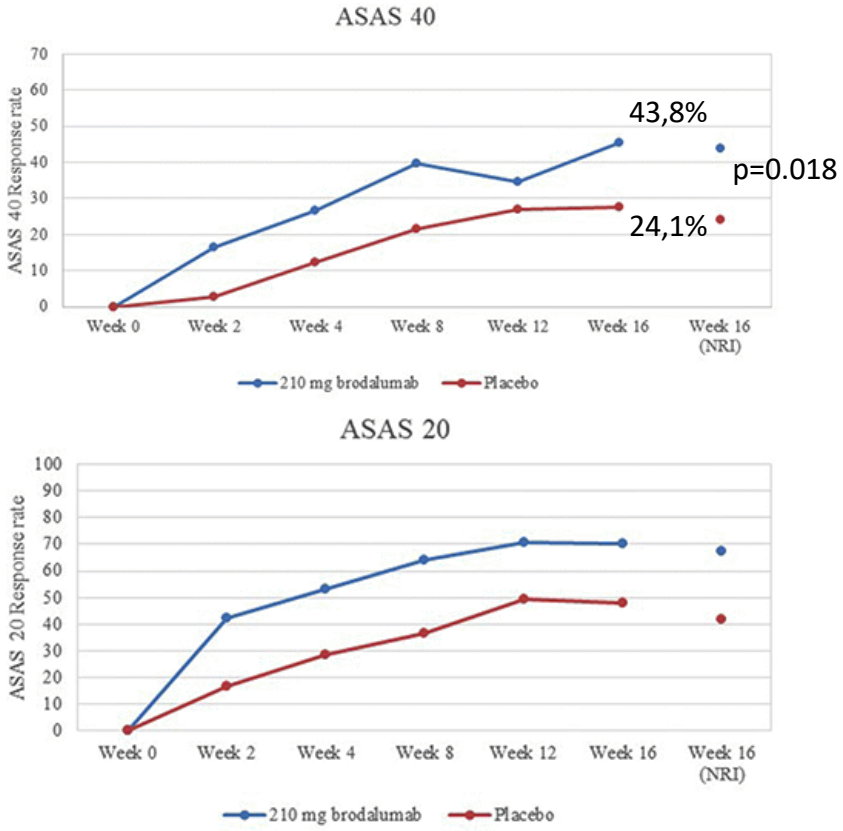
- ECA fase 3, eficacia y seguridad Broda (IL17A-Ri) en EspA axial (EA y EspA-Ax-nr).
- Broda 210 mg vs PBO (n= 159): 0, 1, 2, c/2 sem (sem 16 y después OLE).
- Objetivo 1º: ASAS40 16w.
- Resultados:
  - ASAS40 y ASAS20 (tabla).
  - ASDAS-PCR, BASDAI, BASFI.

- **Broda 210 mg sc c/2w eficaz y seguro en EspA-Ax (16w).**

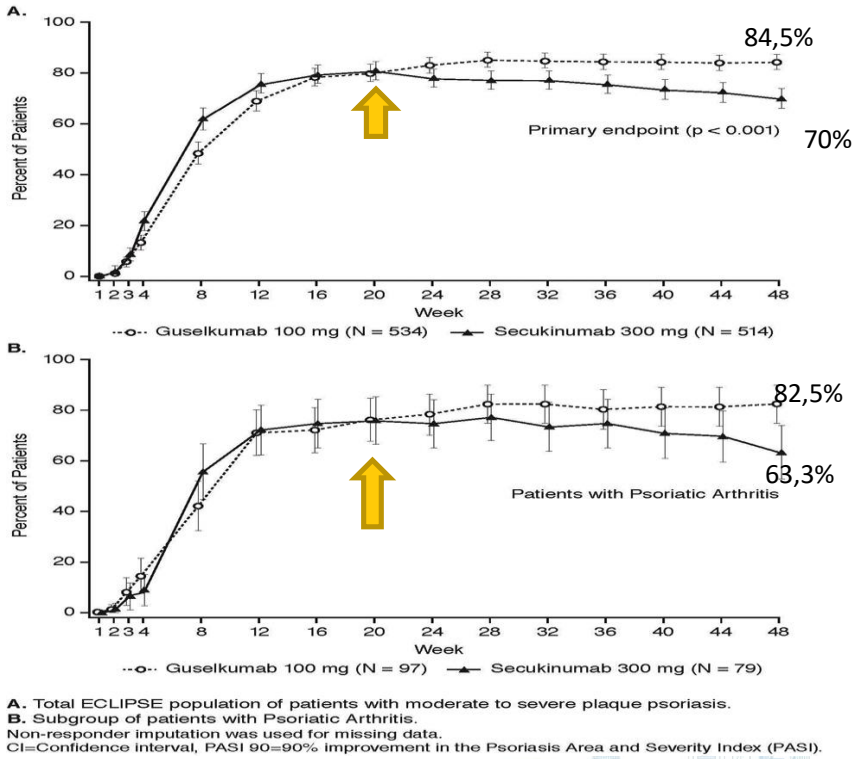


SAT0390

GUSELKUMAB WAS MORE EFFECTIVE THAN SECUKINUMAB IN PATIENTS WITH PLAQUE PSORIASIS AND THE SUBSET OF PATIENTS WITH SELF-REPORTED PSORIATIC ARTHRITIS IN THE RANDOMIZED, DOUBLE-BLIND, HEAD-TO-HEAD COMPARISON STUDY ECLIPSE OVER 1 YEAR

- ECLIPSE (ECA GUS-IL23i- vs SECU).
- Eficacia en psoriasis moderada-severa y secundariamente, eficacia en piel en pacientes con Aps (post-hoc).
- GUS 100 mg sc 0, 4, c/8w (n= 534) / SECU 300mg 0, 1, 2, 3, 4, c/4w (n= 514).
- Objetivo 1º: PASI90 48w.
- Resultados (figura).
- **En el subgrupo de pacientes con Aps, GUS es más eficaz que SECU y mantiene respuesta a 1 año, en el manejo de Pso en placas moderada-severa.**

Figure. Proportion of Patients Achieving PASI 90 Response (95% CI)



A. Total ECLIPSE population of patients with moderate to severe plaque psoriasis.
B. Subgroup of patients with Psoriatic Arthritis.
Non-responder imputation was used for missing data.
CI=Confidence interval, PASI 90=90% improvement in the Psoriasis Area and Severity Index (PASI).

SAT0393

EFFECTIVENESS AND SAFETY OF INFLIXIMAB, GOLIMUMAB AND USTEKINUMAB IN PSORIATIC ARTHRITIS PATIENTS FROM A PROSPECTIVE OBSERVATIONAL REGISTRY

- BioTRAC (n=462 Aps; Canadá).
- Características clínicas de los 3 grupos similares.
- > afectación articular basal en GLM.
- > afectación cutánea basal en UST.

- MDA UST / GLM > MDA IFX.

- **La afectación articular y cutánea basal puede orientar hacia distintas dianas terapéuticas.**

	IFX (n=111)	GLM (n= 281)	UST (n=70)
Hombres (%)	52,3	46,3	37,1
Edad (años)	48,4	52,8	53,1
Duración Enf (años)	5,8	6,1	5,7
TB naïve (%)	85,6	77,9	55,7
DAS28-PCR (1)		3,9	3,4
SJC (2)		5,3	3,8
PASI (3)		2,2	4,8
MDA 12m (%)	40,7	64,7**	58,8*
MDA 24m (%)	50	68,8**	60*
MDA 36m (%)	55	78,9**	83,3*

(1) p=0.0031. (2) p= 0.0046 (3) p = 0.0061
* p<0.001 vs IFX; **p=0.004 vs IFX

SAT0397

DESCRIPTIVE COMPARISONS OF THE IMPACT OF APREMILAST AND METHOTREXATE MONOTHERAPY ON PATIENTS WITH OLIGOARTICULAR PSORIATIC ARTHRITIS IN THE CORRONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS REGISTRY

- Caract. basales / 6 meses en Aps oligoarticular que inicia APR o MTX (monoterapia) en el registro Corrona (como referencia se compara con bDMARD en monoterapia).
- n= 150 (APR n=34, MTX n=15, bDMARD n=101).
- A los 6 meses: mejores resultados globales en el grupo de APR con respecto al de MTX, y comparables al de bDMARD.

- APR más usado que MTX en oligoartritis refractaria, con mayor mejoría y resultados comparables a bDMARD.

Clinical Disease Assessments of Corrona PsA/SpA Registry Patients With Oligoarthritis at the 6-Month Visit

Disease Characteristics	APR n=34	MTX n=15	bDMARD n=101
Swollen joint count (0-66)	n=34	n=15	n=101
Mean (SD) change	−0.4 (1.2)	0.1 (0.4)	0.2 (1.4)
Achieved swollen joint count (0-66) ≤1*	n=17	n=4	n=26
n (%)	7 (41.2)	0 (0.0)	4 (15.4)
cDAPSA (0-154)	n=32	n=11	n=96
Mean (SD) change	−1.5 (5.8)	−0.2 (1.9)	−0.1 (6.8)
cDAPSA category§, n (%)	n=17	n=3	n=36
Remission (≤4)	1 (5.9)	0 (0.0)	2 (5.6)
Low disease activity (>4–≤13)	4 (23.5)	0 (0.0)	6 (16.7)
PtGA-PsO (VAS 0-100 mm)	n=34	n=11	n=97
Mean (SD) change	−2.3 (22.1)	1.7 (10.1)	−2.0 (27.4)
PtGA-PsA (VAS 0-100 mm)	n=34	n=13	n=97
Mean (SD) change	−0.2 (23.8)	2.5 (13.9)	0.4 (25.0)
Patient-reported fatigue (VAS 0-100 mm)	n=33	n=15	n=100
Mean (SD) change	−1.4 (15.7)	0.3 (30.2)	−0.3 (20.1)
Patient-reported overall pain (VAS 0-100 mm)	n=32	n=14	n=99
Mean (SD) change	0.2 (26.3)	−0.1 (15.6)	0.1 (20.4)
Achieved HAQ-DI MCID (≥0.35 point decrease)	n=34	n=14	n=100
n (%)	4 (11.8)	1 (7.1)	8 (8.0)

*Assessed among patients with >1 swollen joint at initiation. §Assessed among patients who did not meet criteria for either cDAPSA remission or low disease activity at the time of treatment initiation. Change at 6 months was calculated as the 6-month visit value minus the baseline value. MCID=minimal clinically important difference; VAS=visual analog scale.

79% de APR había recibido previamente al menos 1 bDMARD, y el 20% de pacientes con MTX.
Pac. con APR eran más jóvenes, más larga enfermedad, más actividad (mayor afectación cutánea, articular, mayor DAPSA) y mayores PROs que el grupo con MTX.