14° Πανελλήνιο Συνέδριο ΕΠΕΜΥ
Ρόδος
29 ΣΕΠΤΕΜΒΡΙΟΥ – 2 ΟΚΤΩΒΡΙΟΥ 2022

Tofacitinib: *Ο πρώτος JAK αναστολέας με **4** ρευματολογικές ενδείξεις*

Δεδομένα από τις Αξονικές Σπονδυλαρθρίτιδες και τη Νεανική Ιδιοπαθή Αρθρίτιδα

Σύγκρουση συμφερόντων

Τιμητική αμοιβή για τη συγκεκριμένη ομιλία από την εταιρεία Pfizer

«Η Pfizer έχει ελέγξει το περιεχόμενο ώστε να ανταποκρίνεται στις ειδικές προδιαγραφές της αλλά δεν έχει επιβεβαιώσει ότι οι βιβλιογραφικές παραπομπές έχουν παρατεθεί ορθά»

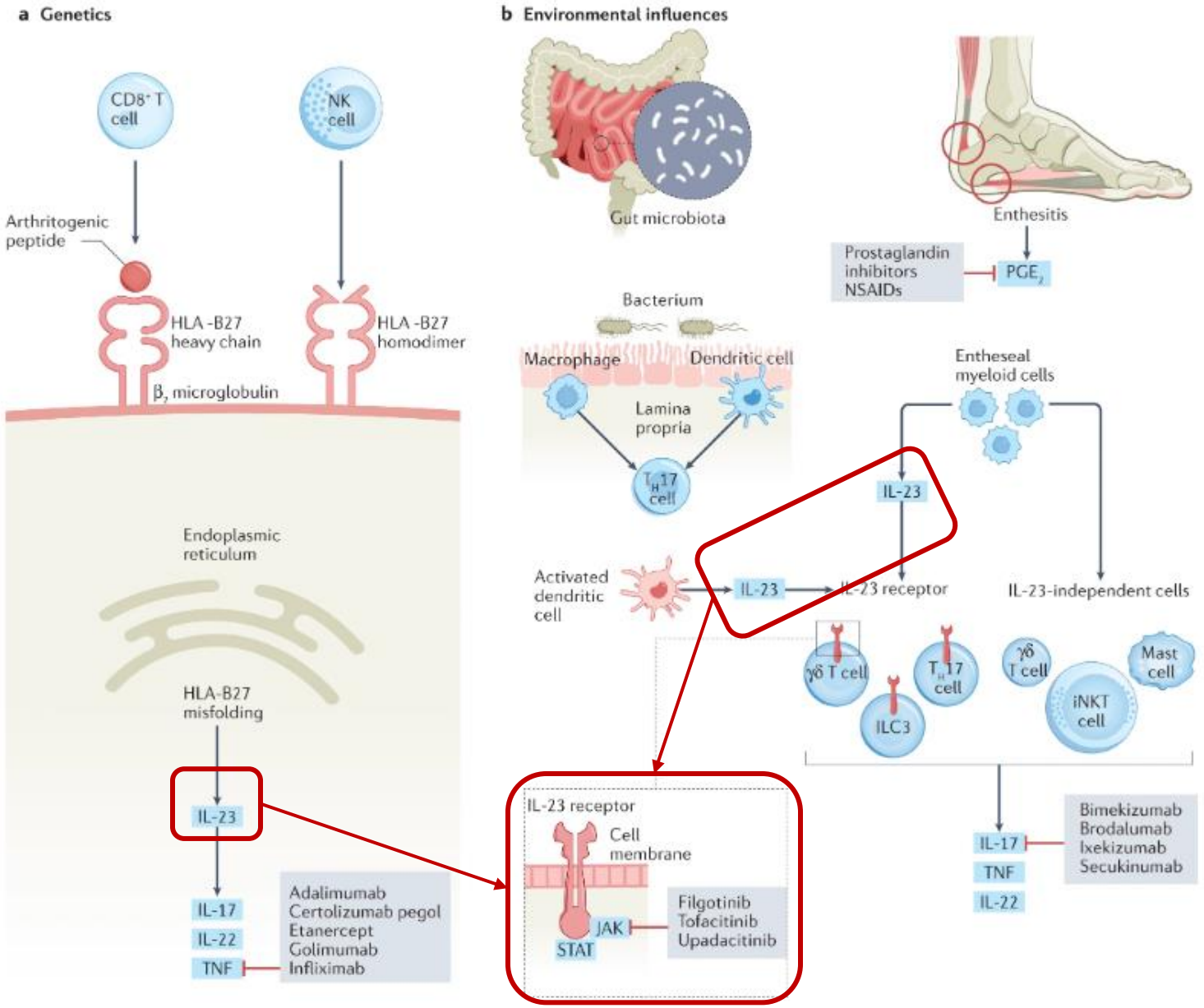
«Για όλα τα φαρμακευτικά προϊόντα που αναφέρονται παρακαλείσθε να συμβουλεύεστε/συμβουλευτείτε τις εγκεκριμένες Περιλήψεις Χαρακτηριστικών των Προϊόντων»

Αξονικές Σπονδυλαρθρίτιδες – the ideal drug?

- Αποτελεσματικό
  - Ανωτερότητα vs PB
  - Ανωτερότητα vs υφιστάμενες θεραπείες
- Ευρύ θεραπευτικό φάσμα
  - Αξονικός σκελετός
  - Περιφερικές αρθρώσεις
  - Ψωρίαση
  - Ενθεσίτιδα
  - ΙΦΕΝ
  - Ραγοειδίτιδα
  - Δακτυλίτιδα
- Διατήρηση θεραπευτικού αποτελέσματος
- Ασφάλεια
  - Δεδομένα από μακροχρόνιες μελέτες και registries

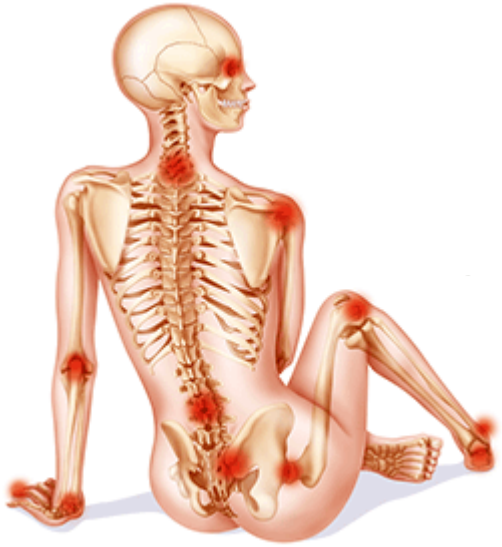
Poddubnyy, D., & Sieper, J. (2019). Current Unmet Needs in Spondyloarthritis. *Current rheumatology reports*, *21*(9), 43.

Concept για τη χρήση JAK-is στην ΑΣ



Danve, A., & Deodhar, A. (2022). Treatment of axial spondyloarthritis: an update. *Nature reviews. Rheumatology*, *18*(4), 205–216.

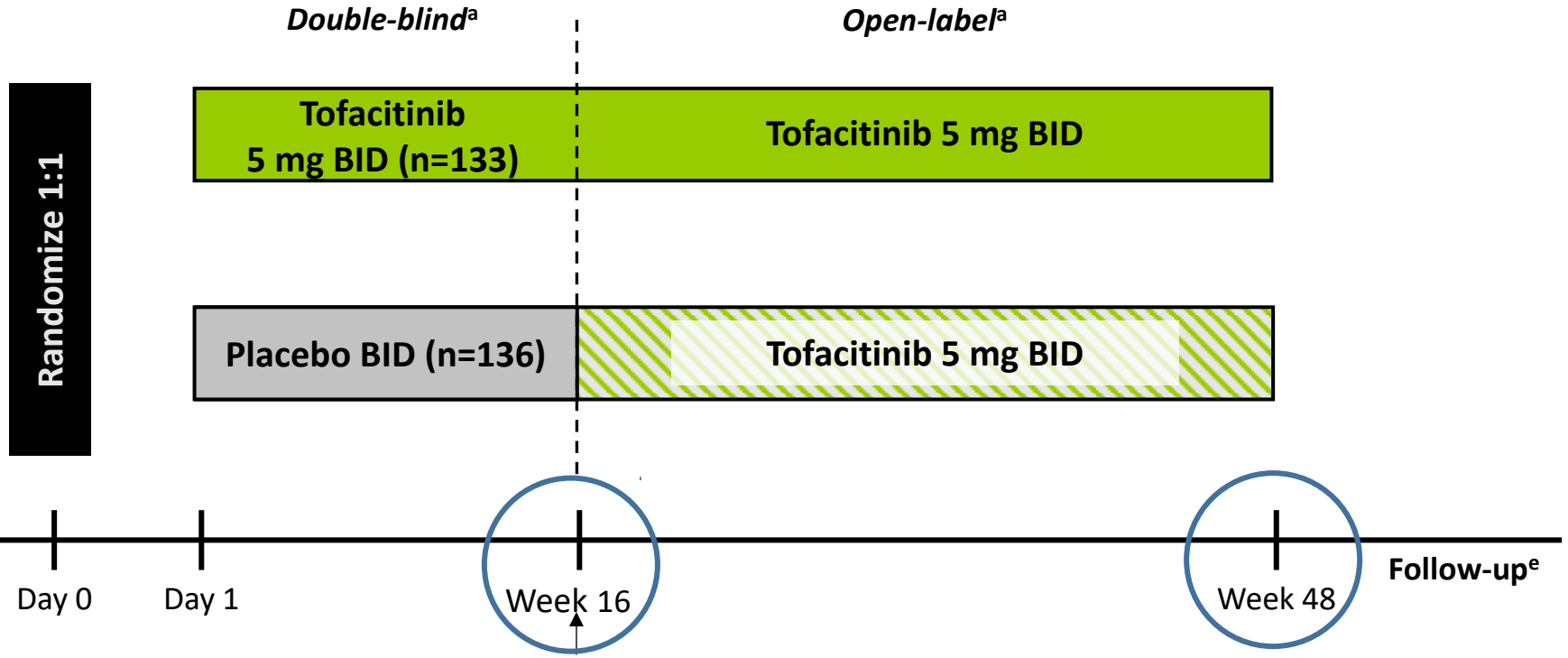
Tofacitinib for the Treatment of Ankylosing Spondylitis

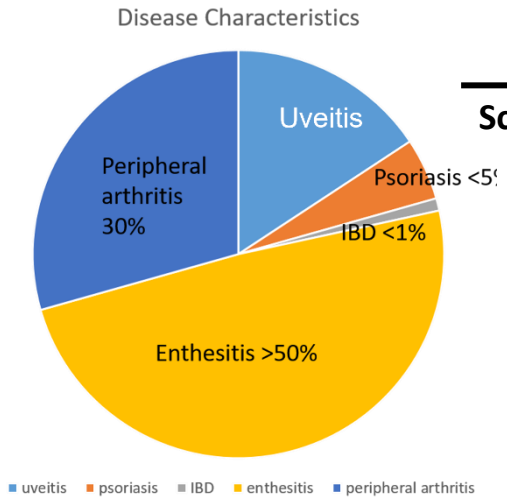


Deodhar A, et al. Ann Rheum Dis 2021;80:1004–1013

AS Phase 3 A3921120 Study Design

Active AS stratified:
- ~80% were to be bDMARD naïve
- ~20% were to have an IR to TNFi[b] or prior bDMARD use (non-IR)





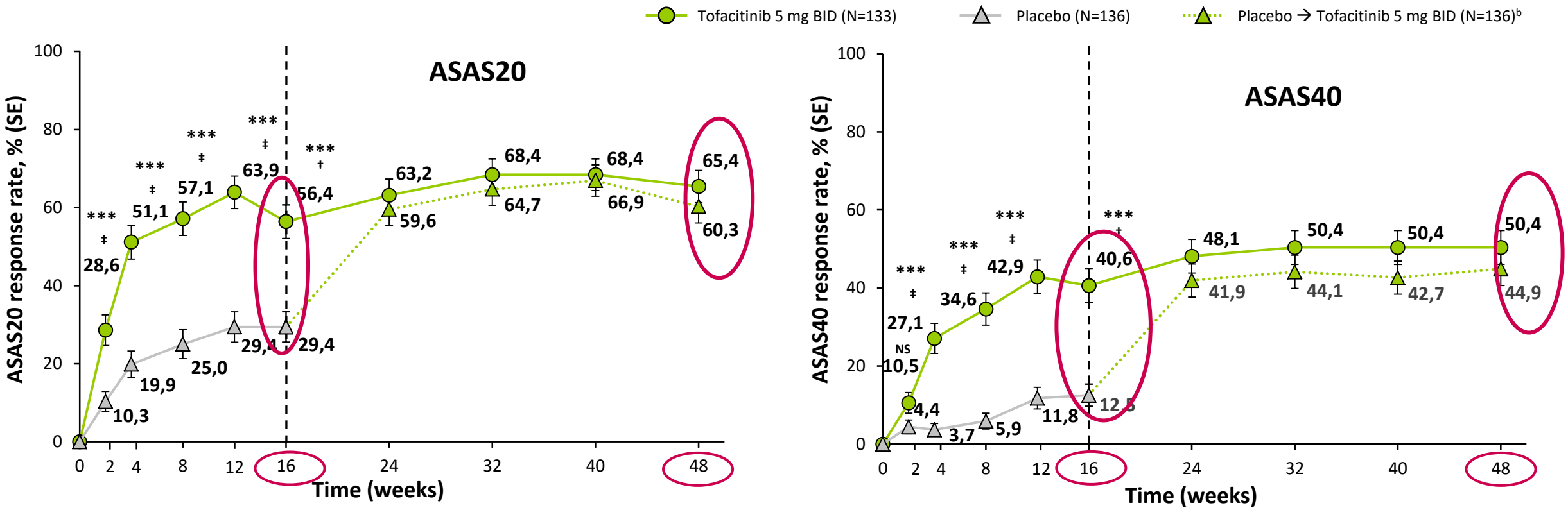
Primary endpoint: ASAS20[c]

Key Secondary Endpoint: ASAS40[d]

Deodhar A, et al. *Ann Rheum Dis.* 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

ASAS20 and ASAS40 Response Rates[a] by Visit Up to Week 48

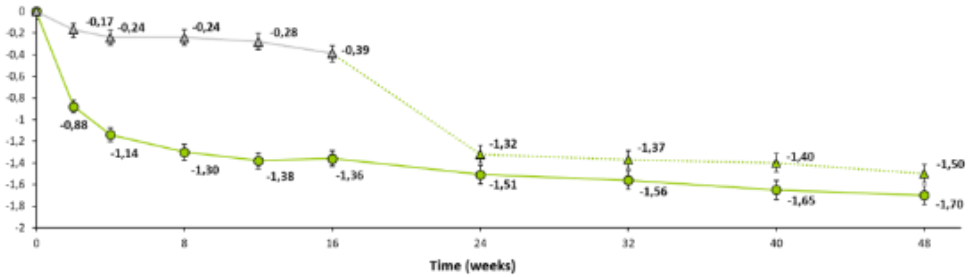
(Primary and Key Secondary Endpoints at Week 16, Respectively)



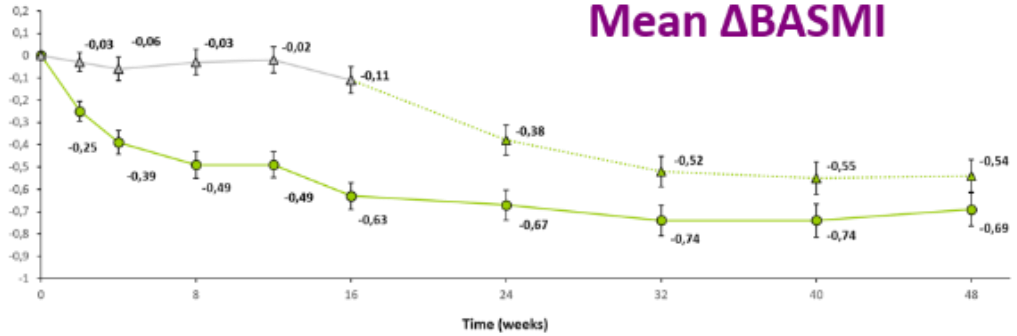
Deodhar A, et al. *Ann Rheum Dis.* 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

Μέση μείωση παραμέτρων (wk16 -wk 48)

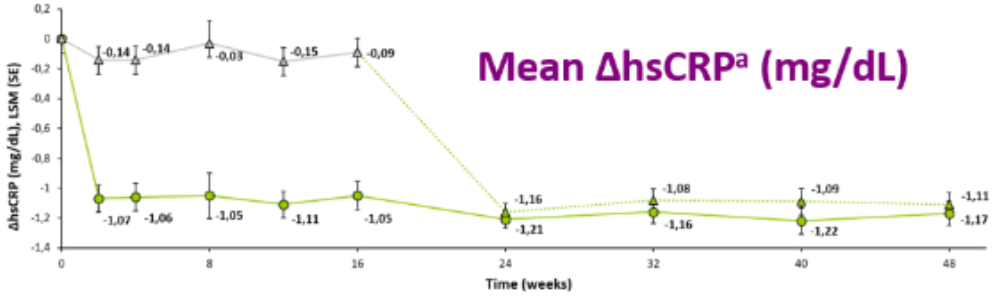
Mean ΔASDAS(CRP)



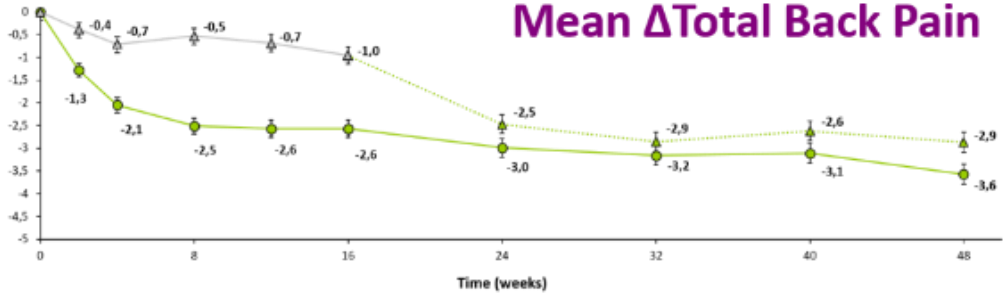
Mean ΔBASMI



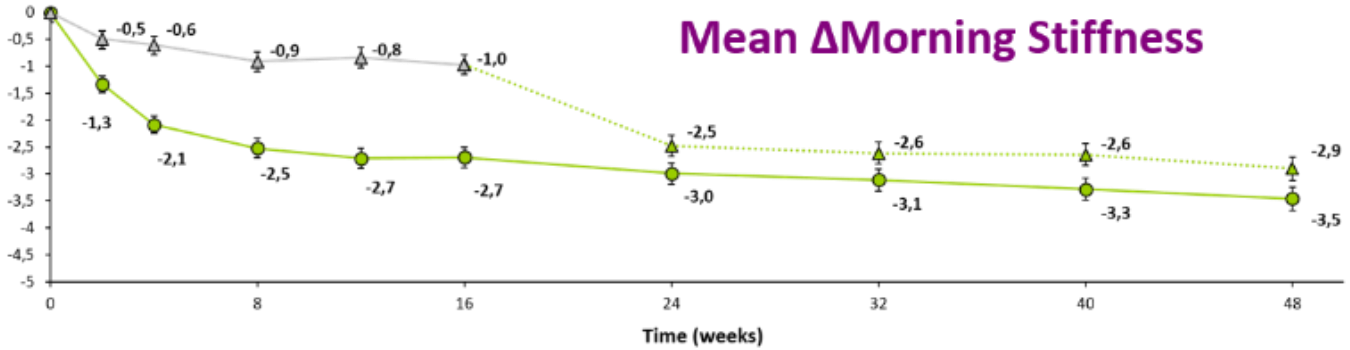
Mean ΔhsCRP[a] (mg/dL)



Mean ΔTotal Back Pain



Mean ΔMorning Stiffness



Deodhar A, et al. *Ann Rheum Dis.* 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

Summary of Adverse Events

Patients with events, n (%)	Up to Week 16 (double-blind phase)		Up to Week 48 (double-blind and open-label phases)	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo → Tofacitinib 5 mg BID (N=136)
AEs	73 (54.9)	70 (51.5)	103 (77.4)	93 (68.4)
SAEs[a]	2 (1.5)	1 (0.7)	7 (5.3)	2 (1.5)
Severe AEs[b]	2 (1.5)	0	6 (4.5)	0
Deaths	0	0	0	0
Upper respiratory tract infection	14 (10.5)	10 (7.4)	21 (15.8)	18 (13.2)
Nasopharyngitis	9 (6.8)	10 (7.4)	11 (8.3)	17 (12.5)
Diarrhea	6 (4.5)	5 (3.7)	10 (7.5)	8 (5.9)

AEs of Special Interest

Patients with events, n (%)	Up to Week 16 (double-blind phase)		Up to Week 48 (double-blind and open-label phases)	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo → Tofacitinib 5 mg BID (N=136)
Malignancies (including NMSC)[a]	0	0	0	0
MACE[a]	0	0	0	0
DVT, PE, or ATE[a]	0	0	0	0
GI perforation[a]	0	0	0	0
Hepatic events[a]	1 (0.8)[b]	0	3 (2.3)[c]	0
DILI[a]	0	0	0	0
HZ (serious and nonserious)	0	0	3 (2.3)[d]	2 (1.5)[d]
Opportunistic infections[a]	0	0	0	0
Serious infections	1 (0.8)[e]	0	1 (0.8)[e]	0
ILD[a]	0	0	0	0

Deodhar A, et al. *Ann Rheum Dis.* 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

Summary of AEs of EAMs (Εξωαρθρικές εκδηλώσεις)

Patients with events, n (%)	Up to Week 16 (double-blind phase)		Up to Week 48 (double-blind and open-label phases)	
	Tofacitinib 5 mg BID (N=133)	Placebo (N=136)	Tofacitinib 5 mg BID (N=133)	Placebo → Tofacitinib 5 mg BID (N=136)
IBD	0	0	0	0
PsO	0	1 (0.7)	0	1 (0.7)
Uveitis	1 (0.8)	3 (2.2)	2 (1.5)	4 (2.9)

- All patients who experienced uveitis **had a history of uveitis**
- All cases of uveitis were mild or moderate in severity; none were SAEs
- No patients discontinued study drug due to uveitis

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Deodhar A, et al. *Ann Rheum Dis.* 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

Συμπεράσματα

- Σημαντική κλινική ανταπόκριση και υπεροχή έναντι του PB
  - Ενεργότητα νόσου/κινητικότητα/λειτουργικότητα/δείκτες ποιότητας ζωής
- Γρήγορη έναρξη ανταπόκρισης (από τη δεύτερη κιόλας εβδομάδα)
- Διατήρηση θεραπευτικού αποτελέσματος στις 48 wks
- Η χορήγηση Tofacitinib στους ασθενείς που λάμβαναν PB οδήγησε σε κλινική απάντηση που διατηρήθηκε μέχρι την εβδομάδα 48

Deodhar A, et al. *Ann Rheum Dis.* 2021;0:1-10. doi:10.1136/annrheumdis-2020-219601.

ASAS/EULAR Recommendations for the Management of Axial Spondyloarthritis– 2022 Update

	Recommendations 2016	Recommendations 2022
9	bDMARDs should be considered in patients with persistently high disease activity despite conventional treatments; current practice is to start with TNFi therapy	**TNFi, IL-17i** or JAKi should be considered in patients with persistently high disease activity despite conventional treatments - current practice is to start a TNFi or IL-17Ai 1ης γραμμής
10	NEW RECOMMENDATION	If there is a history of recurrent **uveitis** or active IBD, preference should be given to a monoclonal antibody against TNFα. In patients with significant psoriasis, an IL-17Ai may be preferred.
11	NEW RECOMMENDATION	Absence of response to treatment should trigger re-evaluation of the diagnosis and consideration of the presence of **comorbidities**
12	If TNFi therapy fails, switching to another TNFi or an anti-IL-17 therapy should be considered	**Following a first b/tsDMARD** failure, switching to another bDMARD (TNFi or IL-17i) or a JAKi should be considered 2ης γραμμής

Tofacitinib for the treatment of PsA

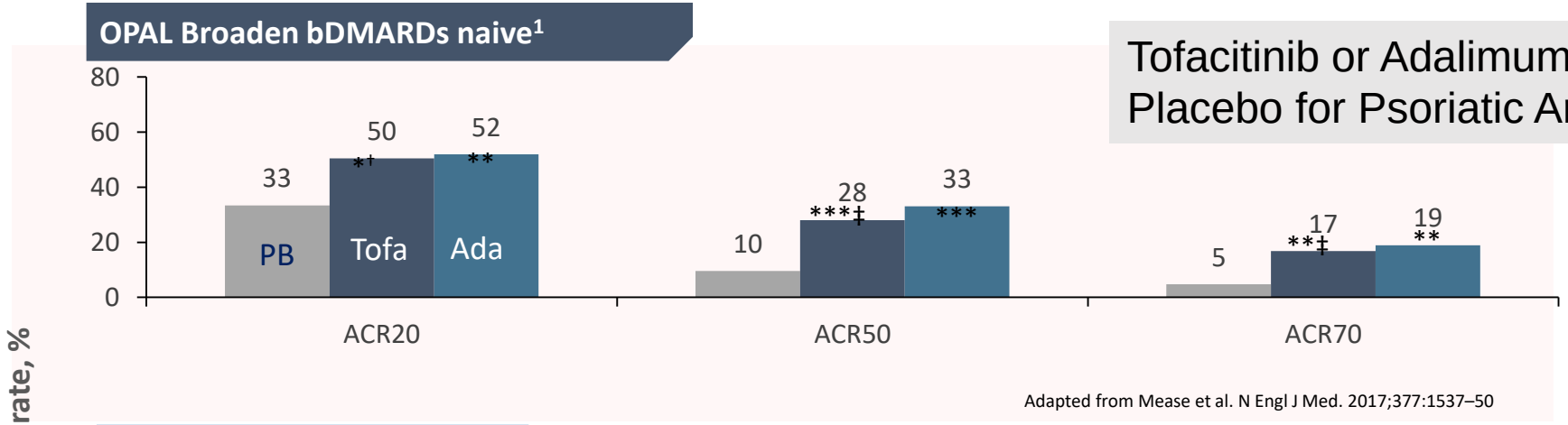
Overview of Tofacitinib studies in PsA

	DMARD-IR OPAL BROADEN	TNFi-IR OPAL BEYOND	OLE OPAL BALANCE
Study (N)	**OPAL Broaden[1] (N=422)**	**OPAL Beyond[2] (N=395)**	**OPAL Balance[3] (N=686)**
Duration	12 months	6 months	36 months
Background treatment	csDMARD	csDMARD	csDMARD
Tofacitinib treatment position	Second-line	Third-line	Long-term treatment

1. Mease et al. N Engl J Med 2017;377:1537–50.
2. Gladman et al. N Engl J Med 2017;377:1525–36;
3. Nash P, et al. Presented at ACR 2017; poster 620.

ACR response rates at Month 3 for Tofacitinib in PsA

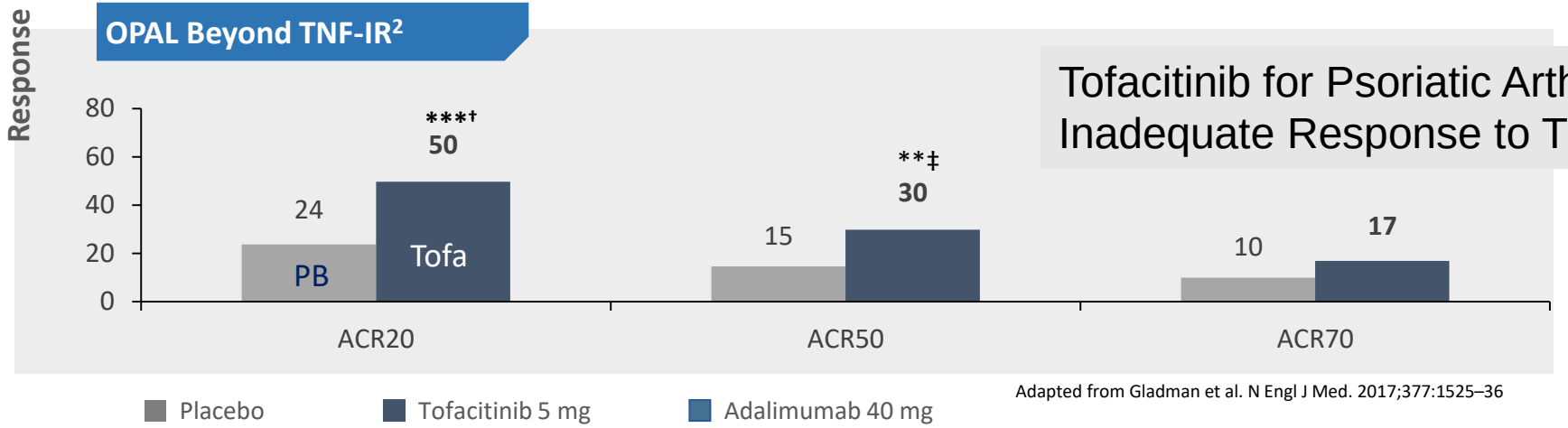
2nd-line



Tofacitinib or Adalimumab versus Placebo for Psoriatic Arthritis

Adapted from Mease et al. N Engl J Med. 2017;377:1537–50

3rd-line



Tofacitinib for Psoriatic Arthritis with an Inadequate Response to TNF Inhibitors

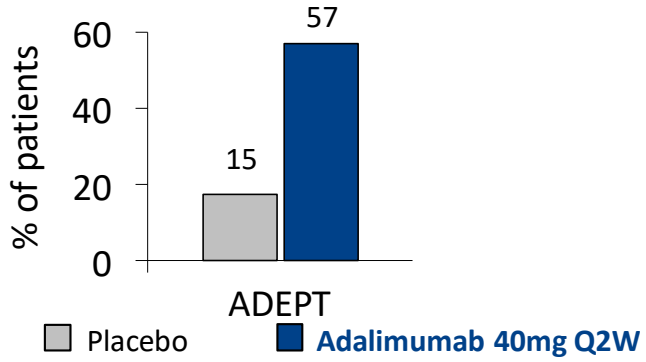
Adapted from Gladman et al. N Engl J Med. 2017;377:1525–36

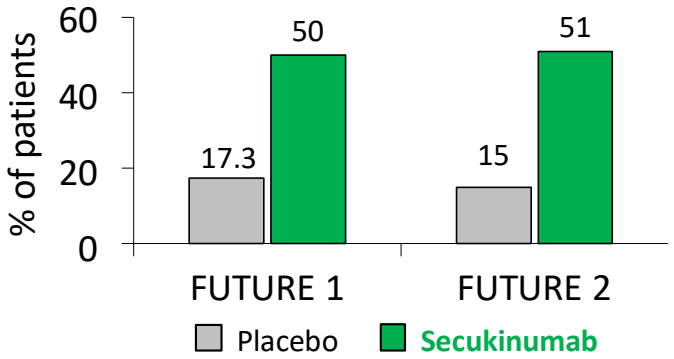
Results were consistent between TNFi-naïve and TNFi-IR patients

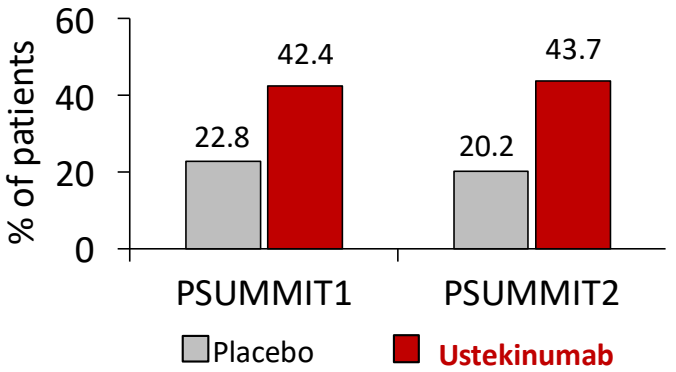
1. Mease et al. N Engl J Med. 2017;377:1537–50;
2. Gladman et al. N Engl J Med. 2017;377:1525–36.

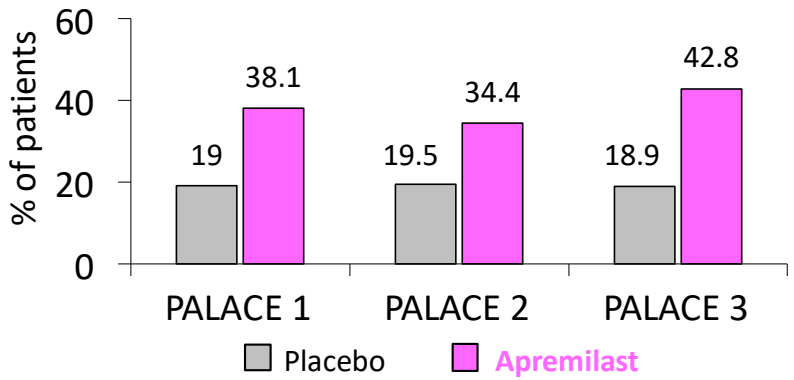
PsA ACR20 Response Overview in Randomised Controlled Trials (6m)

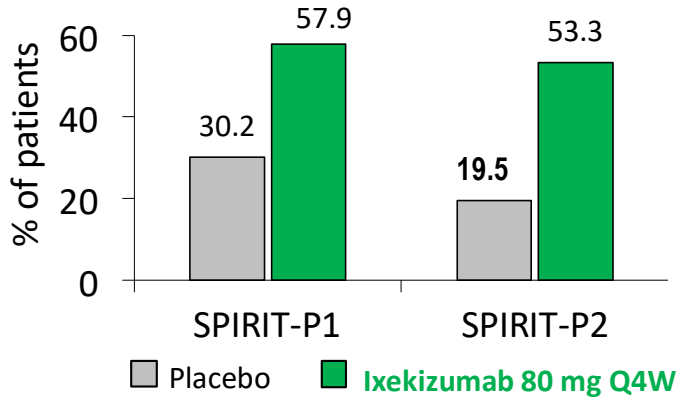
(NO DIRECT COMPARISONS)

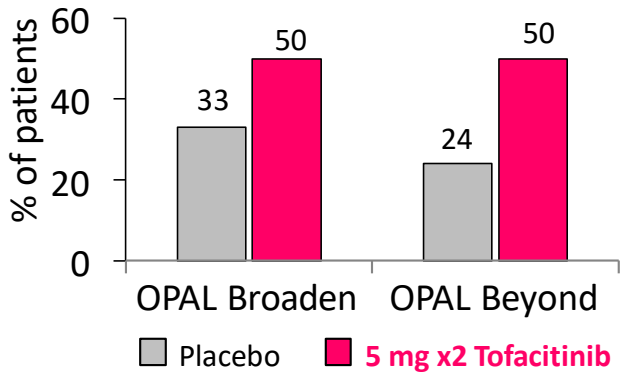






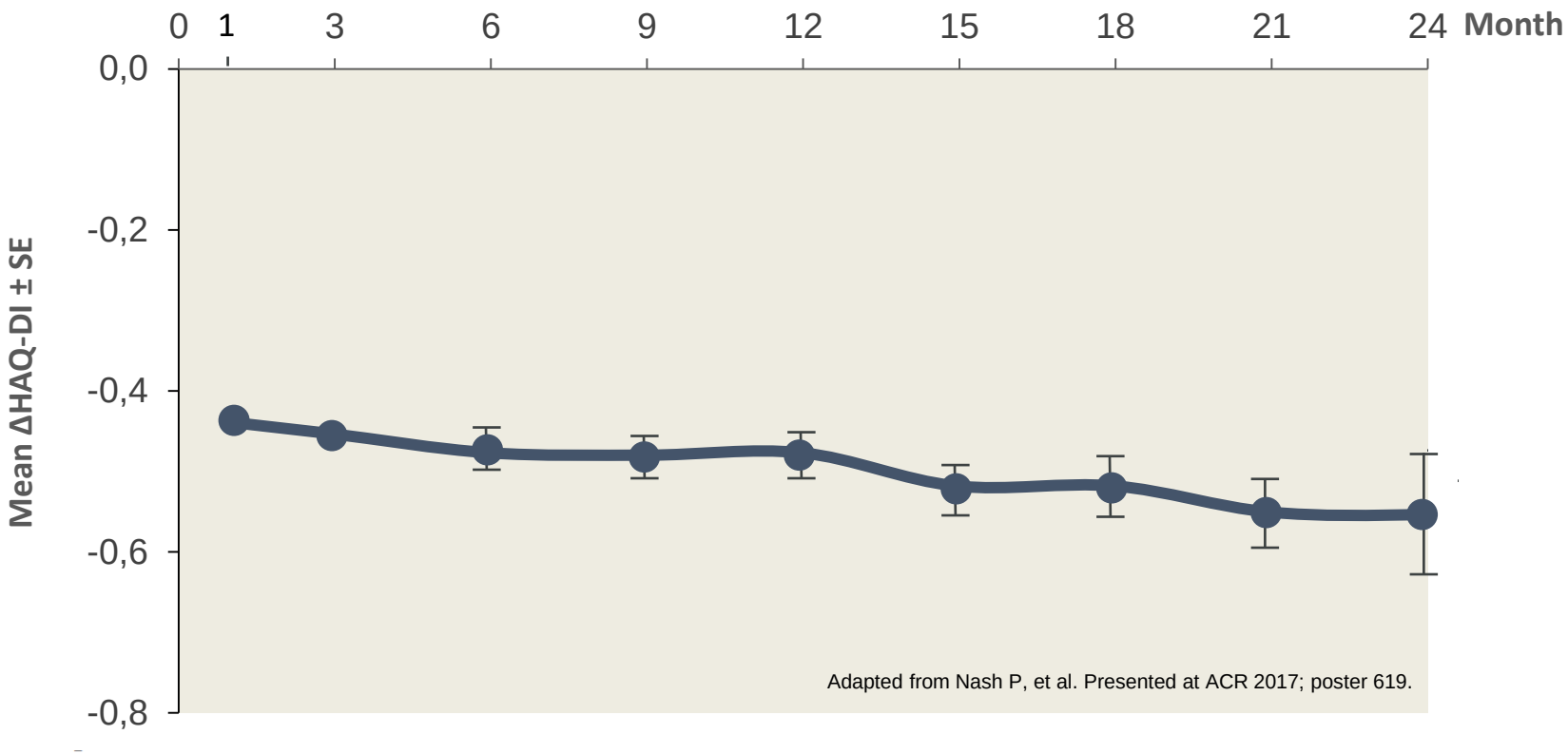






Ramiro S, et al. Ann Rheum Dis 2016 Mar;75(3):490-8.

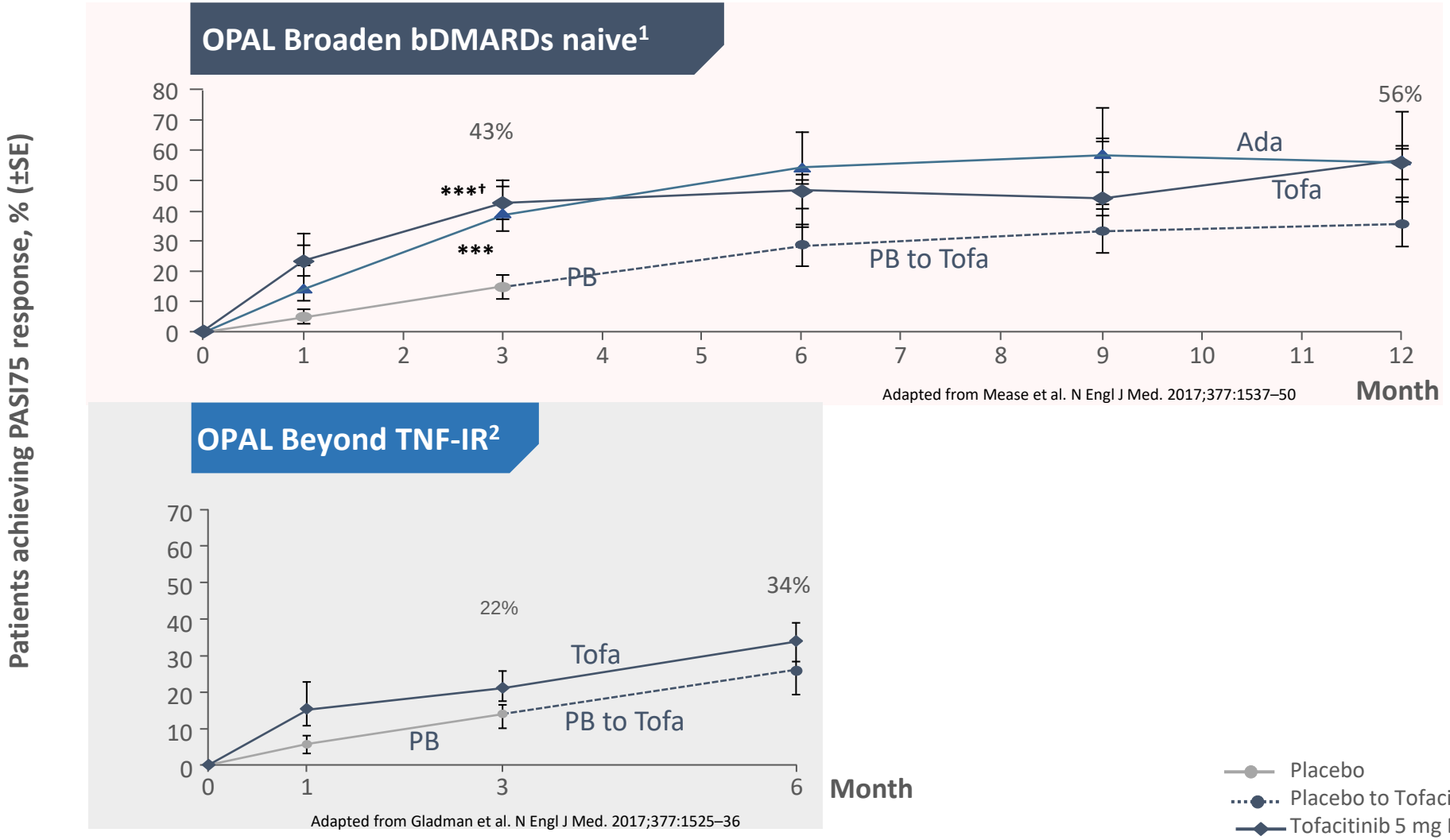
Long-term change in HAQ-DI up to Month 24



decrease from baseline of ≥ 0.35 points

1. Nash P, et al. Presented at ACR 2017; poster 620.

PASI75 response rates over time: Tofacitinib in PsA

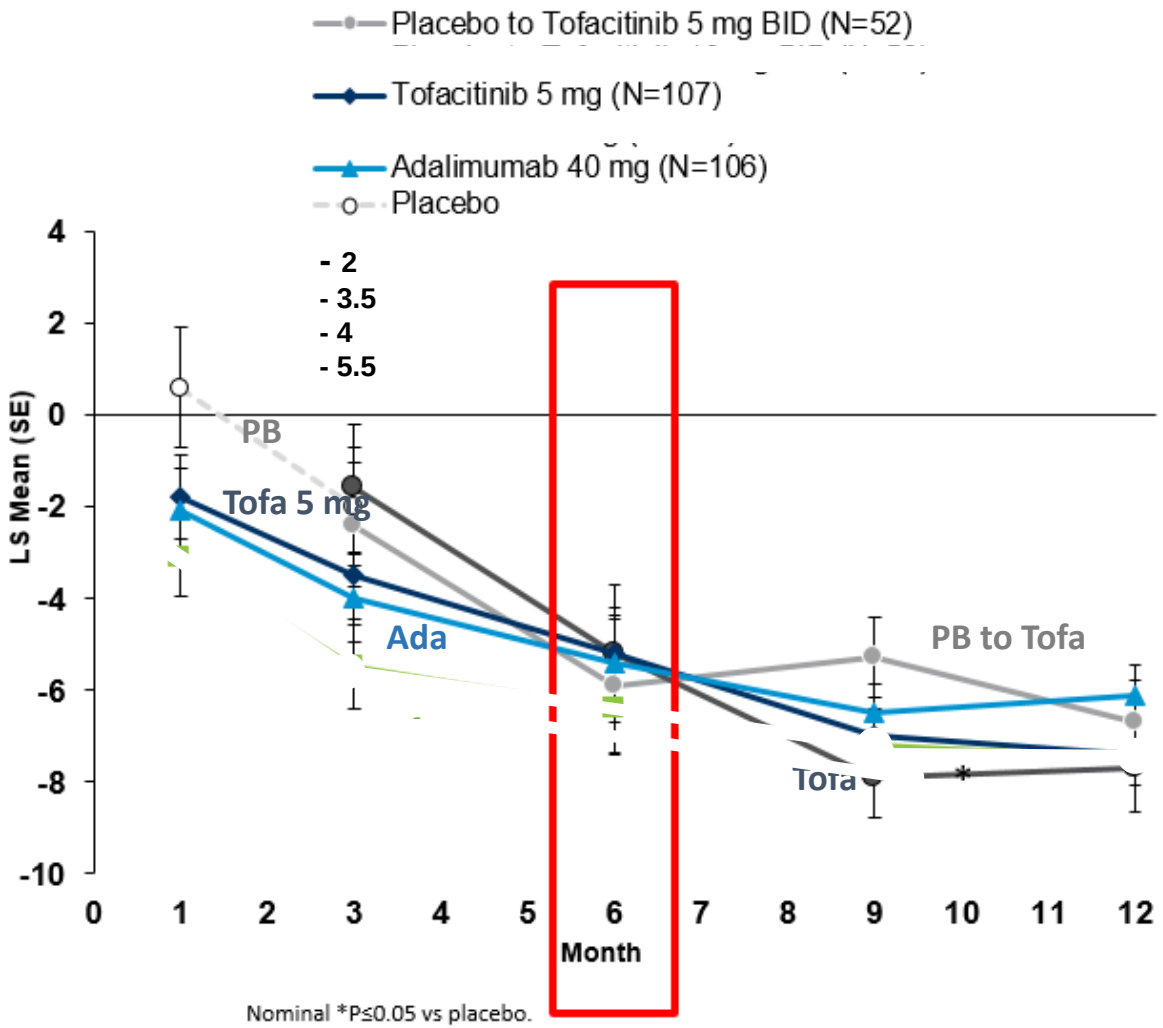


The licensed dose of tofacitinib in PsA is 5 mg BID in combination with csDMARDs

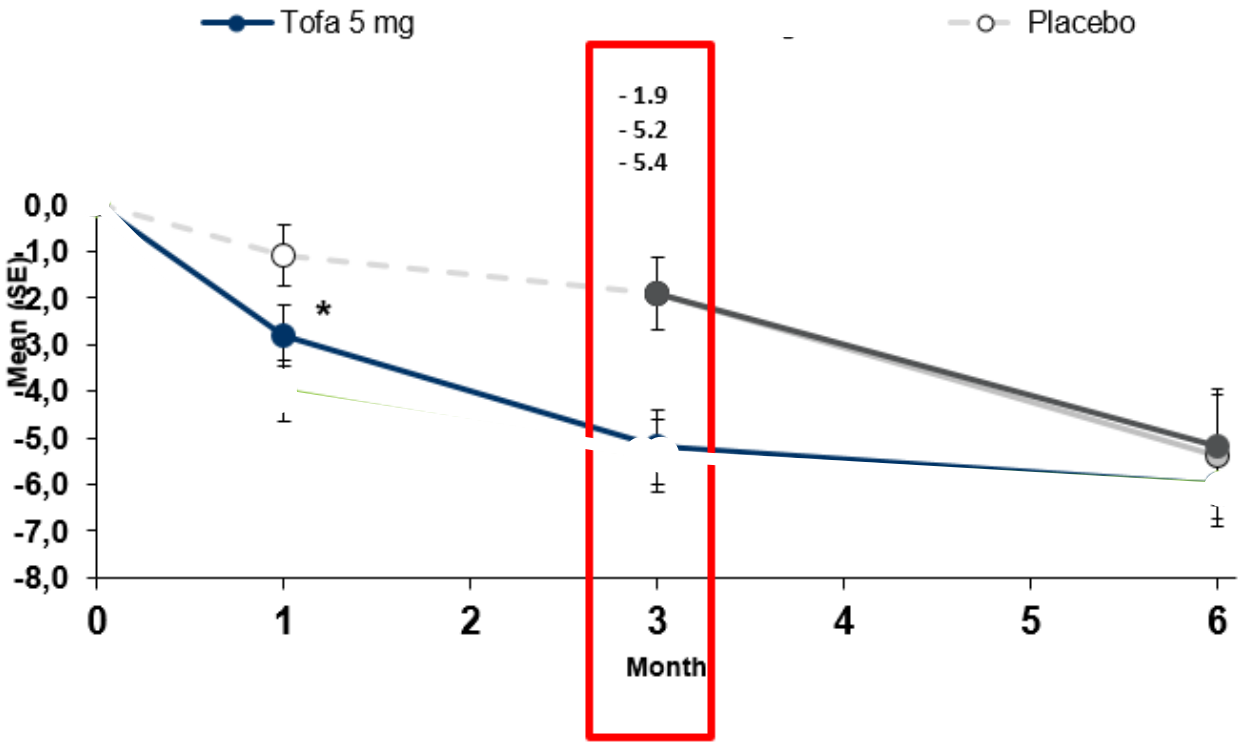
1. Mease et al. N Engl J Med. 2017;377:1537–50;
2. Gladman et al. N Engl J Med. 2017;377:1525–36;

Dactylitis Severity Score

OPAL Broaden bDMARDs naive[1]



OPAL Beyond TNF-IR[2]



1. Mease et al. N Engl J Med. 2017;377:1537–50; Supplementary appendix. 2. Gladman et al. N Engl J Med. 2017;377:1525–36; Supplementary appendix

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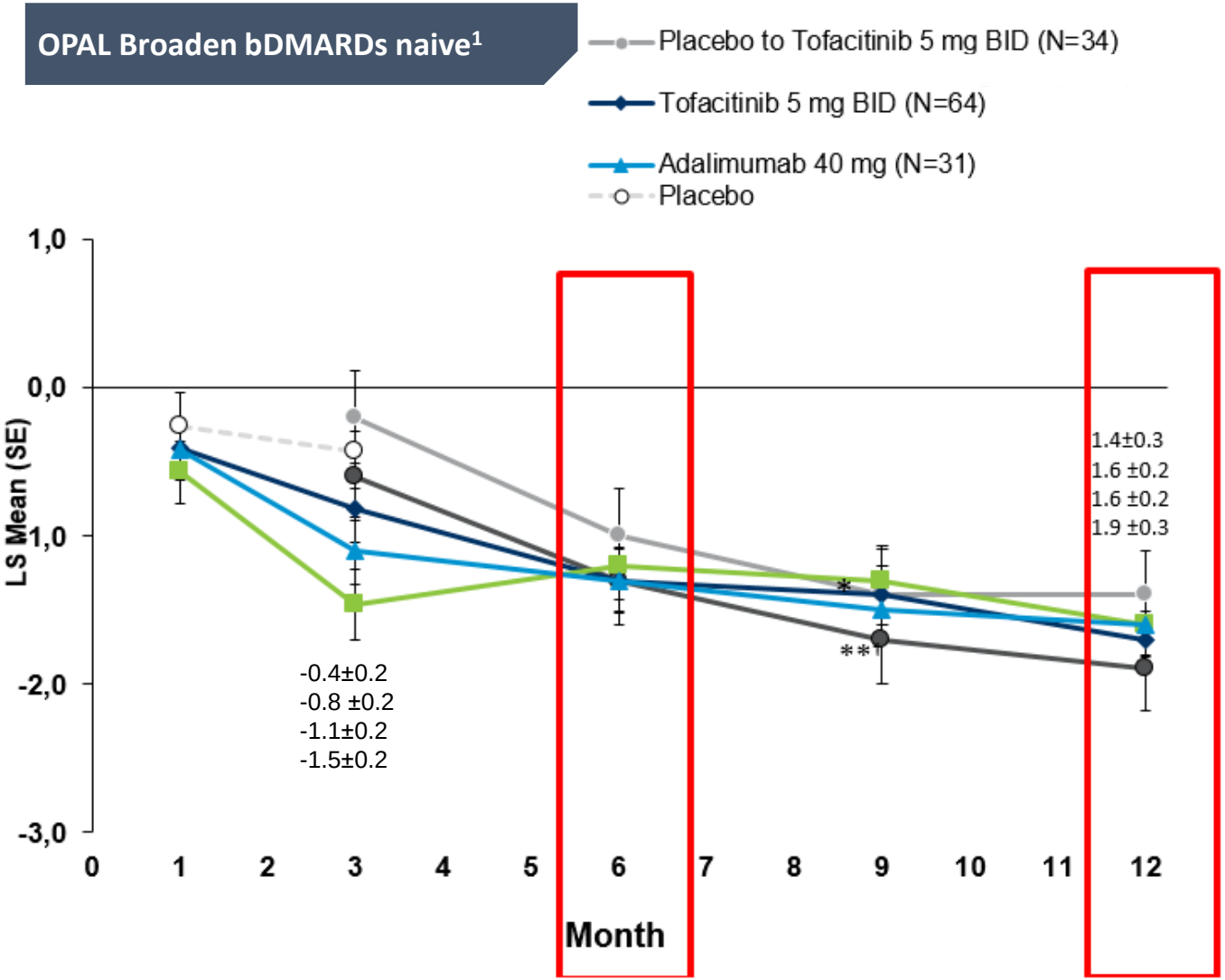
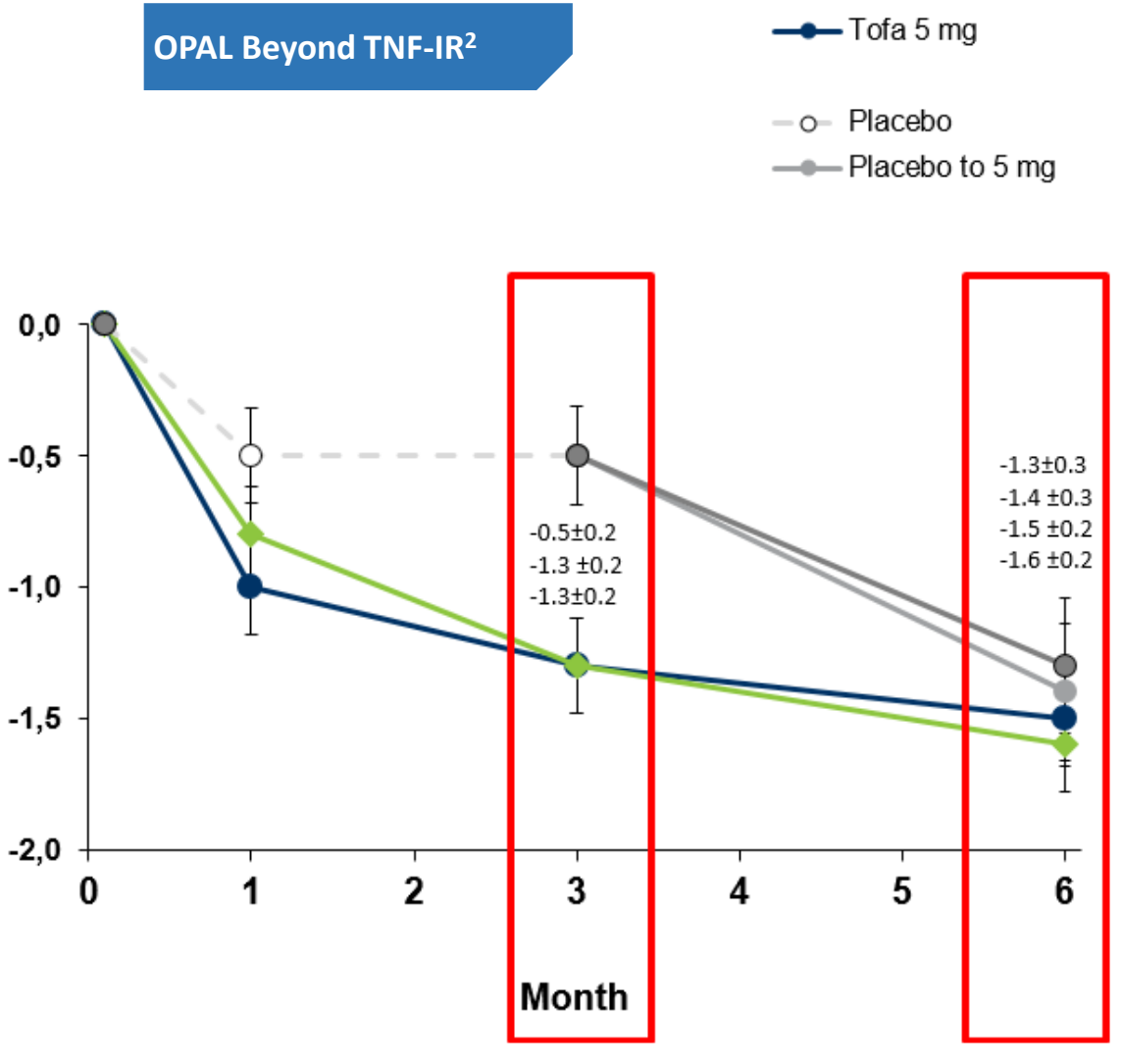
Enthesitis Severity Score LEI=Leeds Enthesitis Index

OPAL Broaden bDMARDs naive[1]



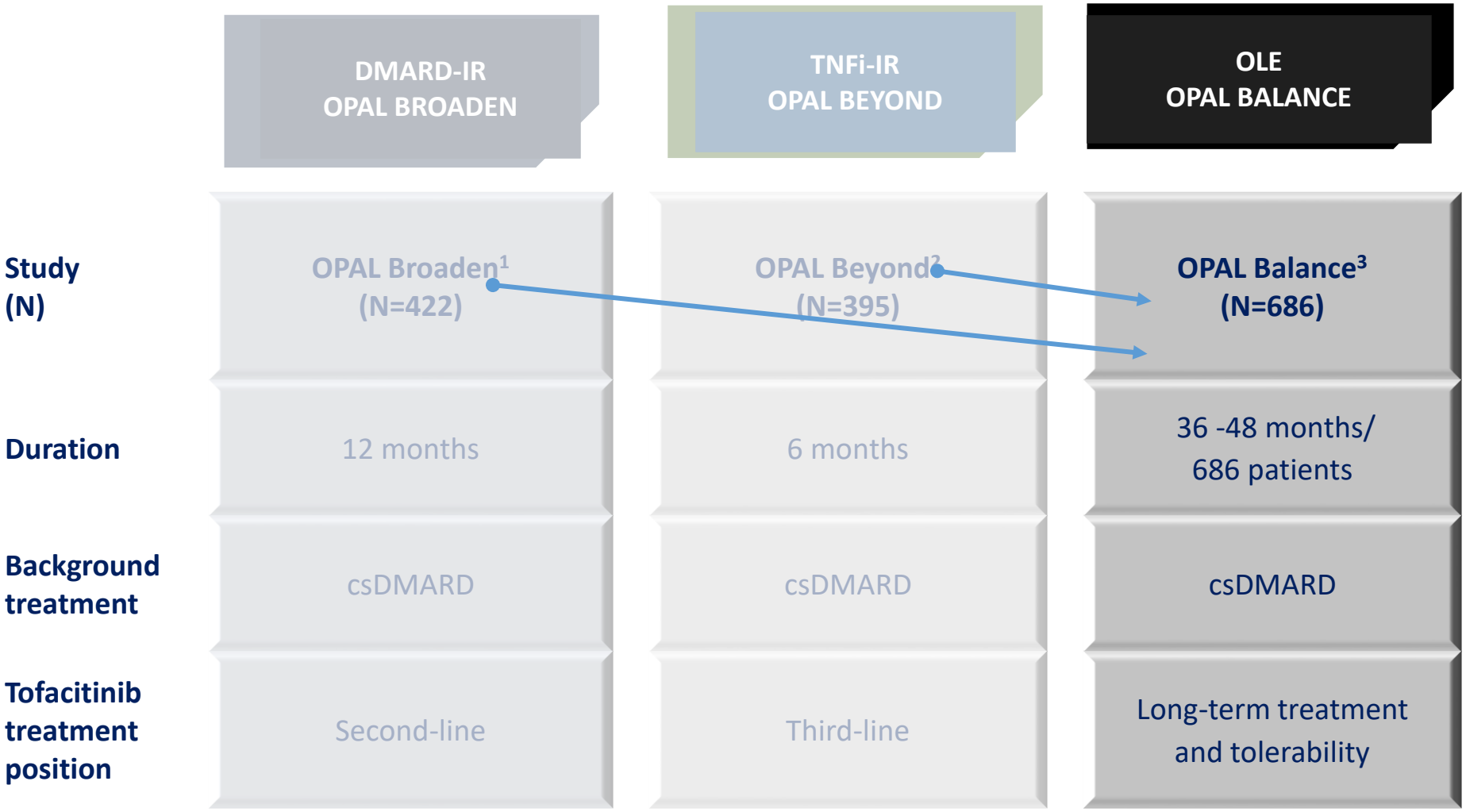
OPAL Beyond TNF-IR[2]



1. Mease et al. N Engl J Med. 2017;377:1537–50; Supplementary appendix. 2. Gladman et al. N Engl J Med. 2017;377:1525–36; Supplementary appendix

The licensed dose of tofacitinib in PsA is 5 mg BID in combination with csDMARDs

Overview of Tofacitinib studies in PsA



1. Mease et al. N Engl J Med 2017;377:1537–50.
2. Gladman et al. N Engl J Med 2017;377:1525–36;
3. Nash, et al, April 2021 The Lancet Rheumatology 3(4):e270-e283.

Safety and efficacy of tofacitinib up to 48 months in patients with active PsA: final analysis of the OPAL Balance long-term extension study

Nash, P., Coates, L. C., Kivitz, A. J., et al, April 2021 The Lancet Rheumatology 3(4):e270-e283

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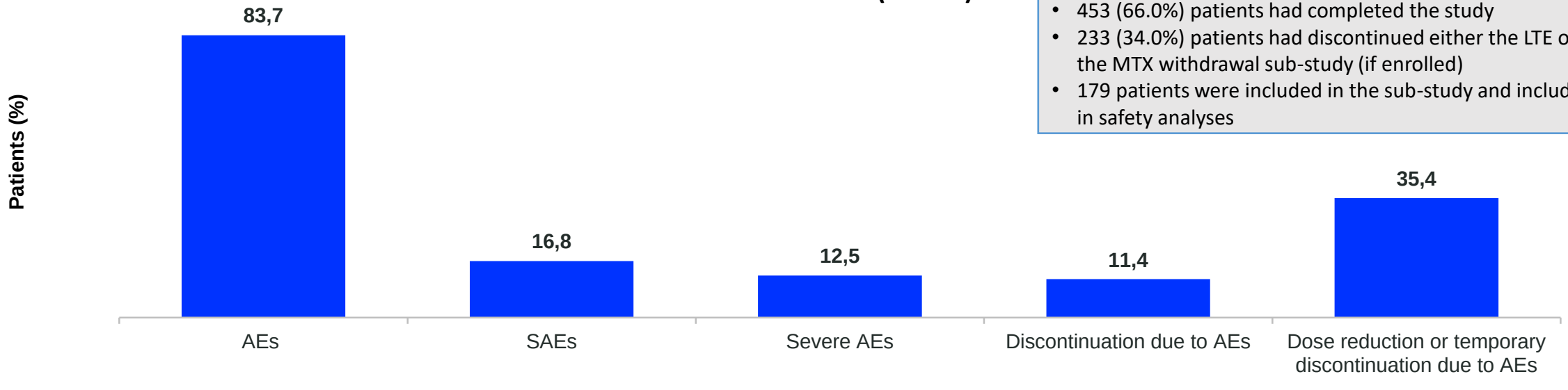
OPAL Balance: Overall Adverse Events up to Month 48 in Adults With Active PsA*

All Tofacitinib (N=686)

At study end (May 20, 2019):
- 453 (66.0%) patients had completed the study
- 233 (34.0%) patients had discontinued either the LTE or the MTX withdrawal sub-study (if enrolled)
- 179 patients were included in the sub-study and included in safety analyses



	AEs	SAEs	Severe AEs	Discontinuation due to AEs	Dose reduction or temporary discontinuation due to AEs
Patients with event*	574	115	86	78	243

Nash P, et al. *Lancet Rheumatol*. 2021;3(4):e270-e283.

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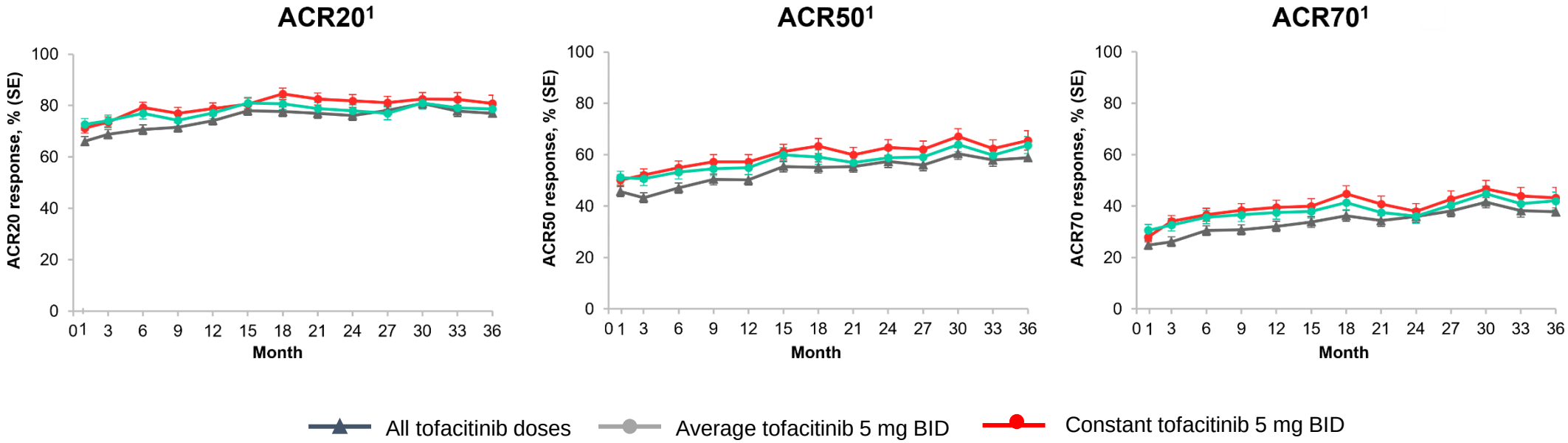
OPAL Balance – Διατήρηση κλινικής απάντησης



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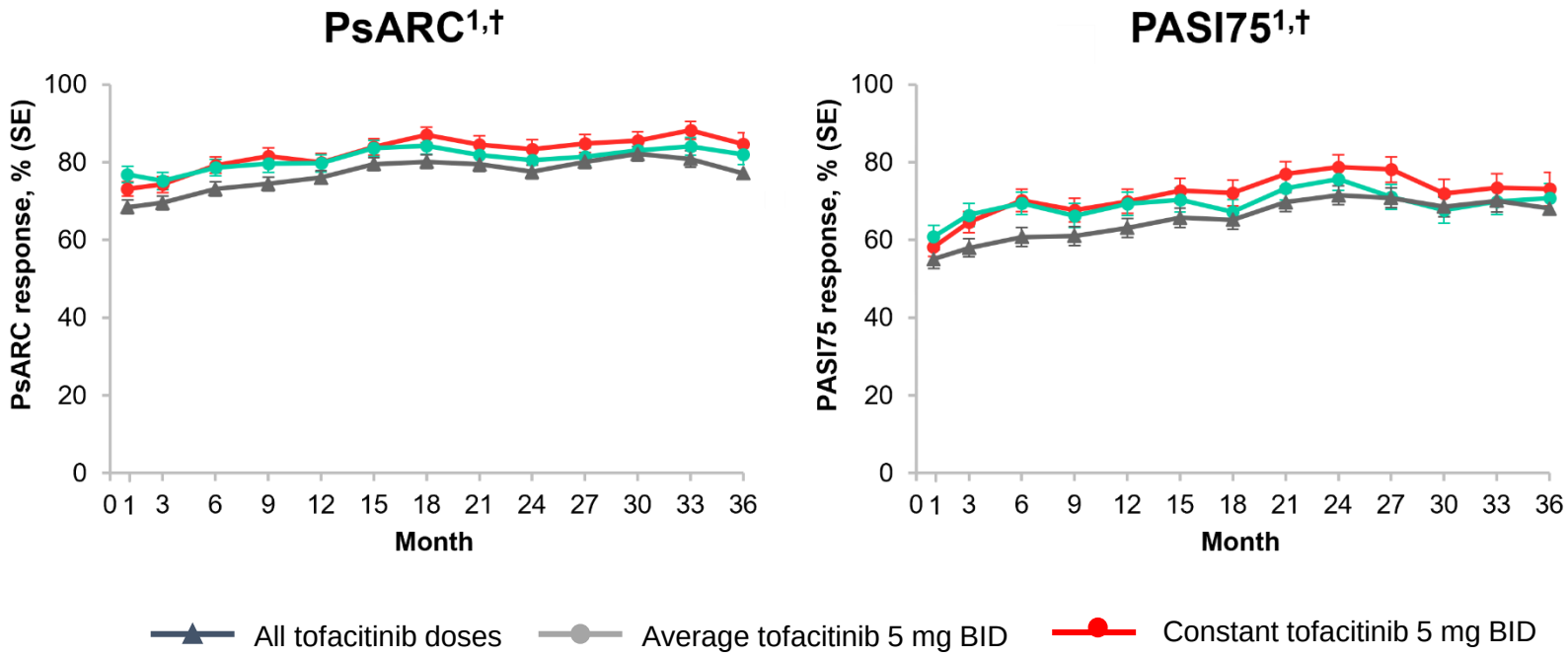
OPAL-balance: Διατήρηση κλινικής απάντησης



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Συμπεράσματα

- 2/3 των ασθενών ολοκλήρωσαν την μελέτη
- Κατά την μακροχρόνια χορήγηση (48 wks)
  - Δεν παρατηρείται αύξηση του κινδύνου για ανεπιθύμητες ενέργειες
    - Χαμηλά ποσοστά σοβαρών ΑΕ
    - Ήπια διακύμανση στην ηπατική βιοχημία, ειδικά σε όσους λάμβαναν MTX, και στις τιμές των λιπιδίων
  - Δεν προέκυψαν νέες ανεπιθύμητες ενέργειες
- Η ανταπόκριση στην αγωγή διατηρείται στις 36 εβδομάδες σε αρθρώσεις και δέρμα

Nash P, et al. *Lancet Rheumatol*. 2021;3(4):e270-e283.

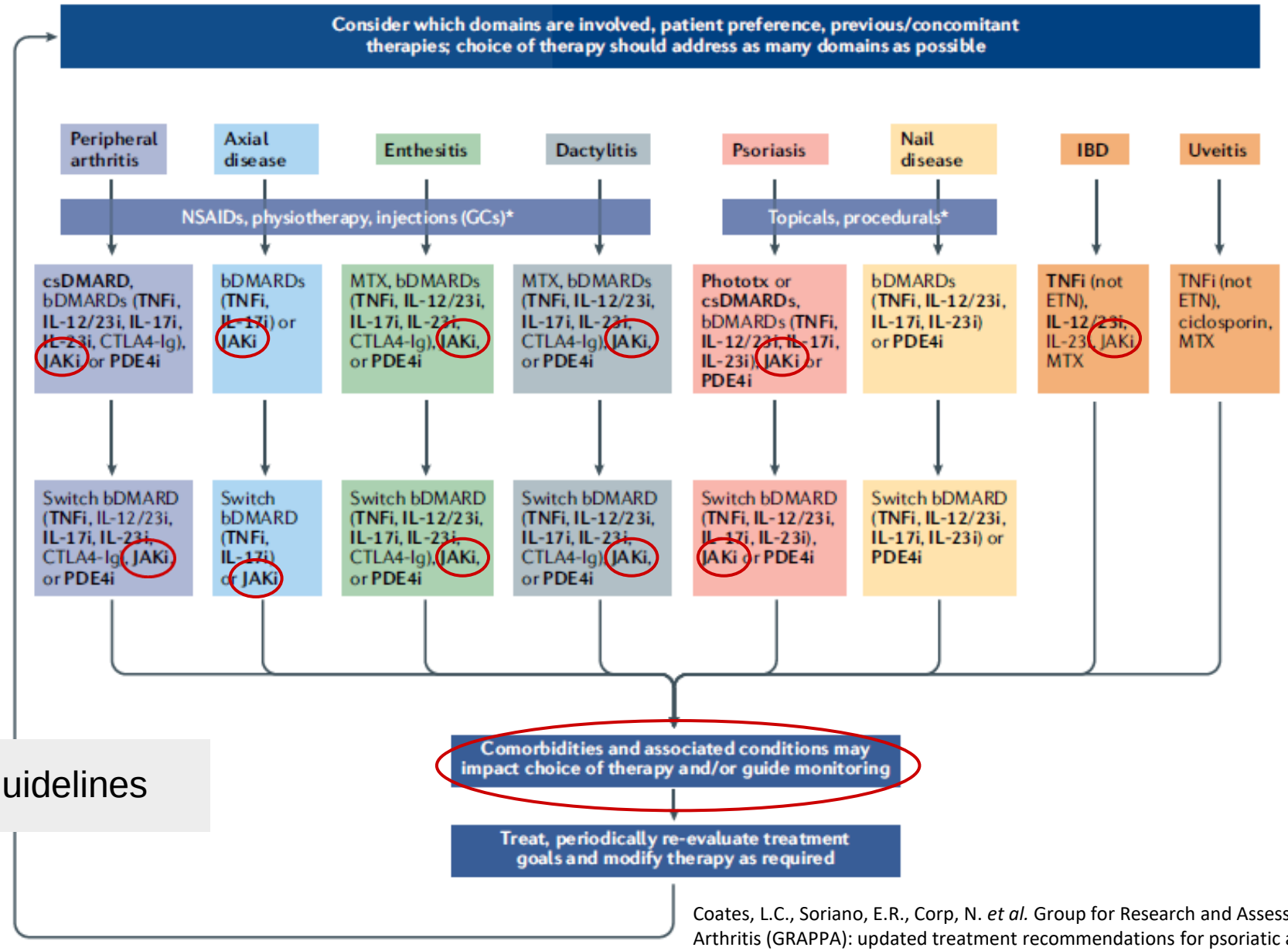
Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021

Table 3 | **Summary of recommendations for treatment of PsA**

Indication	Strong recommendation for	Conditional recommendation for	Conditional recommendation against	Strong recommendation against	No recommendation: insufficient or conflicting evidence
Peripheral arthritis, DMARD naive	csDMARDs (except CsA), TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	NSAIDs, oral GC, IA GC	–	–	–
Peripheral arthritis, DMARD inadequate response	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	csDMARDs, NSAIDs, oral GC, IA GC, CTLA4-Ig	–	–	–
Peripheral arthritis, bDMARD experienced	TNFi, IL-17i, IL-23i, JAKi	NSAIDs, oral GC, IA GC, IL-12/23i, PDE4i, CTLA4-Ig	–	–	–
Axial disease, bDMARD naive	NSAIDs, physiotherapy, simple analgesia, TNFi, IL-17i, JAKi	GC SIJ injections, bisphosphonates	PDE4i	csDMARDs	IL-12/23i, IL-23i
Enthesitis	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	NSAIDs, physiotherapy, MTX, CTLA4-Ig, GC injections (with extreme caution)	–	–	Other csDMARDs
Dactylitis	TNFi, IL-12/23i, IL-17i, IL-23i, JAKi, PDE4i	NSAIDs, GC injections, MTX, CTLA4-Ig	Other csDMARDs	–	–
Psoriasis (plaque)	Topical therapies, phototherapy, cdDMARDs (MTX, fumarate, fumaric acid esters, CsA), TNFi, IL-12/23i, IL-17i, IL-23i, PDE4i, JAKi	Acitretin	–	–	–
Nail psoriasis	TNFi, IL-12/23i, IL-17i, IL-23i, PDE4i	Topical GC, tacrolimus and calcipotriol combination or individual therapies, pulsed dye laser, csDMARDs (MTX, LEF, CsA), acitretin, JAKi	–	–	Topical CsA, tazarotene, fumarate, fumaric acid esters, UVA and UVB phototherapy, alitretinoin
IBD: Crohn's disease	TNFi (not ETN), IL-12/23i	IL-23i, JAKi, MTX	–	IL-17i	ETN
IBD: UC	TNFi (not ETN), IL-12/23i	IL-23i, JAKi, MTX	–	IL-17i	ETN, PDE4i
Uveitis	–	TNFi (not ETN), CsA, MTX	ETN	–	Other csDMARDs, IL-17i, IL-12/23i

Coates, L.C., Soriano, E.R., Corp, N. *et al.* Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol* **18**, 465–479 (2022).

Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021



GRAPPA PsA Guidelines

Coates, L.C., Soriano, E.R., Corp, N. *et al.* Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol* **18**, 465–479 (2022).

Tofacitinib: *Ο πρώτος JAK αναστολέας με* ***4*** *ρευματολογικές ενδείξεις*

Tofacitinib: ρευματολογικές ενδείξεις	
Ρευματοειδής αρθρίτιδα	√
Αγκυλοποιητική σπονδυλίτιδα	√
Ψωριασική αρθρίτιδα	√
Νεανική ιδιοπαθής αρθρίτιδα	**√**

Tofacitinib in juvenile idiopathic arthritis: a double-blind, placebo-controlled, withdrawal phase 3 randomised trial

Nicolino Ruperto Lancet 2021; 398: 1984–96*

REFERENCE: Xeljanz SmPC 09/2022

Tofacitinib in juvenile idiopathic arthritis: a double-blind, placebo-controlled, withdrawal phase 3 randomised trial

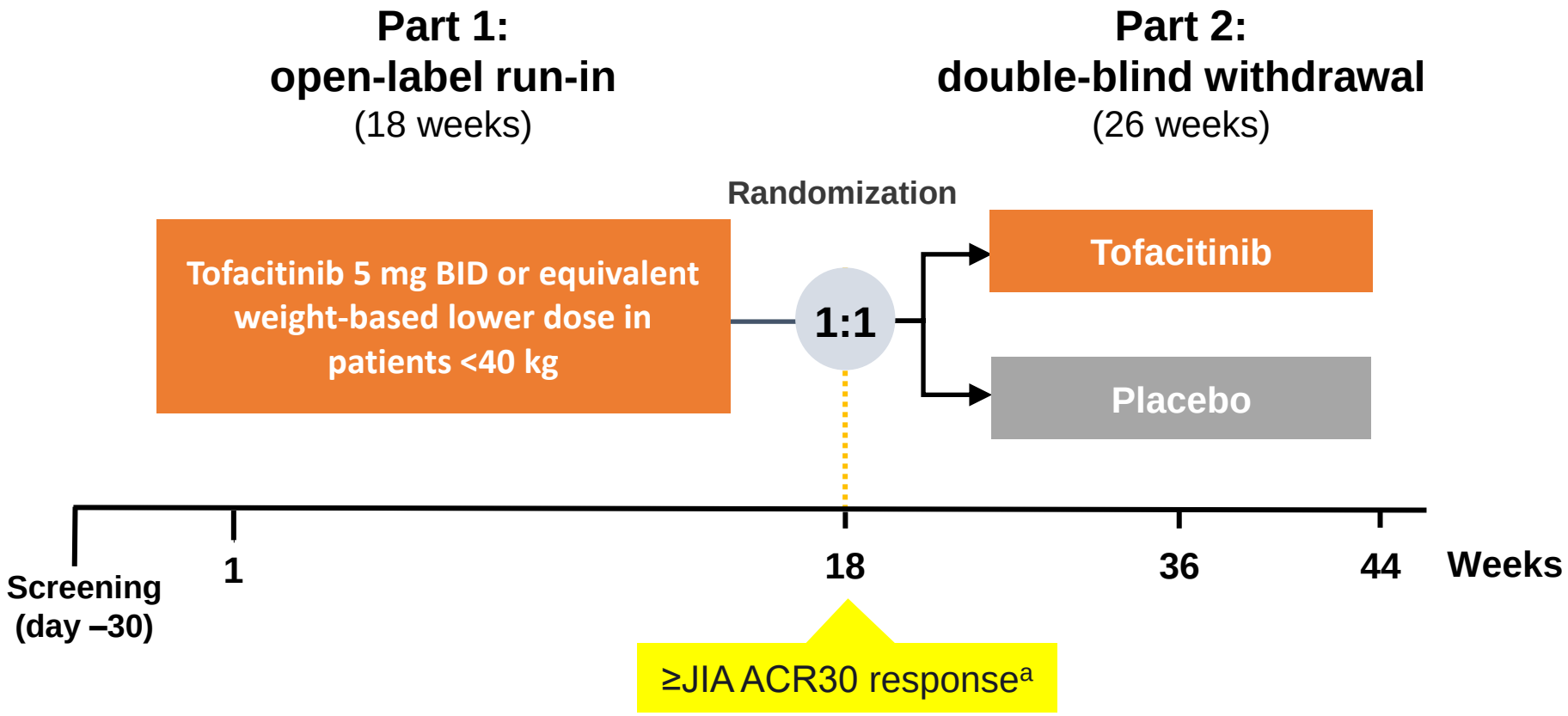
Nicolino Ruperto Lancet 2021; 398: 1984–96*

Key inclusion criteria

- Age 2 to <18 years
- **Active pcJIA, jPsA, or ERA**
  - *≥5 active joints and Inadequate response or intolerance to >1 DMARD in pcJIA*
  - *≥3 active joints and an*
  - *Inadequate response to NSAIDs in jPsA or ERA*

Key exclusion criteria

- Systemic JIA with active systemic features
- Persistent oligoarthritis
- Undifferentiated JIA
- Active uveitis



Ruperto N et al, Lancet 2021; 398: 1984–96

Primary Endpoint[1]	Occurrence of JIA flare[a] at Wk 44 in Part 2 (Weeks 18–44)
Key Secondary Endpoints[1]	JIA ACR30/50/70 response[b] rates at Week 44 (vs Part 1 baseline)
	Mean change from Part 2 baseline in CHAQ-DI at Week 44
Select Secondary Endpoints[1]	Time to JIA flare in Part 2
	JIA ACR30/50/70/90/100 response rates and JIA/ACR inactive disease rates over time in parts 1 and 2
	Mean JADAS27-CRP over time in Part 1 and Part 2
Safety Endpoints[1]	AEs, AESEs
	Clinical laboratory abnormalities
	Laboratory values over time

Efficacy reported only in patients with pcJIA[2]

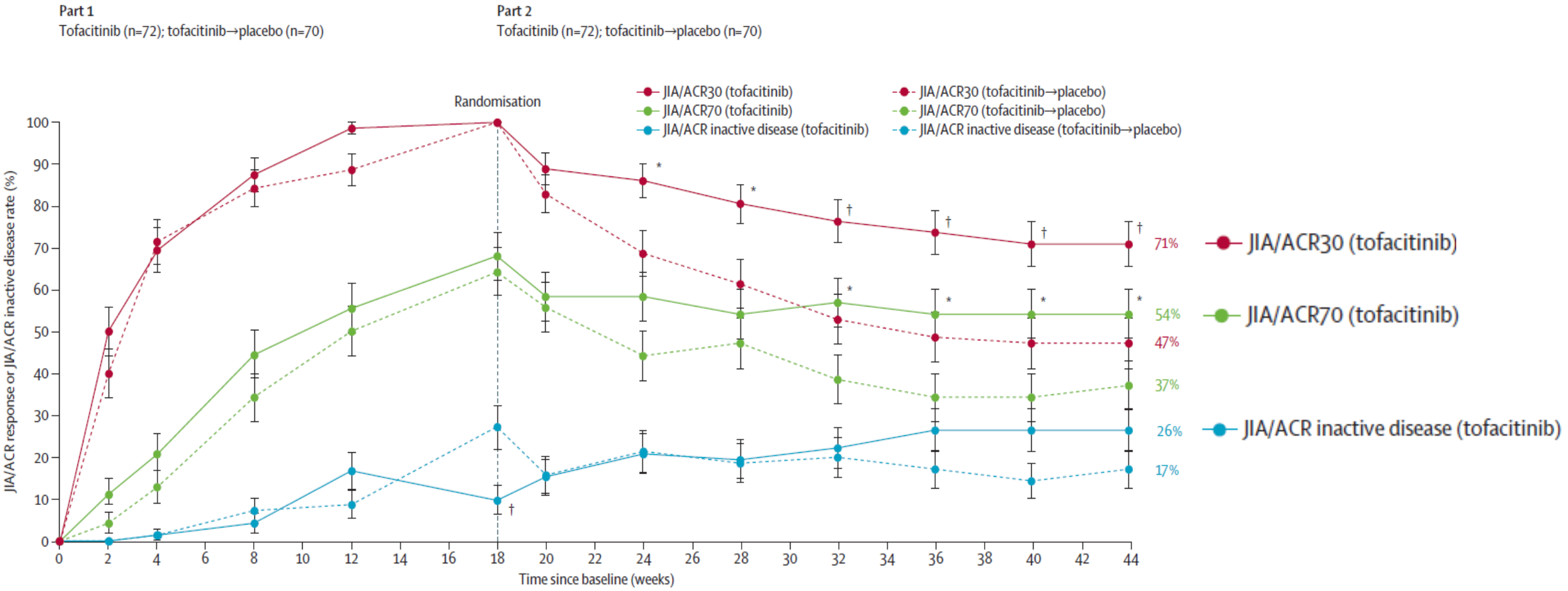
Efficacy in patients with jPsA and ERA assessed separately

Safety evaluated throughout study in all patients (pcJIA/PsA/ERA)[2]

1. Ruperto N, et al. *Lancet.* 2021; 398(10315):1984-1996.
2. Ruperto N, et al. [Abstract: OP0291]. *Ann Rheum Dis* 2020; 79(S1): 180-181.

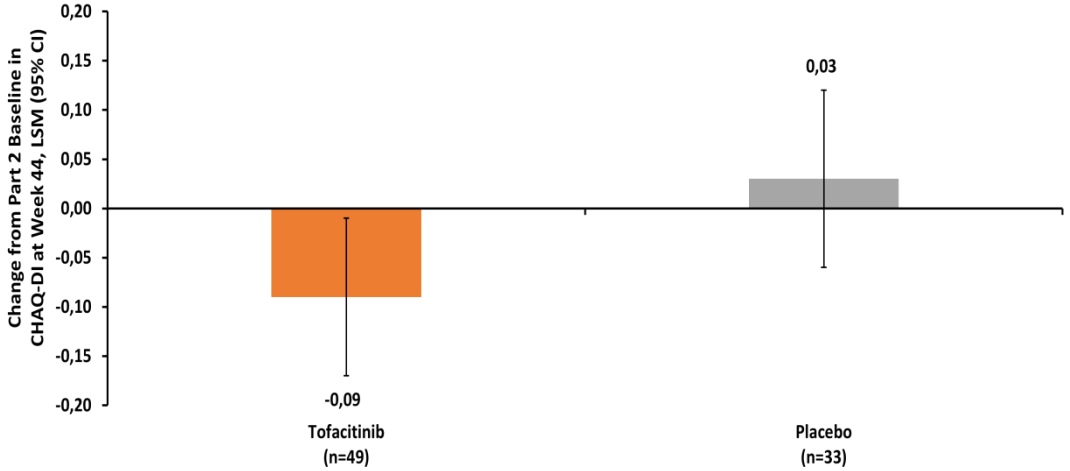
Key Secondary Endpoint (pcJIA)

Higher Response Rates
in Patients Receiving Tofacitinib

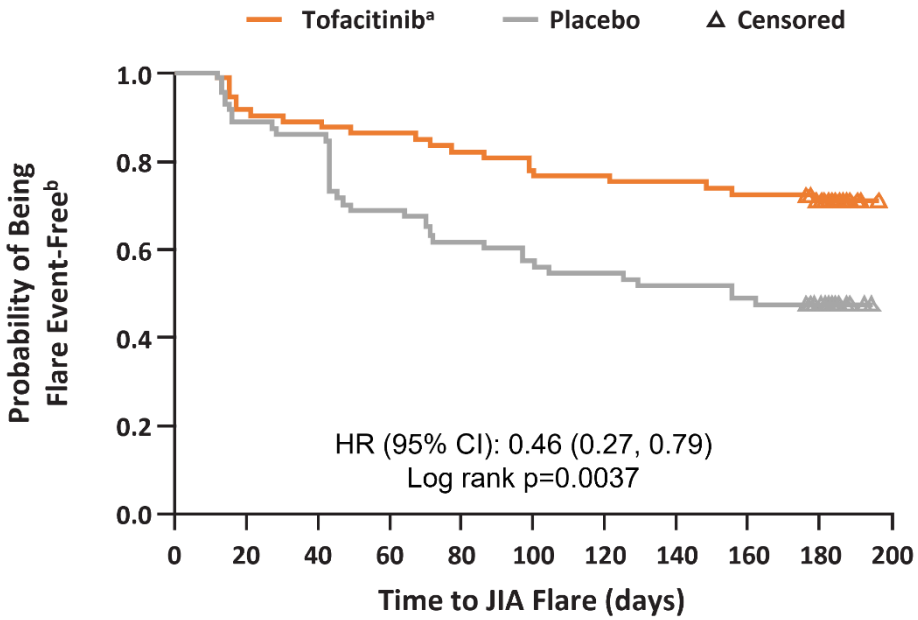


Error bars represent standard error. *p<0.05. †p<0.01.
ACR, American College of Rheumatology; JIA, juvenile idiopathic arthritis; pcJIA, polyarticular course juvenile idiopathic arthritis.
Ruperto N, et al. *Lancet.* 2021; 398(10315):1984-1996.

Greater improvement in CHAQ-DI in Patients Receiving Tofacitinib

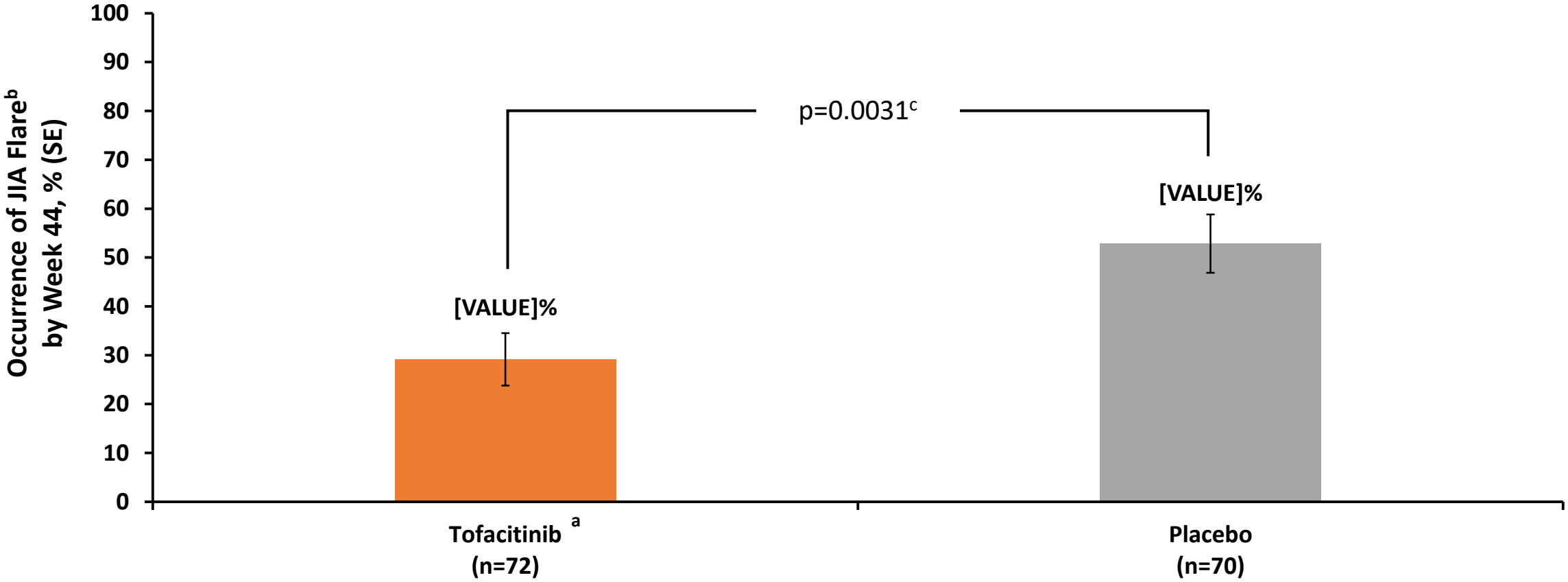


Greater Time to Disease Flare in Patients Receiving Tofacitinib



a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg.
b. Data are as observed and evaluated by MMRM.
CHAQ-DI, Childhood Health Assessment Questionnaire-Disability Index; LSM, least squares mean; MMRM, mixed-effect model with repeated measures.
Ruperto N, et al. *Lancet.* 2021; 398(10315):1984-1996.

Lower JIA Flare
in Patients Receiving Tofacitinib



a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg.
b. Flare is defined as a worsening of ≥30% in ≥3 out of 6 JIA core set variables, with ≤1 variable improving by ≥30% (Brunner HI et al. *J Rheumatol* 2002; 29: 1058–1064).
c. Normal approximation approach for binomial proportions.
pcJIA, polyarticular course juvenile idiopathic arthritis; SE, standard error.
Ruperto N, et al. *Lancet*. 2021; 398(10315):1984-1996.

Adverse Events

Patients with events, n (%)	Open-label (0-18 weeks) Tofacitinib [a] N=225	Double-blind (18-44 weeks) Tofacitinib [a] N=88	Double-blind (18-44 weeks) Placebo N=85
AEs	153 (68.0)	68 (77.3)	63 (74.1)
Serious AEs	7 (3.1)	1 (1.1)	2 (2.4)
Permanent discontinuations due to AEs	26 (11.6)	16 (18.2)	29 (34.1)
Temporary dose reductions or temporary hold due to AEs	20 (8.9)	9 (10.2)	8 (9.4)
Most common AEs by preferred term (≥10% of any treatment group)			
Upper respiratory tract infection	24 (10.7)	13 (14.8)	9 (10.6)
Disease progression	5 (2.2)	8 (9.1)	13 (15.3)
JIA exacerbation	6 (2.7)	3 (3.4)	12 (14.1)

AEs of Special Interest

Patients with events, n (%)	Open-label (Weeks 0-18) Tofacitinib[a] N=225	Double-blind (Weeks 18-44) Tofacitinib[a] N=88	Double-blind (Weeks 18-44) Placebo N=85
Death	0	0	0
Gastrointestinal perforation[b]	0	0	0
Hepatic events[b]	3 (1.3)	0	0
Herpes zoster[b,c]	2 (0.9)	0	0
Interstitial lung disease[b]	0	0	0
Major adverse cardiovascular events[b]	0	0	0
Malignancy (excluding NMSC)[b]	0	0	0
Macrophage activation syndrome[b]	0	0	0
Opportunistic infections[b]	0	0	0
Serious infections	3 (1.3)	1 (1.1) [d]	1 (1.2)
Thrombotic events (DVT, PE,[b] or ATE)	0	0	0
Tuberculosis[b]	0	0	0

a. Tofacitinib 5 mg BID or equivalent weight-based lower dose in patients <40 kg.
AE, adverse event; ERA, enthesitis-related arthritis; jPsA, juvenile psoriatic arthritis; pcJIA, polyarticular course juvenile idiopathic arthritis.
Ruperto N, et al. *Lancet.* 2021; 398(10315):1984-1996.

Tofacitinib in juvenile idiopathic arthritis: a double-blind, placebo-controlled, withdrawal phase 3 randomised trial

Nicolino Ruperto Lancet 2021; 398: 1984–96*

Η χορήγηση Tofacitinib στην JIA συσχετίζεται με:

- Γρήγορη κλινική βελτίωση
- Διατήρηση του θεραπευτικού αποτελέσματος
- Απουσία νέων ανεπιθύμητων ενεργειών από το φάρμακο
- Επιβεβαίωση των ευρημάτων σε μελέτες μακροχρόνιας παρακολούθησης

Nicolino Ruperto Lancet 2021; 398: 1984–96*

Tofacitinib: *Ο πρώτος JAK αναστολέας με* ***4*** *ρευματολογικές ενδείξεις*

Δεδομένα από τις Αξονικές Σπονδυλαρθρίτιδες και τη Νεανική Ιδιοπαθή Αρθρίτιδα

Tofacitinib: ρευματολογικές ενδείξεις	
Ρευματοειδής αρθρίτιδα	√
Αγκυλοποιητική σπονδυλίτιδα	√
Ψωριασική αρθρίτιδα	√
Νεανική ιδιοπαθής αρθρίτιδα	√

Tofacitinib	
Αποτελεσματικότητα	√
Ασφάλεια	√
Διατήρηση θεραπευτικού αποτελέσματος	√
Εξωαρθρικές εκδηλώσεις	√
Νέες ενδείξεις	√

REFERENCE: Xeljanz SmPC 09/2022


Ευχαριστώ πολύ!

Incidence of venous and arterial thromboembolic events reported in the tofacitinib rheumatoid arthritis, psoriasis and psoriatic arthritis development programmes and from real-world data

Philip Mease et al, Ann Rheum Dis 2020;79:1400–1413

Ασφάλεια – θρομβωτικά επεισόδια

Σύγκριση με bDMARDs – παράγοντες κινδύνου

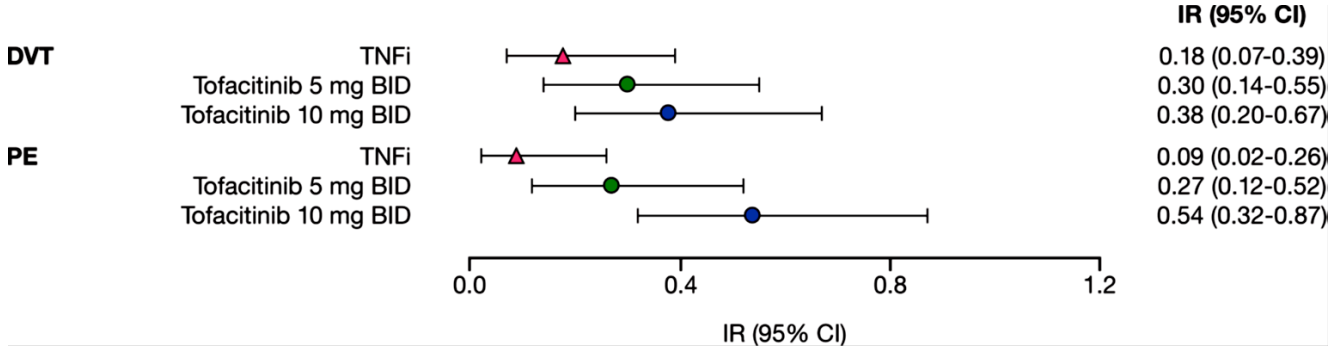


Figure 4 Incidence rates (95% CI) for DVT and PE among patients in Study A3921133 (ad hoc safety analysis). BID, twice daily; DVT, deep vein thrombosis; IR, incidence rate (number of patients with an event per 100 PY of exposure); PE, pulmonary embolism; PY, patient-years;
TNFi, tumour necrosis factor inhibitor.

- Η ανάλυση δεδομένων σε ΡΑ, και ΨΑ έδειξε ότι η επίπτωση DVT, PE, VTE για το tofacitinib, placebo, adalimumab και methotrexate ήταν παρόμοια
- Στην υποανάλυση φάνηκε ότι οι ασθενείς με υπάρχουσα ή με παράγοντες κινδύνου για καρδιαγγειακή νόσο είχαν μεγαλύτερο κίνδυνο εμφάνισης θρομβωτικού επεισοδίου
- Αντιθέτως, σε ασθενείς χωρίς ιστορικό και παράγοντες κινδύνου, η επίπτωση της φλεβοθρόμβωσης είναι πολύ μικρή

Onnly 5mg BID is the approved dose of tofacitinib in RA and PsA. Psoriasis is not an approved indication in Europe, γιατι το Tofa δεν έχει πάρει ένδειξη για ψωριαση στην Ευρώπη.

Mease P, et al. Ann Rheum Dis 2020;**79**:1400–1413