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Sociedad Española de Reumatología

EULAR REVIEW

MADRID JUNIO 2017

Annual European Congress of Rheumatology

Artritis psoriásica. Tratamiento

José Francisco García Llorente

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THU0038: BIMEKIZUMAB DUAL INHIBITION OF IL-17A AND IL-17F PROVIDES EVIDENCE OF IL-17F CONTRIBUTION TO CHRONIC INFLAMMATION IN DISEASE-RELEVANT CELLS.

Presenting Author

Ash Maroof (United Kingdom)

- IL17A: papel relevante en las enfermedades inflamatorias de etiología inmune.

- IL17F: ??

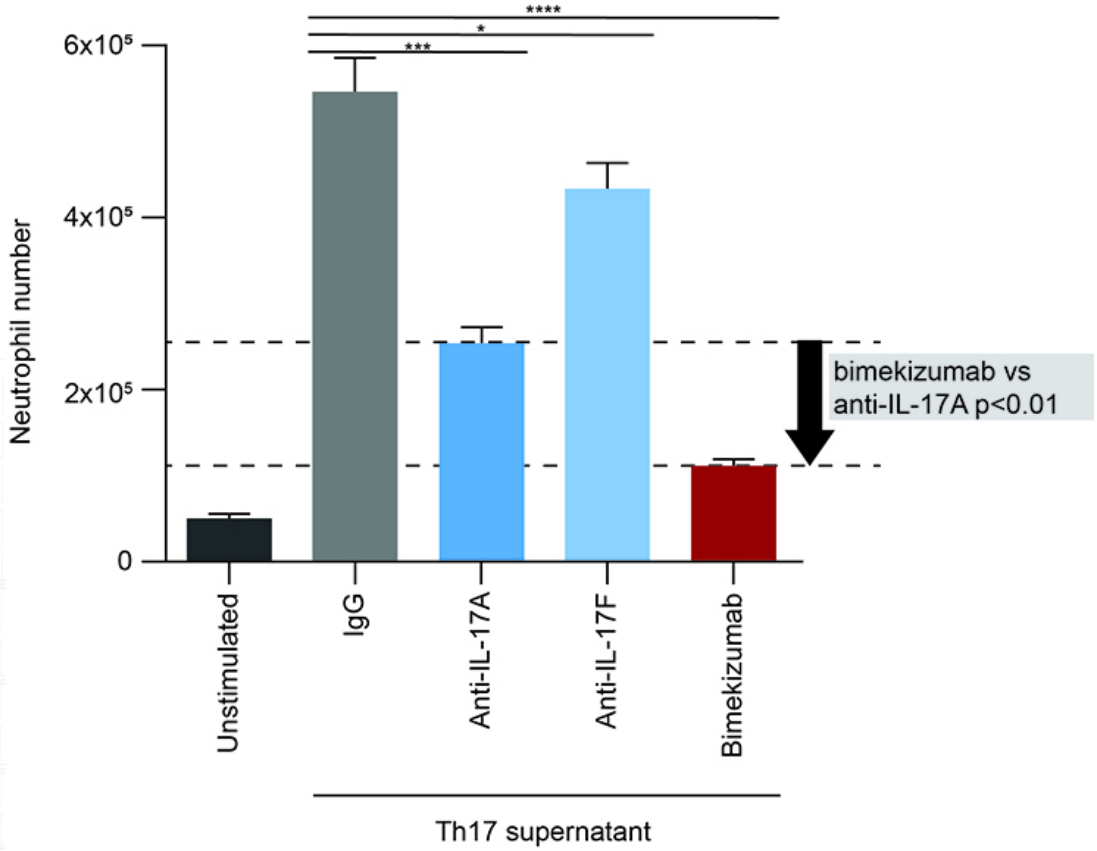
Bimekizumab: anticuerpo monoclonal humanizado anti IL17A e IL17F (UCB).

Estudios en APso y otras enfermedad de etiología inmune.

Valoran el papel de IL17F en la inflamación crónica en tejidos de pacientes con APso y sobre las células asociadas.

Ver el efecto de la neutralización dual frente a la de la IL17A sola:

- Estímulo con IL17F produce un incremento de mediadores inflamatorios (IL-6 e IL-8), pero menos que IL17A.
- EL bloqueo dual da mayores reducciones de IL-6 e IL-8 que el bloqueo solo de IL17A.


****
*
***
6x10⁵
4x10⁵
2x10⁵
0
Neutrophil number
bimekizumab vs
anti-IL-17A p<0.01
Unstimulated
IgG
Anti-IL-17A
Anti-IL-17F
Bimekizumab
Th17 supernatant

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THU0155: IMPACT OF BASELINE MODIFIED RHEUMATIC DISEASE COMORBIDITY INDEX (MRDCI) ON DRUG SURVIVAL AND EFFECTIVENESS OF BIOLOGICAL DRUGS IN PATIENTS AFFECTED WITH RHEUMATOID ARTHRITIS (RA), SPONDYLOARTHRITIS (SPA), AND PSORIATIC ARTHRITIS (PSA) IN REAL-WORLD SETTINGS.

Presenting Author

Marco Fornaro (Italy)

mRDCI: Índice de comorbilidades en enfermedades reumáticas modificado.

Valoran: Impacto en la supervivencia y la efectividad de las terapias biológicas (DAS28 < 2.6). Retrospectivo.

Resultados:

- mDRCI basal está asociado con el número de cambios de tratamiento biológico.
- Persistencia del fármaco es mayor en aquellos cuyo mRDCI=0 que en los que es >2 (no en AR).
- Predictor de descontinuación definitiva del fármaco y de la imposibilidad de alcanzar la remisión DAS28.

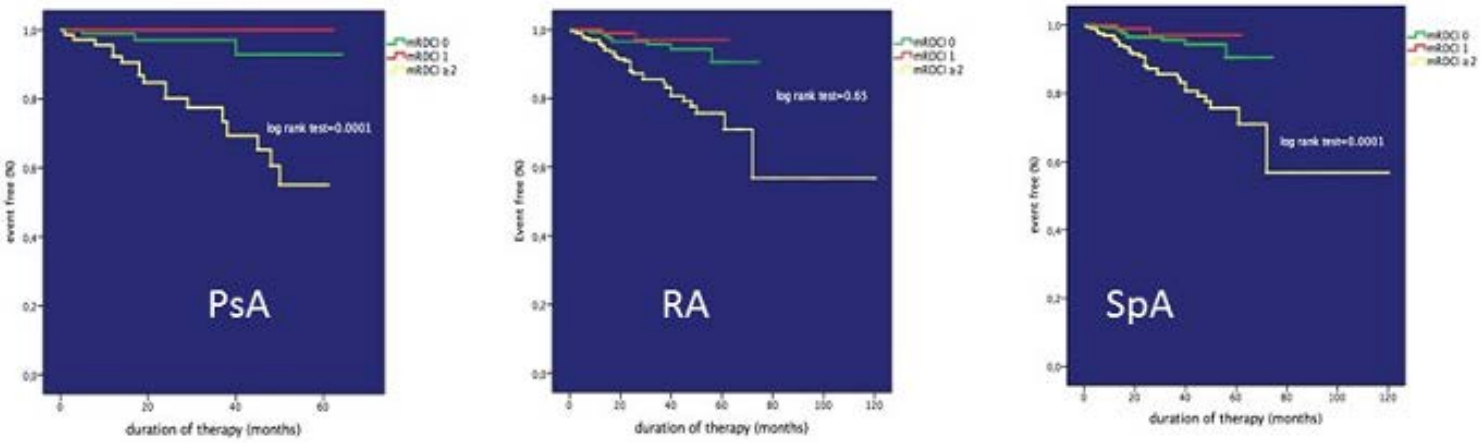

Figure 1. Kaplan-Meier curves for patients affected with Rheumatoid arthritis (RA), Spondyloarthritis (SpA), and Psoriatic Arthritis (PsA)

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THU0381: CERTOLIZUMAB PEGOL IS EFFECTIVE IN UVEITIS ASSOCIATED TO SPONDYLOARTHRITIS REFRACTORY TO OTHER TUMOUR NECROSIS FACTOR INHIBITORS.

Presenting Author

María Victoria Hernández (Spain)

Retrospectivo: EA (7), APSo (4), nr-axSpA (1) y SpA asociada a EII (1).

24 ojos de 13 pacientes, 84.6%: TB previa.

Seguimiento de 13.1 ± 6.6 meses (6-27):

- 9 pacientes siguen CZP.
- 10 ojos mejoraron la agudeza visual AV, 10 se mantuvieron estables y 2 empeoraron.
- 4 abandonos: 2 por empeoramiento articular, 1 edema macular y 1 uveitis activa.

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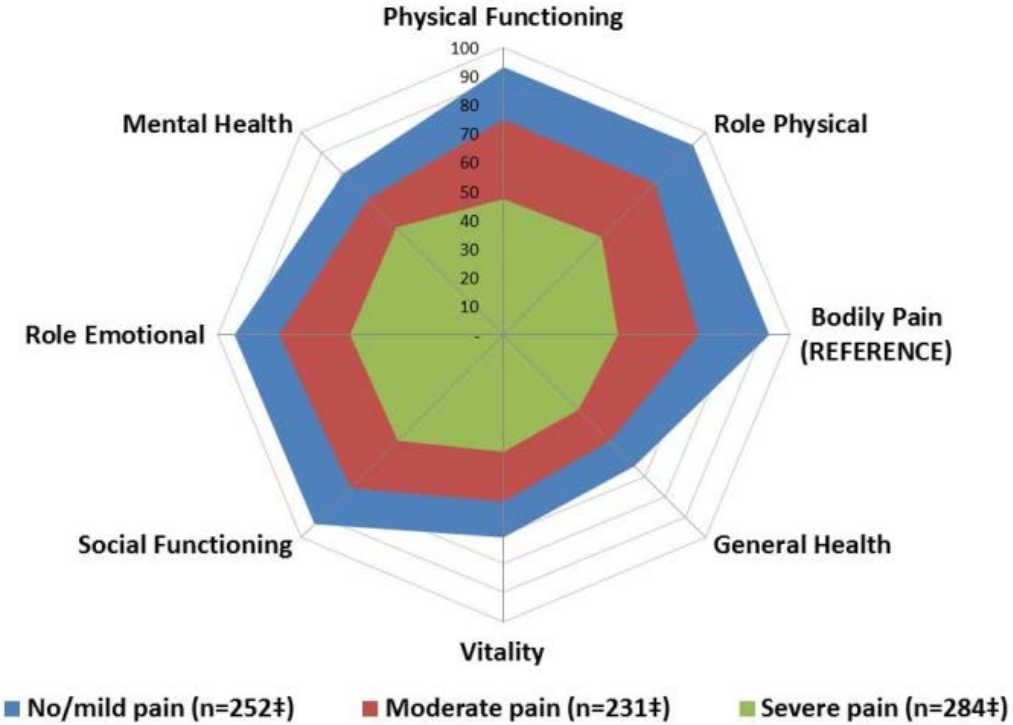
OP0107: PAIN STILL REMAINS A HIGH UNMET NEED AMONG PSORIATIC ARTHRITIS PATIENTS RECEIVING EXISTING BIOLOGIC TREATMENT: RESULTS FROM A MULTI NATIONAL REAL-WORLD SURVEY. Hall 7A

Abstract Speaker

Philip Conaghan (United Kingdom)

- Pacientes con TB, 782 N, multinacional, transversal.
- 36% tiene dolor severo.
- Condiciona el deterioro de las medidas de desenlace más comunes HRQOL, SF-36, EQ-5D, HAQ-DI, perfil laboral, desempleo y jubilación.

Spydergram[1] of Health-Related Quality of Life by SF-36*



*P<0.0001 for all domains shown
‡Minimum base, base varies for each domain

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OP0148: IMPACT OF A CARDIOVASCULAR EVENT ON DMARD TREATMENT AMONG PATIENTS WITH RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, OR PSORIASIS N105 / N106.

Abstract Speaker
Jeffrey Sparks (United States)

Tras un evento CV: buscar cambios en los tratamientos inmunosupresores.

Evento CV: IAM, ACV, repermeabilización cardíaca.

9 años de seguimiento: de 2006 a 2015, N=9529:

- 73% persisten en su tratamiento previo: más los que solo toman sFAMES solo y i-TNF asociados a sFAMES combinados.
- Menos persistencia en aquellos con TB no i-TNF.
- Aquellos que los suspendían eran más mayores, tenían PSO y ACV.

Table 1. DMARD treatment patterns for RA, PsA, or PsO patients following an initial CV event (N=9,529)

Treatment prior to CV event	N	DMARD treatment persisted, n (%)	DMARD treatment switched, n (%)	All DMARDs treatment discontinued, n (%)
Entire study sample	9,529	6,985 (73.3%)	1,498 (15.7%)	1,046 (11.0%)
TNFi monotherapy	1,760	1,323 (75.2%)	232 (13.2%)	205 (11.6%)
TNFi + csDMARD combination therapy	1,514	1,160 (76.7%)	299 (19.7%)	55 (3.6%)
csDMARD monotherapy	4,369	3,320 (76.0%)	528 (12.1%)	521 (11.9%)
≥2 csDMARDs combination therapy	808	518 (64.1%)	248 (30.7%)	42 (5.2%)
Non-TNFi biologic monotherapy	718	445 (62.0%)	63 (8.8%)	210 (29.2%)
Non-TNFi biologic + csDMARD combination therapy	360	219 (60.8%)	128 (35.6%)	13 (3.6%)

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OP0201: A PHASE 3 STUDY OF THE EFFICACY AND SAFETY OF IXEKIZUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND INADEQUATE RESPONSE TO TUMOUR NECROSIS FACTOR INHIBITOR(S). Hall 8

Abstract Speaker
Peter Nash (Australia)

- Ixekizumab: Ac monoclonal de alta afinidad para IL-17.
- vs PBO en iTNF- IR, estudio de 24 semanas.
- iTNF-IR: IR o intolerancia a 1 ó 2 iTNF.
- IXE 160 mg dosis inicial, seguida de 80 mg cada 2 ò 4 semanas.

No hubo diferencias en las entesitis, pero sí en las dactilitis en el grupo que tomaba cada 4 semanas.

Outcomes	Week 12			Week 24		
	Placebo (N=118)	IXEQ4W (N=122)	IXEQ2W (N=123)	Placebo (N=118)	IXEQ4W (N=122)	IXEQ2W (N=123)
ACR20 n (%)	26 (22.0)	61 (50.0)**	59 (48.0)**	23 (19.5)	65 (53.3)**	59 (48.0)**
ACR50 n (%)	4 (3.4)	38 (31.1)**	41 (33.3)**	6 (5.1)	43 (35.2)**	41 (33.3)**
ACR70 n (%)	2 (1.7)	18 (14.8)*	13 (10.6)*	0	27 (22.1)**	15 (12.2)**
HAQ-DI CFB LSM (SE)	-0.1 (0.06)	-0.4 (0.06)**	-0.4 (0.06)**	-0.2 (0.08)	-0.6 (0.07)**	-0.4 (0.07)**
DAS28-CRP CFB LSM (SE)	-0.6 (0.17)	-1.8 (0.17)**	-1.5 (0.16)**	-0.8 (0.20)	-2.1 (0.19)**	-1.8 (0.18) **
LEI (0)[a] n/N (%)	20/69 (29.0)	19/68 (27.9)	29/84 (34.5)	15/69 (21.7)	24/68 (35.3)	26/84 (31.0)
LDI-B (0)[b] n/N (%)	5/14 (35.7)	19/28 (67.9)	12/20 (60.0)			
PASI 75[c] n/N (%)	7/67 (10.4)	39/68 (57.4)**	42/68 (61.8)	10/67 (14.9)	38/68 (55.9)**	41/68 (60.3)**
Minimal disease activity (MDA) n (%)	6 (5.1)	31 (25.4)**	21 (17.1)*	4 (3.4)	34 (27.9)**	29 (23.6)**
Safety, n (%)						
TEAE	--	--	--	76 (64.4)	83 (68.0)	90 (73.2)
SAE	--	--	--	4 (3.4)	3 (2.5)	8 (6.5)
Discontinued from AE	--	--	--	6 (5.1)	5 (4.1)	8 (6.5)
Infections	--	--	--	35 (29.7)	47 (38.5)	47 (38.2)
Serious	--	--	--	0	0	3 (2.4)
Oral candida	--	--	--	0	0	4 (3.3)
Injection site reactions[d]	--	--	--	5 (4.2)	14 (11.5)**	29 (23.6)**

Abbreviations: CFB=change from baseline; SAE=serious adverse event.
[a]Only pts with enthesitis at baseline (LEI >0) were included in the analysis.
[b]Only pts with dactylitis (LDI-B>0) at baseline were included.
[c]Only pts with psoriatic lesions ≥3% of BSA at baseline were included.
[d]Injection site reactions is a high-level term consisting of multiple lower-level terms.
*P<0.05,**P <0.001.

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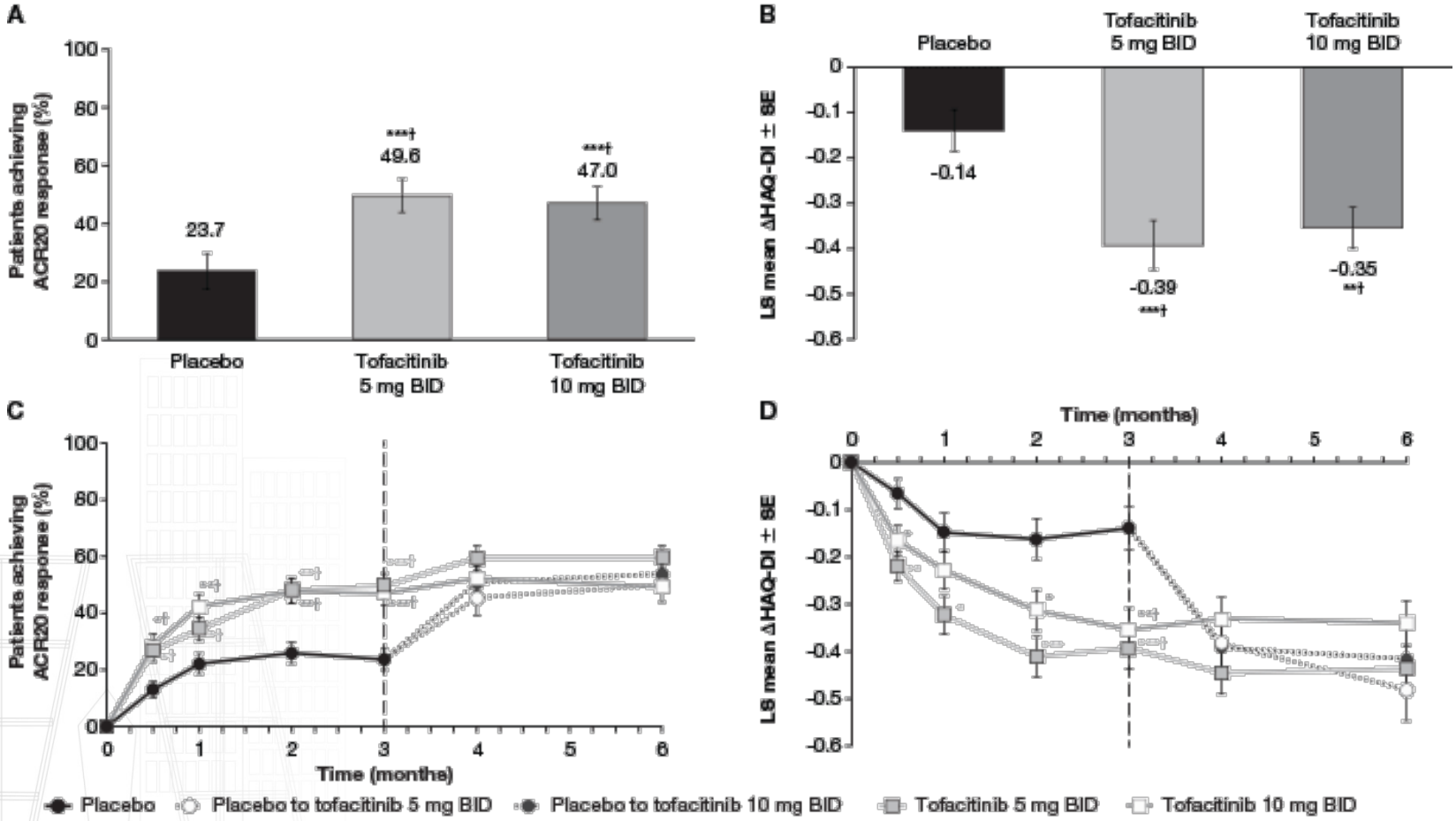
OP0202: EFFICACY AND SAFETY OF TOFACITINIB, AN ORAL JANUS KINASE INHIBITOR, IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND AN INADEQUATE RESPONSE TO TUMOUR NECROSIS FACTOR INHIBITORS: OPAL BEYOND, A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE 3 TRIAL. Hall 8

Abstract Speaker

Dafna Gladman (Canada)

- Fase 3, de 6 meses de duración.
- > 1 iTNF-IR.
- Placa de psoriasis al inicio.
- Requería seguir con csFAME.
- 5mg y 10 mg, en dos tomas diarias.


A
Patients achieving ACR20 response (%)
100
80
60
40
20
0
23.7
***†
49.6
***†
47.0
Placebo
Tofacitinib 5 mg BID
Tofacitinib 10 mg BID
B
LS mean ΔHAQ-DI ± SE
Placebo
Tofacitinib 5 mg BID
Tofacitinib 10 mg BID
0
-0.1
-0.2
-0.3
-0.4
-0.5
-0.6
-0.14
-0.39
***†
-0.35
**†
C
Patients achieving ACR20 response (%)
Time (months)
0
1
2
3
4
5
6
D
LS mean ΔHAQ-DI ± SE
Time (months)
Placebo
Placebo to tofacitinib 5 mg BID
Placebo to tofacitinib 10 mg BID
Tofacitinib 5 mg BID
Tofacitinib 10 mg BID

E

	Up to M3	Up to M6			
	Placebo (N=131)	Placebo → tofacitinib 5 mg BID (N=66)	Placebo → tofacitinib 10 mg BID (N=65)	Tofacitinib 5 mg BID (N=131)	Tofacitinib 10 mg BID (N=132)
AEs, n (%)	58 (44.3)	40 (60.6)	38 (58.5)	93 (71.0)	96 (72.7)
SAEs, n (%)	3 (2.3)	2 (3.0)	1 (1.5)	5 (3.8)	8 (6.1)
Discontinuation due to AEs, n (%)	5 (3.8)	2 (3.0)	3 (4.6)	5 (3.8)	11 (8.3)
Deaths, n (%)	0	0	0	0	0
AEs of special interest, n (%) [day of onset]					
Serious infection	0	0	0	2 (1.5) [135, 166]	2 (1.5) [10, 69]
Herpes zoster (all non-serious)	0	0	0	1 (0.8) [77]	2 (1.5) [8, 156]
Malignancy[b]	0	0	0	0	0
MACE[c]	0	0	0	1 (0.8) [245]	1 (0.8) [94]

Nominal *p≤0.05, **p<0.001, ***p<0.0001 vs placebo; [†]Achieved statistical significance at p≤0.05 per the pre-specified step-down testing procedure; dashed line indicates the end of the placebo-controlled period; [a]All patients who received ≥1 dose of study medication; [b]Including non-melanoma skin cancer; [c]For this trial, MACE included one myocardial infarction and one cerebrovascular event (stroke)

ACR, American College of Rheumatology; AE, adverse event; BID, twice daily; HAQ-DI, Health Assessment Questionnaire-Disability Index; M, month; MACE, major adverse cardiovascular event; n, number of patients with event; SAE, serious adverse event; SE, standard error