PATRAS UNIVERSITY HOSPITAL

Ολοκληρωμένη αντιμετώπιση της Ψωριασικής Αρθρίτιδας

9ο Συνέδριο ΕΠΕΜΥ
3 Ιουν, Ρόδος

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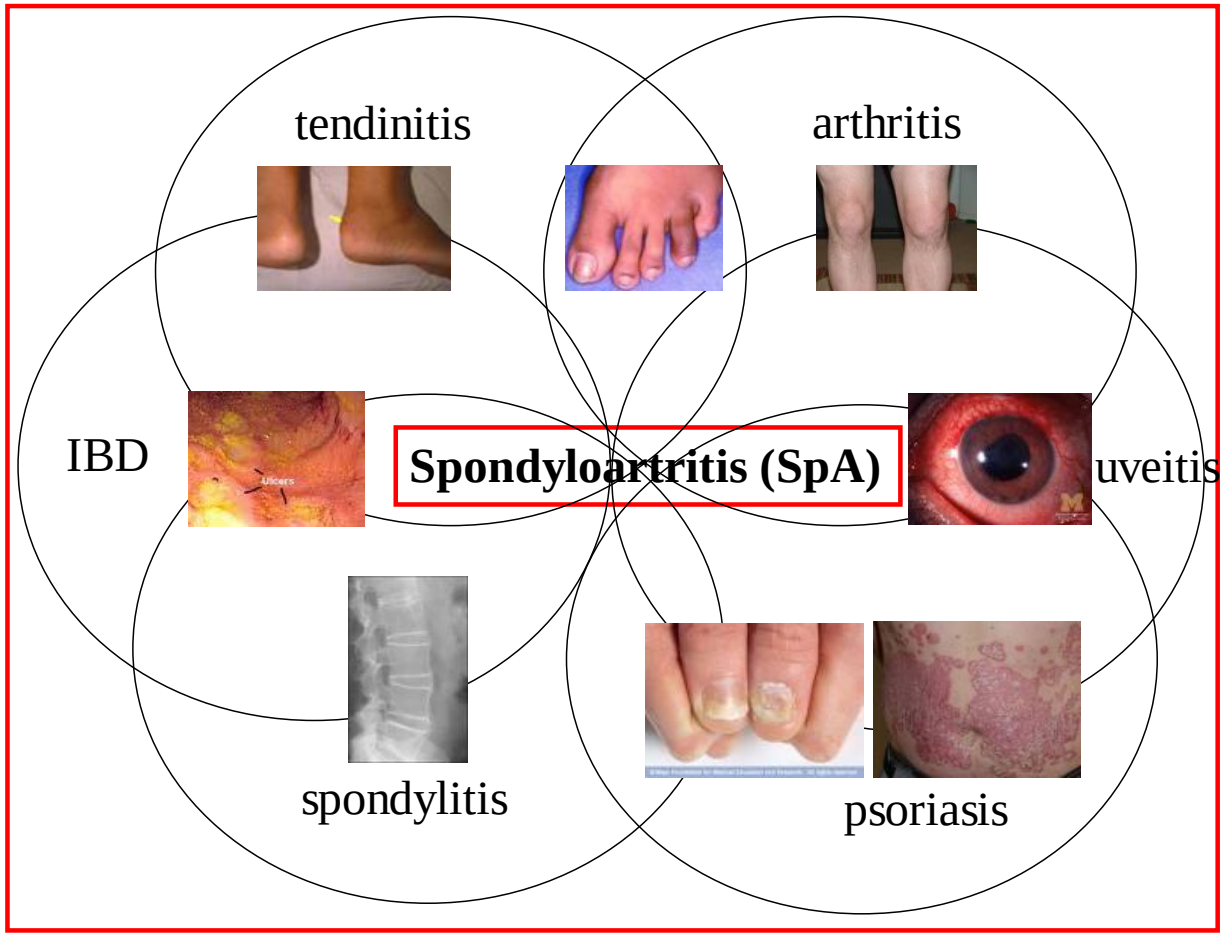
Σύγκρουση συμφερόντων

Τιμητική αμοιβή για ομιλίες και συμμετοχή σε advisory boards από τις εταιρείες UCB, Pfizer, Novartis, BMS, MSD, Jansen,

Σπονδυλοαρθροπάθειες

- Ισχυρό γενετικό υπόβαθρο
- Φλεγμονή σε σημεία που δέχονται stress (μηχανικό ή μικροβιακό)
- Προσβολή αξονικού σκελετού-Οστεοπαραγωγή



Overview of the Clinical Features of Psoriatic Arthritis

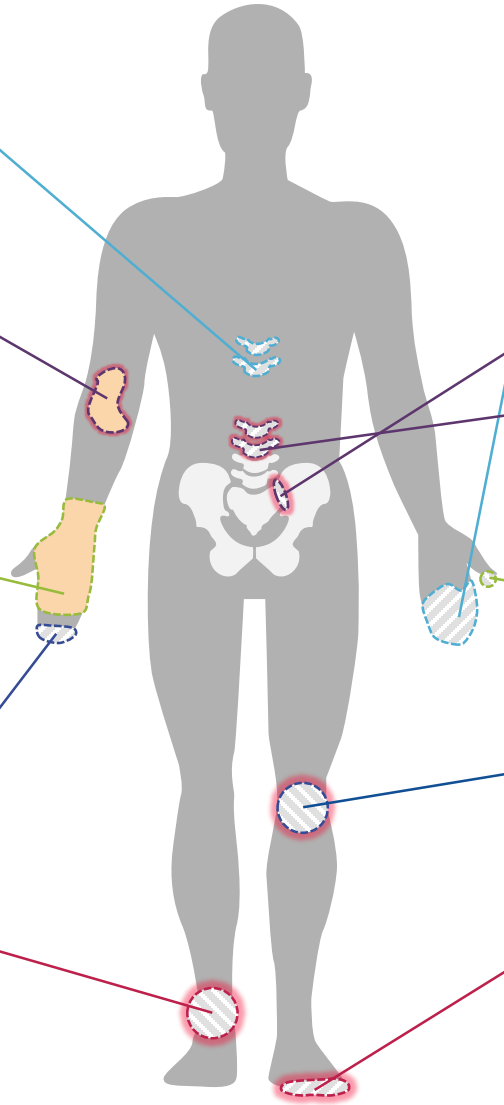
Syndesmophytes
- Bony outgrowths at the site of erosion or in adjacent soft tissue.

Psoriasis[2]
- Psoriasis presents with red, sharp bordered lesions with white/silver, dry scaling, which may lead to pain and itching.

Arthritis mutilans
- Involves severe erosion and joint space narrowing of the hands and feet, bone oedema and osteolysis of phalanges, metatarsals and metacarpals.
- Rare, seriously damaged digits, 'pencil-in-cup' and 'telescoping'

Nail abnormalities

Peripheral enthesitis
- Inflammation of the sites where tendons or ligaments insert into the bone, occurring most frequently in joints of the lower limbs, eg. the Achilles tendon.



Symmetrical polyarthritis similar to RA
- A predominant subtype of PsA involving the small joints of the hands and feet, in addition to larger joints.

Sacroiliitis / spondylitis
- Sacroiliitis involves active inflammation of the sacroiliac joint that can lead to inflammatory back pain.
- Spondylitis is inflammation of vertebrae which occurs most commonly in the lumbar spine.

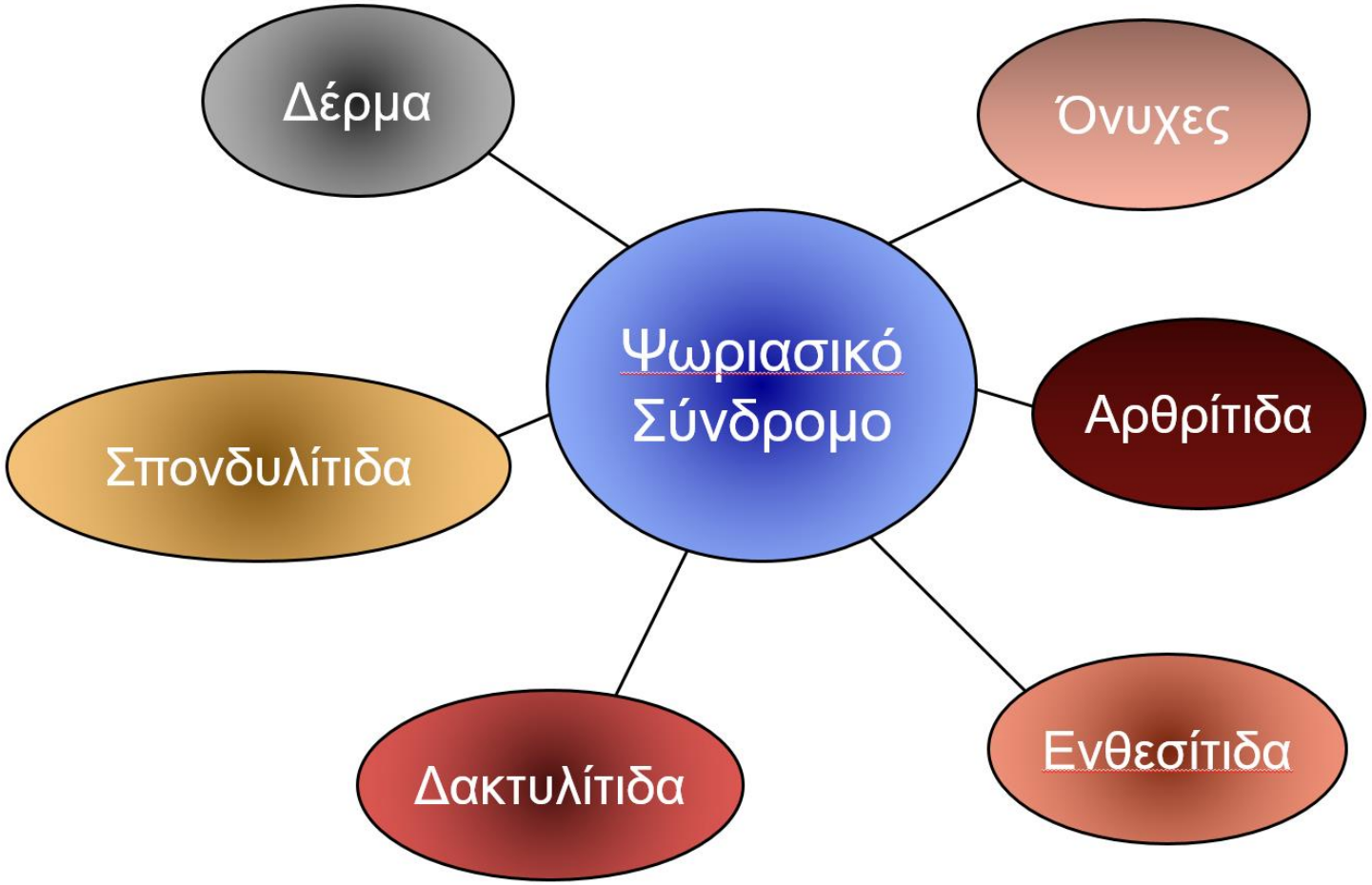
DIP PsA
- Involves the distal joints (the joint closest to the nail) of the fingers and toes.

Oligoarthritis
- Asymmetric arthritis, occurring in one to four joints, is very common in PsA.

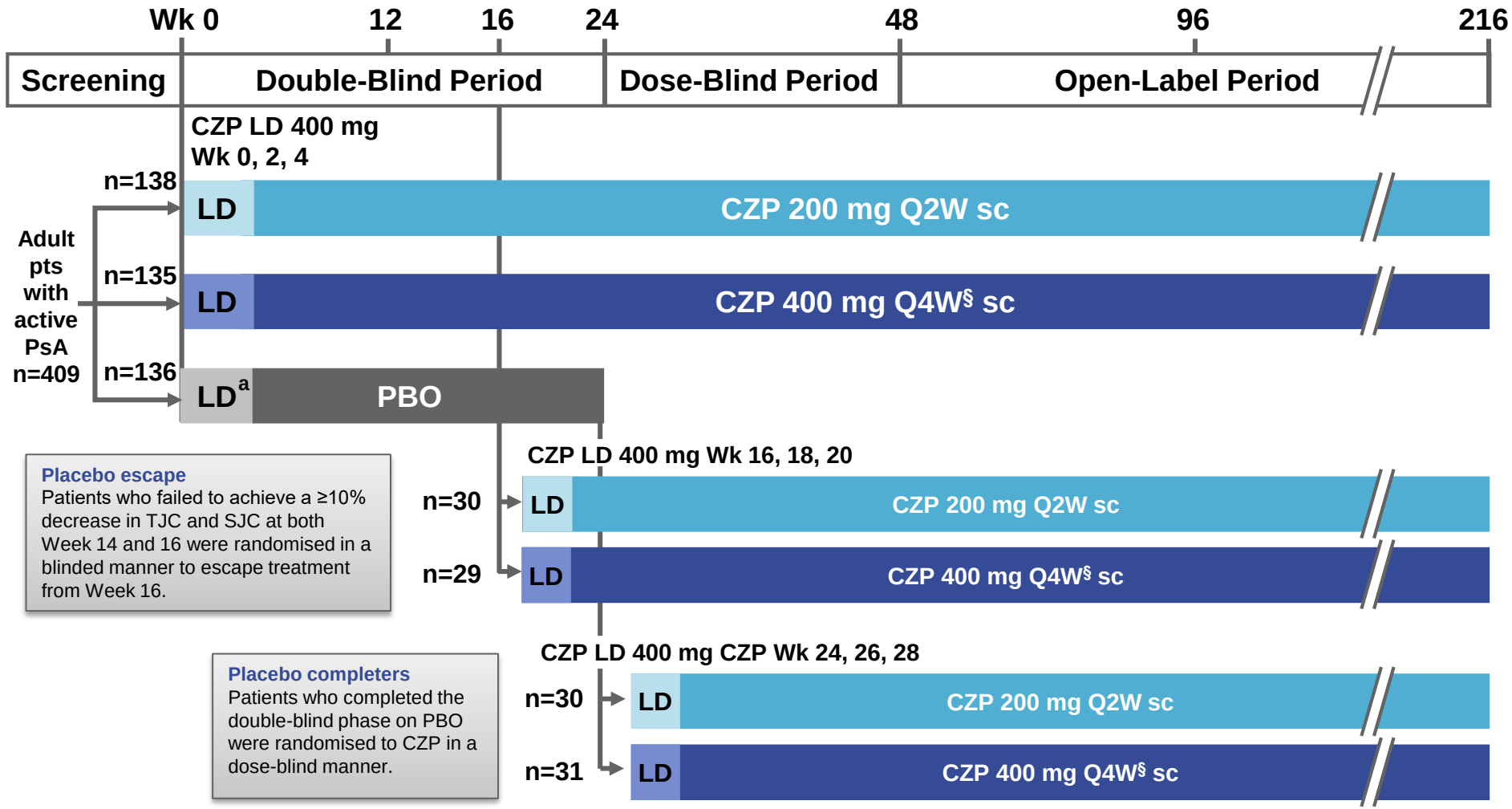
Dactylitis
- The swelling of a finger or toe, very common in PsA.

[1]Cantini F et al. Int J Rheum Dis. 2010;13(4):300–17
[2]Lueng YY et al. J Postgrad Med. 2007;53:63–71

Το φάσμα της ψωριασικής αρθρίτιδας είναι ευρύ



RAPID-PsA Trial Design to Week 216



§For maintenance in PsA, CZP 400 mg Q4W before clinical response is confirmed is not an approved dose in the European Union

[a]Loading dose of PBO;
LD: Loading Dose; **sc**: subcutaneously; **TJC**: Tender Joint Count; **SJC**: Swollen Joint Count.

Adapted from Mease PJ et al. RMD Open. 2015;1(1):e000119

Baseline Characteristics of RAPID-PsA Patients (1/2)

	Placebo (n=136)	CZP 200 mg Q2W (n=138)	CZP 400 mg Q4W§ (n=135)
Demographic Characteristics			
Age (years), mean (SD)	47.3 (11.1)	48.2 (12.3)	47.1 (10.8)
Females, (%)	58.1	53.6	54.1
Weight (kg), mean (SD)	82.6 (19.9)*	85.8 (17.7)	84.8 (18.7)
BMI (kg/m^2), mean (SD)	29.2 (6.7)*	30.5 (6.2)	29.6 (6.6)
Prior and Concomitant Medications			
Prior use of synthetic DMARDs, (%)			
1	54.4	44.2	53.3
≥2	44.1	52.9	44.5
Prior anti-TNF exposure, (%)	19.1	22.5	17.0
Concomitant methotrexate, (%)	61.8	63.8	65.2
No concomitant DMARDs, (%)	35.3	28.3	25.9

*n=135
BMI: Body Mass Index; **DMARD**: Disease-modifying Antirheumatic Drug.

Adapted from Mease PJ et al. Ann Rheum Dis. 2014;73(1):48–55

Baseline Characteristics of RAPID-PsA Patients (2/2)

	Placebo (n=136)	CZP 200 mg Q2W (n=138)	CZP 400 mg Q4W§ (n=135)
Disease Characteristics			
Disease duration, mean years (SD)	7.9 (7.7)	9.6 (8.5)	8.1 (8.3)
TJC, mean (SD)*	19.9 (14.7)	21.5 (15.3)	19.6 (14.8)
SJC, mean (SD)*	10.4 (7.6)	11.0 (8.8)	10.5 (7.5)
Enthesitis, (%)†	66.9	63.8	62.2
Dactylitis, (%)‡	25.7	25.4	28.1
HAQ-DI, mean (SD)	1.3 (0.7)	1.3 (0.7)	1.3 (0.6)
Psoriasis BSA ≥3%, (%)	63.2	65.2	56.3
PASI, median (min-max)#	7.1 (0.3–55.2)	7.0 (0.6–72.0)	8.1 (0.6–51.8)
Nail disease, (%)	75.7	66.7	77.8
mNAPSI, mean (SD)§	3.4 (2.2)	3.1 (1.8)	3.4 (2.2)
CRP** (mg/L), median (min-max)	9.0 (0.2–131.0)	7.0 (0.2–238.0)	8.7 (0.1–87.0)
ESR (mm/h), median (min-max)	34.0 (6.0–125.0)	35.0 (5.0–125.0)	33.0 (4.0–120.0)

*68 joints examined for tenderness and 66 joints assessed for swelling; †Presence of enthesitis at baseline defined as a baseline Leeds Enthesitis Index score >0; ‡Presence of dactylitis at baseline assessed using Leeds Dactylitis Index; #PASI scores for those patients with psoriasis body surface area (BSA) ≥3% at baseline; §mNAPSI scores for those patients with nail disease at baseline; **Normal range of CRP <8.0 mg/L.

Adapted from Mease PJ et al. Ann Rheum Dis. 2014;73(1):48–55

Concomitant DMARDs at Baseline

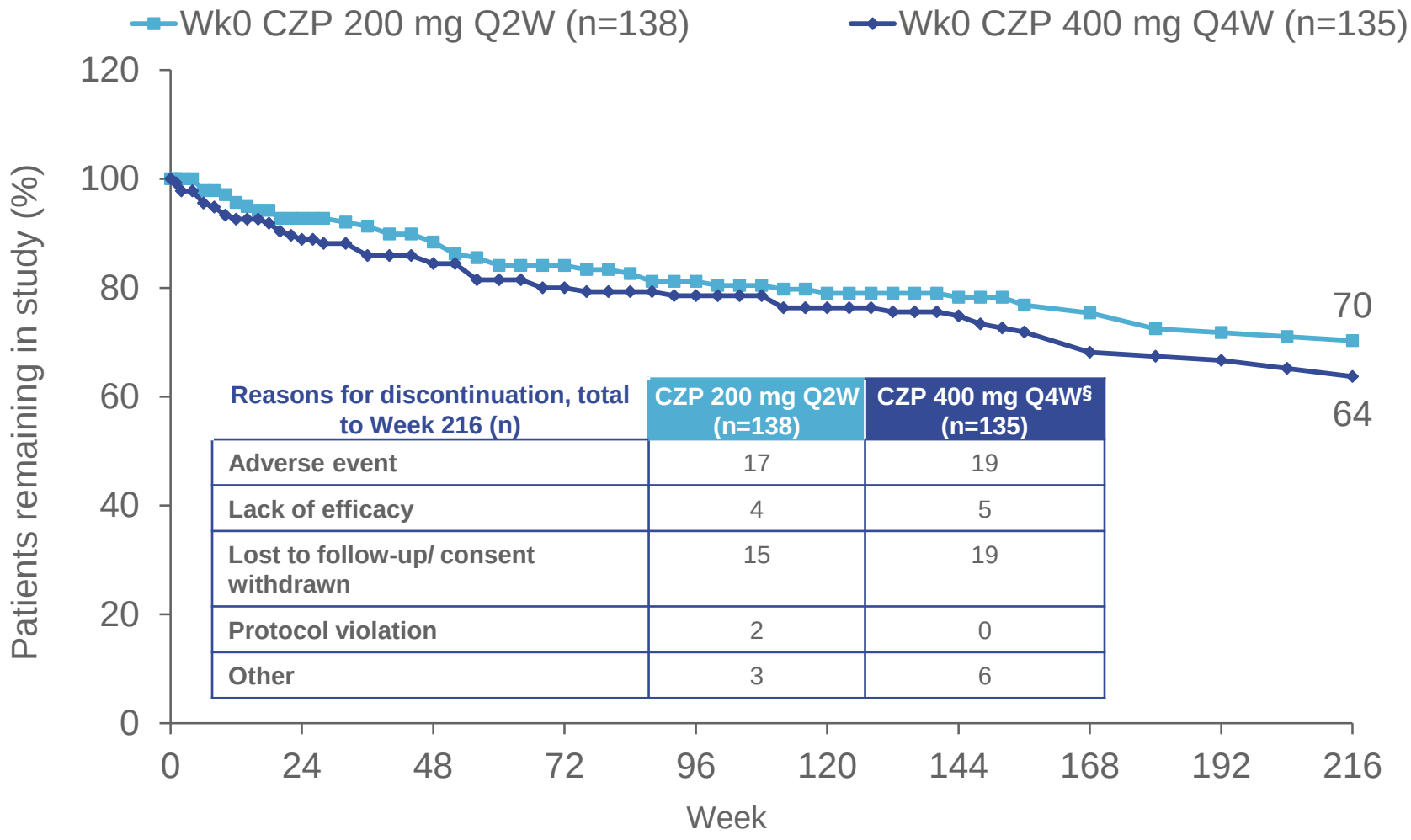
n (%)	Placebo n=136	CZP 200 mg Q2W n=138	CZP 400 mg Q4W§ n=135	CZP Combined§ n=273	All§ n=409
Any concomitant DMARD	88 (64.7)	100 (72.5)	101 (74.8)	201 (73.6)	289 (70.7)
Hydroxychloroquinine	0	0	1 (0.7)	1 (0.4)	1 (0.2)
Methotrexate	80 (58.8)	86 (62.3)	86 (63.7)	172 (63.0)	252 (61.6)
Methotrexate sodium	4 (2.9)	2 (1.4)	2 (1.5)	4 (1.5)	8 (2.0)
Leflunomide	2 (1.5)	4 (2.9)	8 (5.9)	12 (4.4)	14 (3.4)
Sulfasalazine	3 (2.2)	8 (5.8)	4 (3.0)	12 (4.4)	15 (3.7)

RS; Multiple DMARDs may be counted more than once;
CZP combined=CZP 200 mg Q2W + CZP 400 mg Q4W maintenance dose regimens.

Long-Term Data

Patient Retention
to Week 216

Patient Retention to Week 216

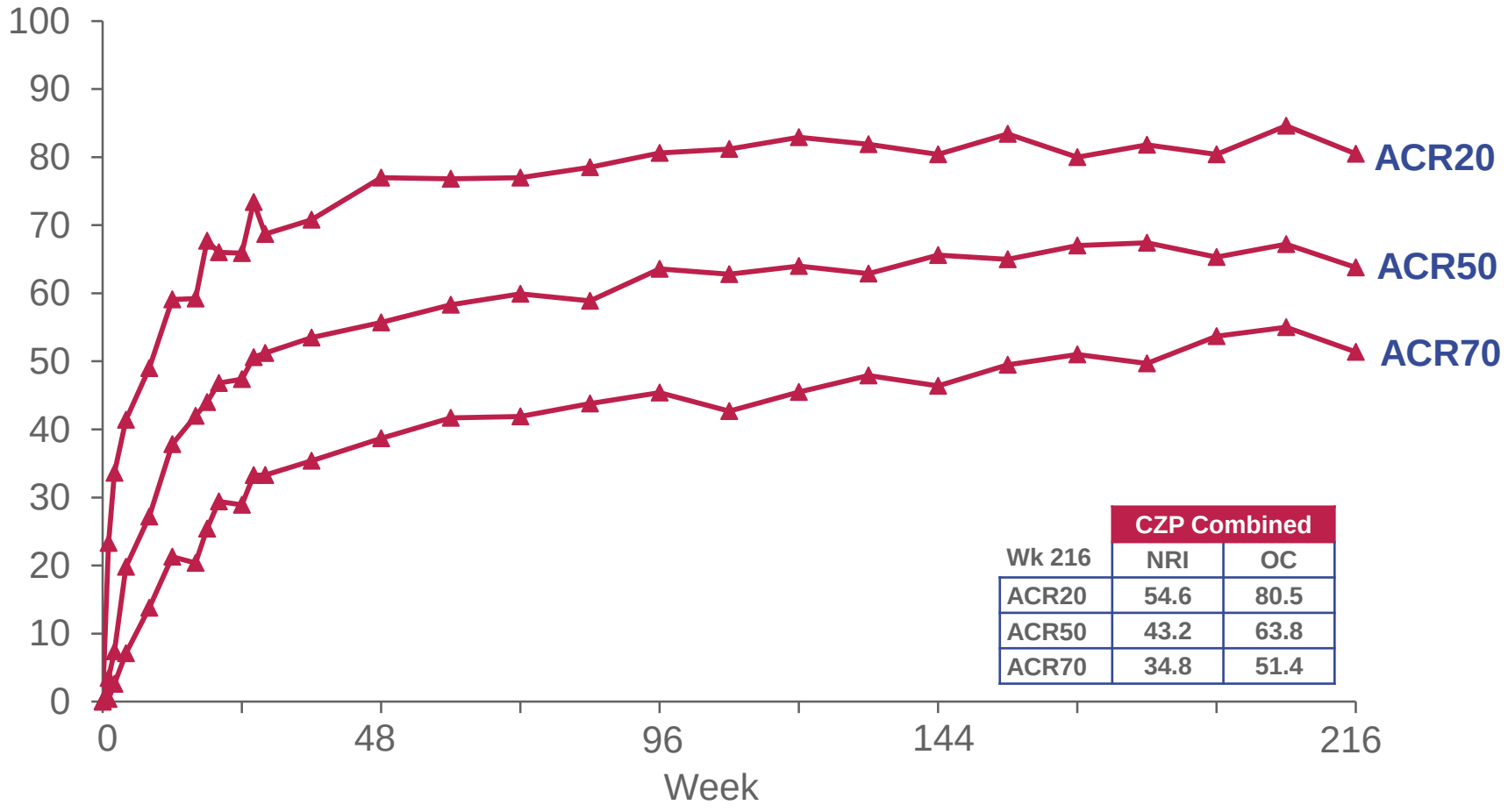


Reasons for discontinuation, total to Week 216 (n)	CZP 200 mg Q2W (n=138)	CZP 400 mg Q4W§ (n=135)
Adverse event	17	19
Lack of efficacy	4	5
Lost to follow-up/ consent withdrawn	15	19
Protocol violation	2	0
Other	3	6

Long-Term Data

ACR Response
to Week 216

ACR Response Over 216 Weeks (Observed)



Wk 216	CZP Combined	
	NRI	OC
ACR20	54.6	80.5
ACR50	43.2	63.8
ACR70	34.8	51.4

RS; CZP combined=CZP 200 mg Q2W + CZP 400 mg Q4W maintenance dose regimens.

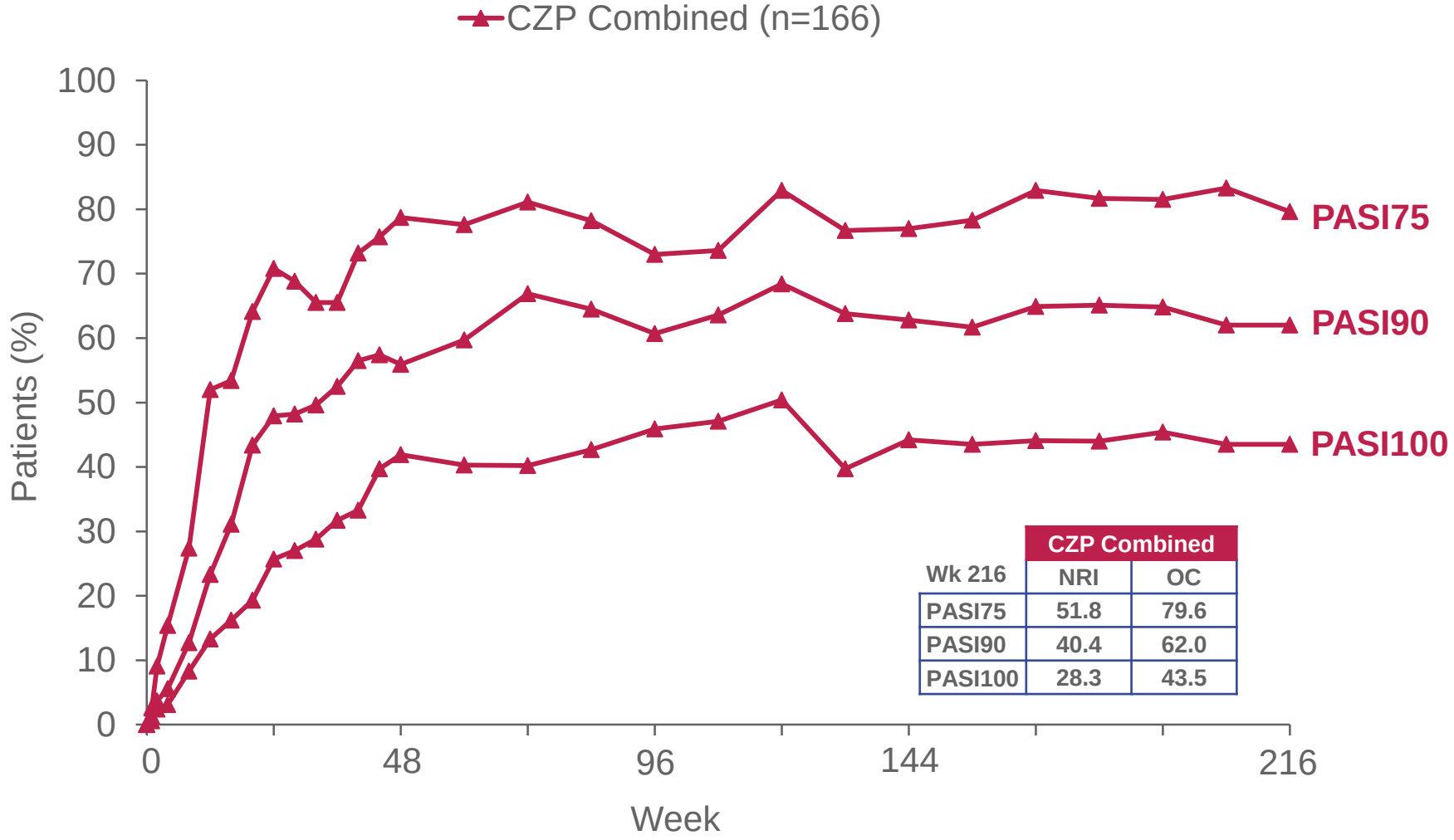
1. Adapted from Mease PJ et al. EULAR 2016. Poster FRI0471

Long-Term Data

PASI Response
to Week 216

PASI Response Over 216 Weeks (Observed)

In Patients with Psoriasis Involving ≥3% BSA at Baseline



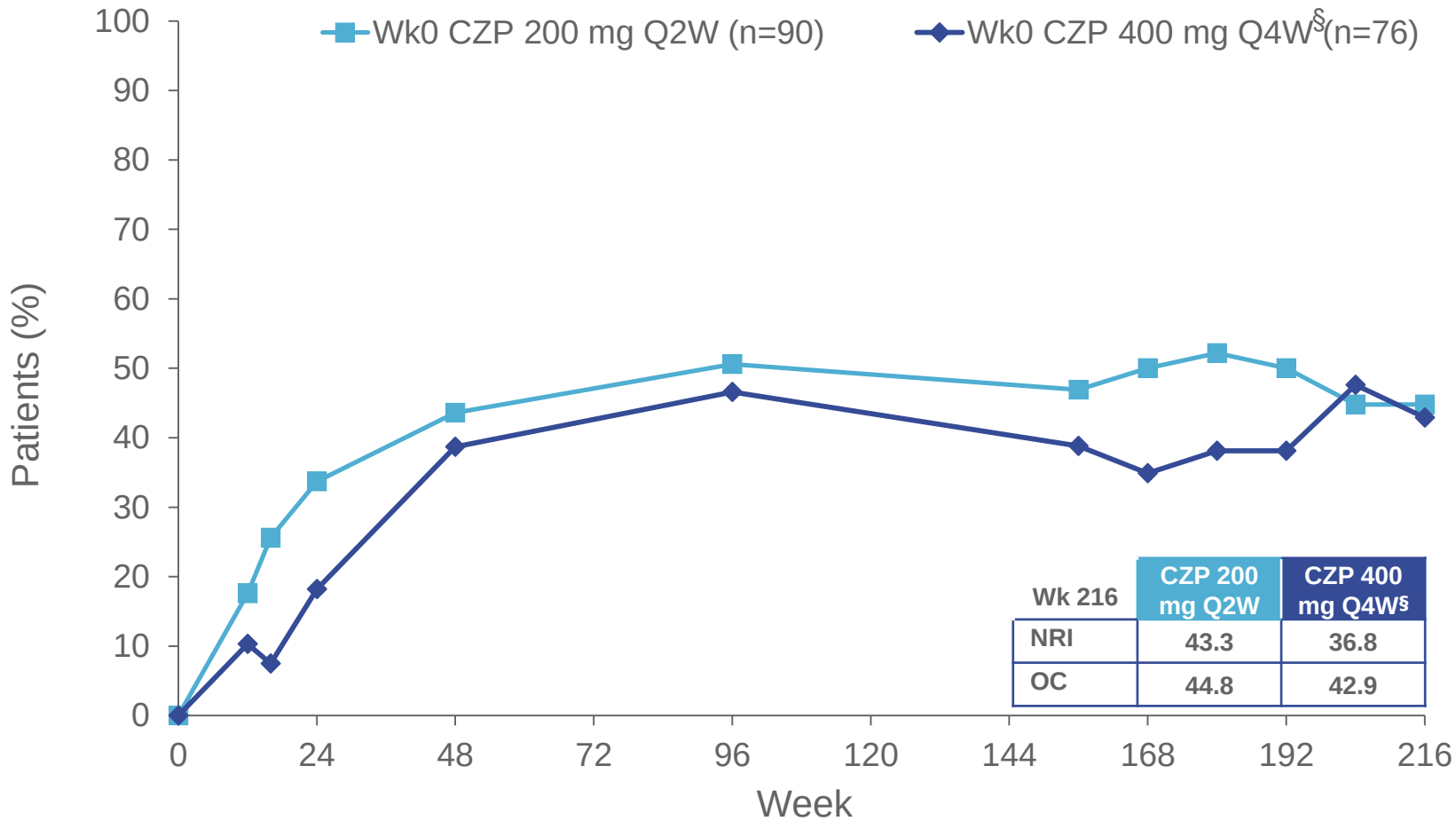
Wk 216	CZP Combined	
	NRI	OC
PASI75	51.8	79.6
PASI90	40.4	62.0
PASI100	28.3	43.5

RS;
CZP combined=CZP 200 mg Q2W + CZP 400 mg Q4W maintenance dose regimens.

1. Adapted from Khraishi et al. EULAR 2016. Poster 1724

Resolution of Psoriasis Over 216 Weeks (Observed)*

In Patients with ≥3% Psoriasis BSA at Baseline



Wk 216	CZP 200 mg Q2W	CZP 400 mg Q4W§
NRI	43.3	36.8
OC	44.8	42.9

§For maintenance in PsA, CZP 400 mg Q4W before clinical response is confirmed is not an approved dose in the European Union

RS; OC

*Total resolution defined as the % of pts with baseline involvement achieving complete clearance (0% BSA)

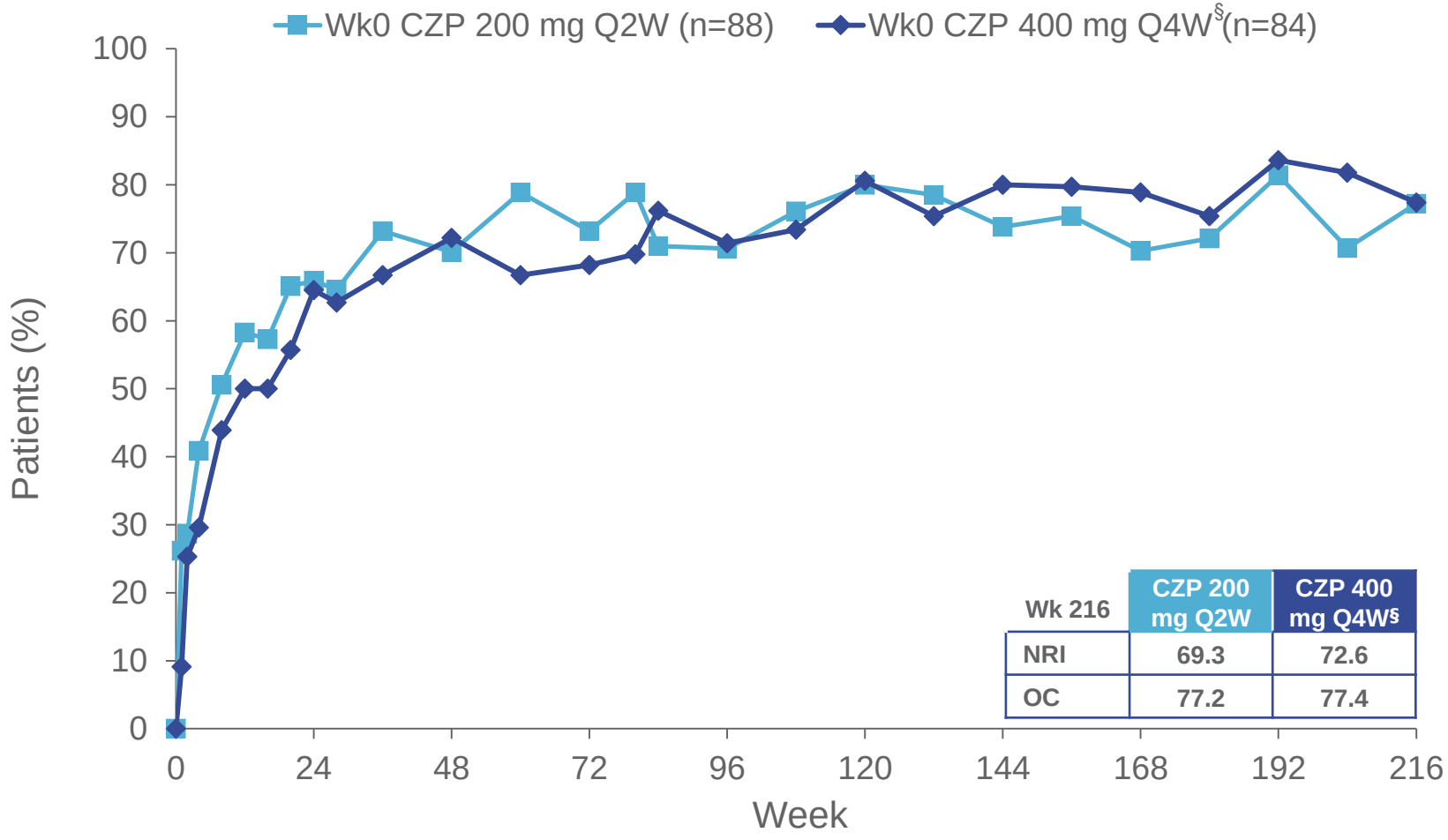
UCB Data on File (PsA001 Wk216 Post-hoc Tables 2016. Table 4.50.5.1.1, 4.50.5.2.1) – Data are available on request

Long-Term Data

Other Clinical Outcomes
to Week 216

Resolution of Enthesitis Over 216 Weeks (Observed)*

In Patients with Enthesitis at Baseline† *(post-hoc analysis)*



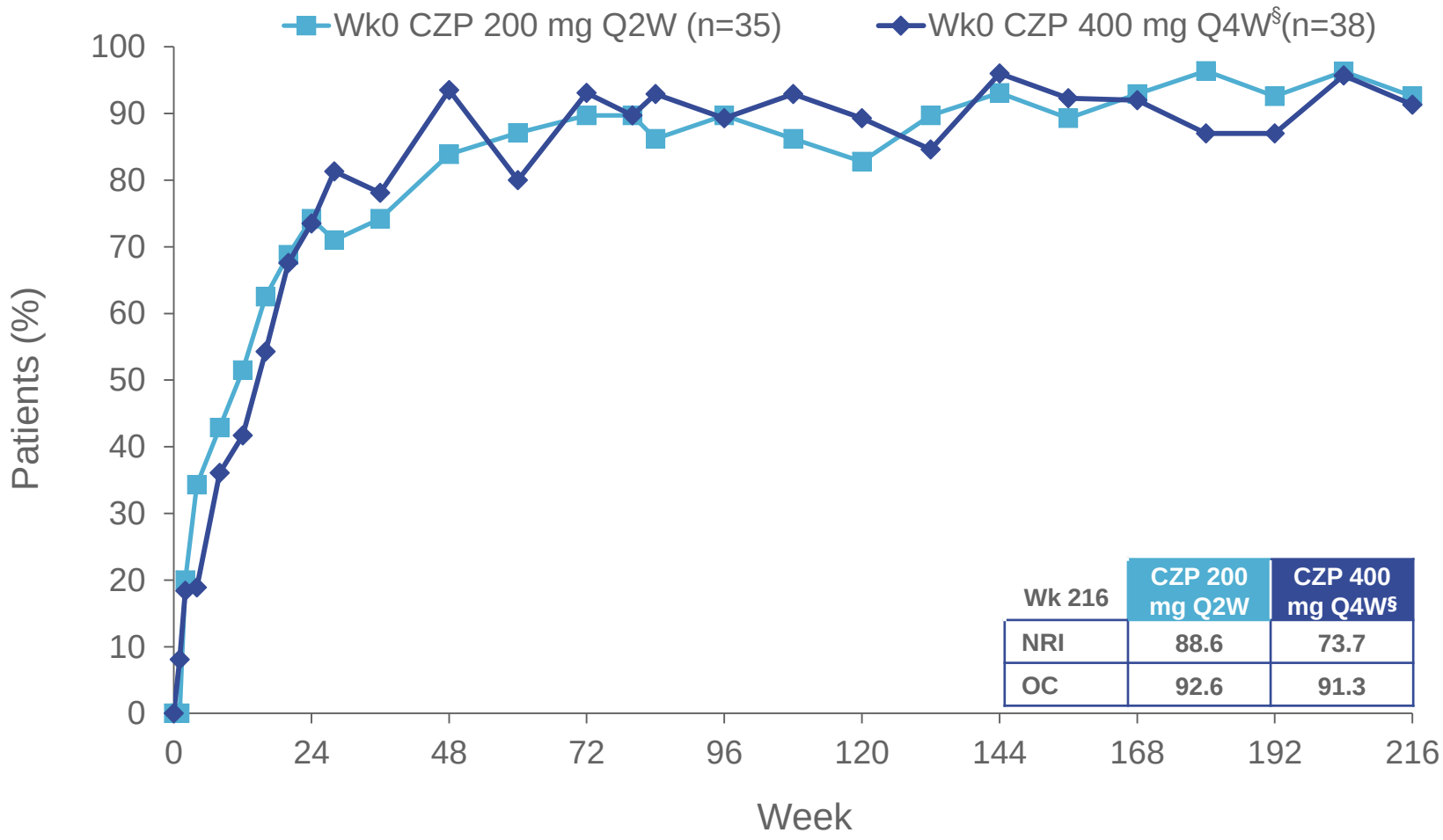
Wk 216	CZP 200 mg Q2W	CZP 400 mg Q4W§
NRI	69.3	72.6
OC	77.2	77.4

RS; OC
*Total resolution defined as the % of pts with baseline involvement achieving complete clearance; †LEI ≥1;
LEI: Leeds Enthesitis Index

1. Adapted from FitzGerald et al. AAD 2017. ePoster 4386

Resolution of Dactylitis Over 216 Weeks (Observed)*

In Patients with Dactylitis at Baseline† *(post-hoc analysis)*



Wk 216	CZP 200 mg Q2W	CZP 400 mg Q4W§
NRI	88.6	73.7
OC	92.6	91.3

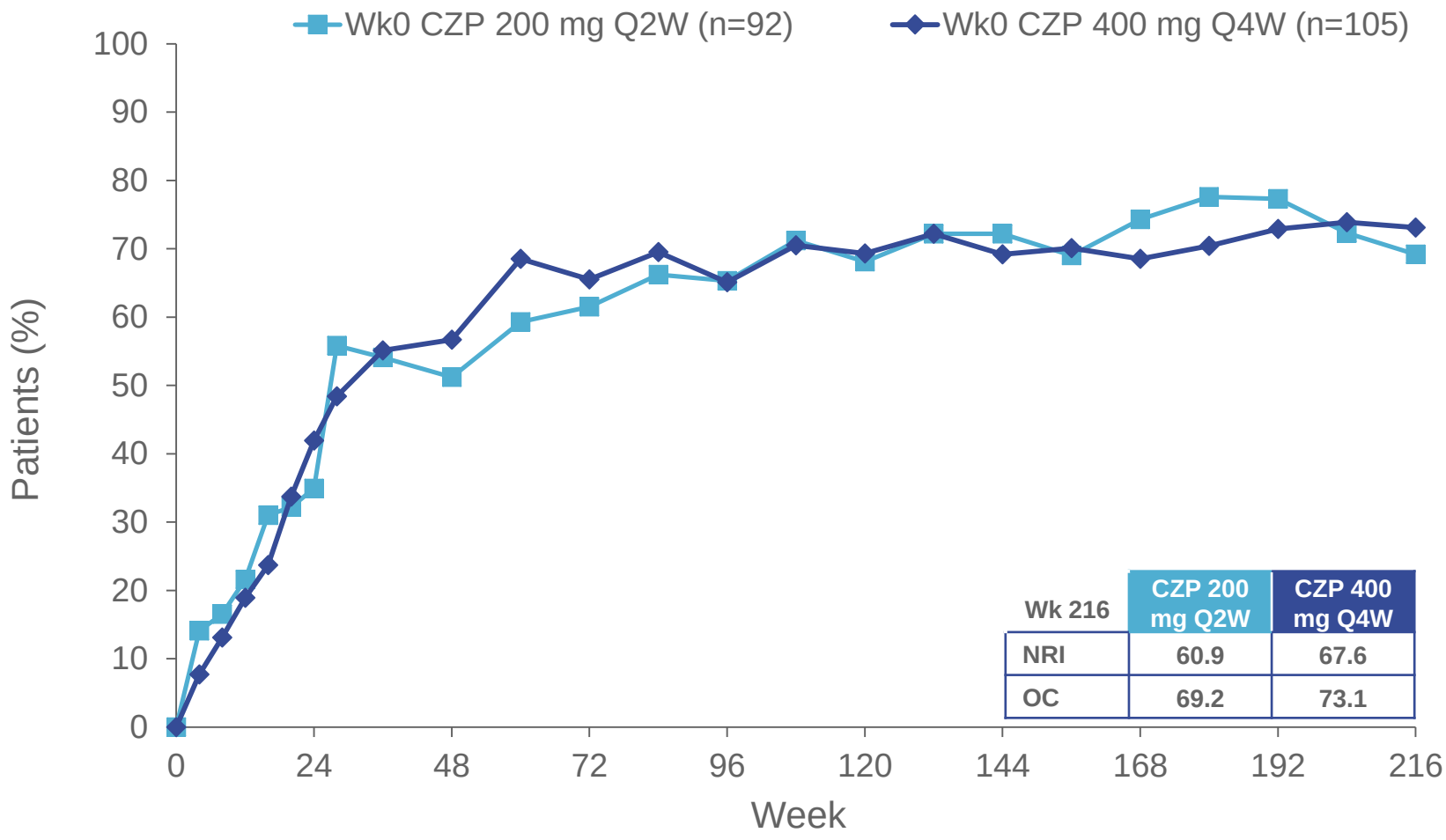
RS; OC

*Total resolution defined as the % of pts with baseline involvement achieving complete clearance; †≥1 dactylitic digit with a circumference ≥10% larger compared with the contralateral digit; **LDI**: Leeds Dactylitis Index.

1. Adapted from FitzGerald et al. AAD 2017. ePoster 4386

Resolution of Nail Disease Over 216 Weeks (Observed)*

In Patients with Nail Psoriasis at Baseline *(post-hoc analysis)*



Wk 216	CZP 200 mg Q2W	CZP 400 mg Q4W
NRI	60.9	67.6
OC	69.2	73.1

RS; OC
*Total resolution defined as the % of pts with baseline involvement achieving complete clearance.
mNAPSI: Modified Nail Psoriasis Severity Index

1. Adapted from FitzGerald et al. AAD 2017. ePoster 4386

Συμπεράσματα

- **Οι ασθενείς με ΨΑ υπό CZP παραμένουν στην αγωγή για μεγάλο χρονικό διάστημα κάτι που υποδηλώνει διατήρηση κλινικής αποτελεσματικότητας σε βάθος χρόνου και καλό προφίλ ασφάλειας**
- **Το CZP έχει πολύ καλά αποτελέσματα σε όλο το φάσμα της Ψωριασικής νόσου**
  - Αρθρώσεις
  - Ενθέσεις
  - Ψωρίαση/ ψωριασική ονυχία
  - δακτυλίτιδα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