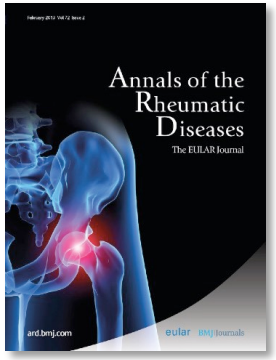
r-axPsA
T2T: differenti prospettive medico-paziente

Ennio Giulio Favalli

PP-IX-IT-1360 Data di deposito AIFA: gg/mm/2021

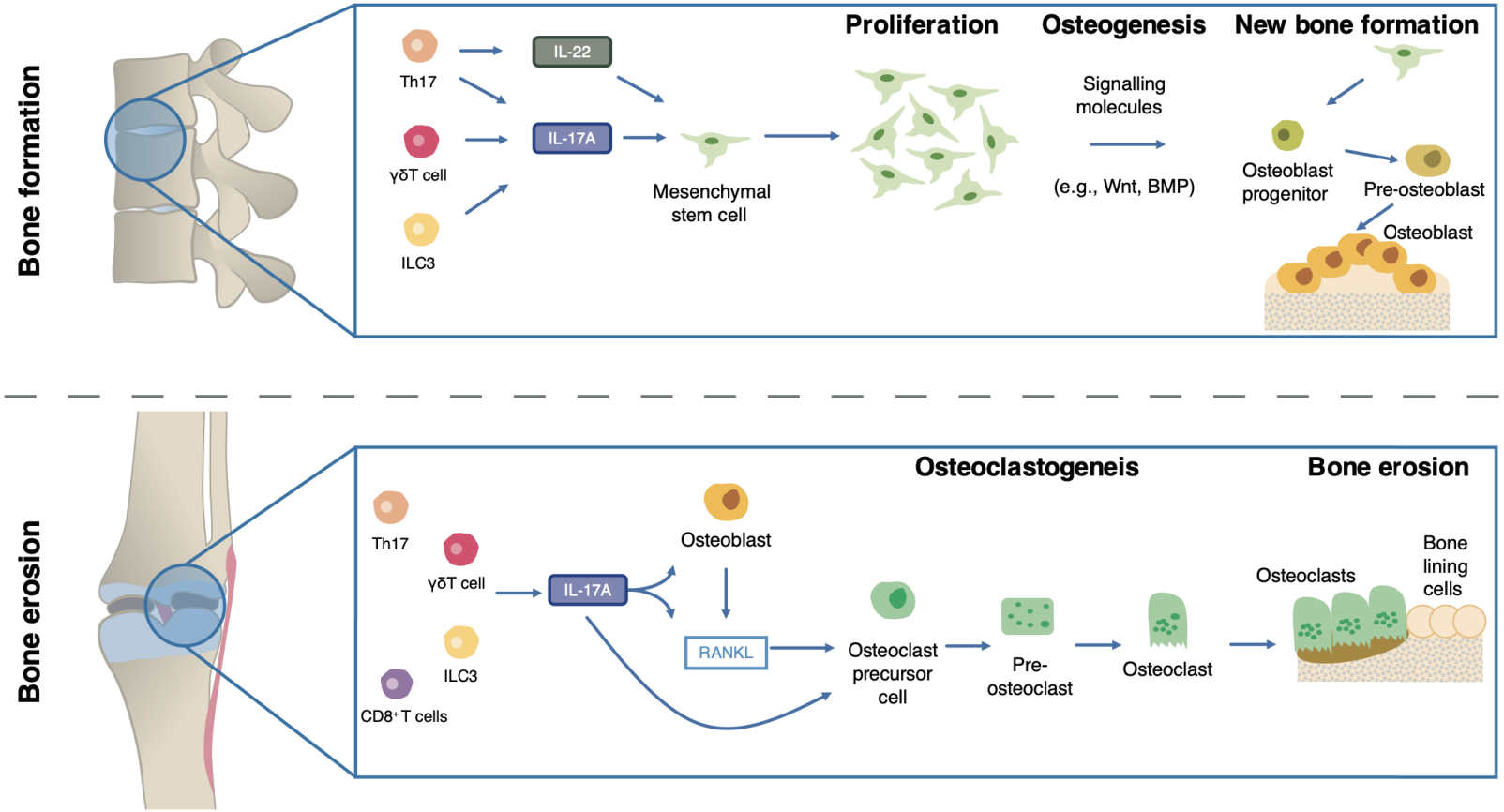
IXEVOLUTION
un passo avanti nella gestione delle spondiloartriti



The role of IL-17A in axial spondyloarthritis and psoriatic arthritis: recent advances and controversies

Dennis G McGonagle,[1,2] Iain B McInnes,[3] Bruce W Kirkham,[4] Jonathan Sherlock,[5,6] Robert Moots[7,8]

Ann Rheum Dis 2019



Ixekizumab axSpA: Clinical Trials Overview

Patients who complete 52 weeks in these 3 registration trials have the option to enroll in the long-term trial COAST-Y

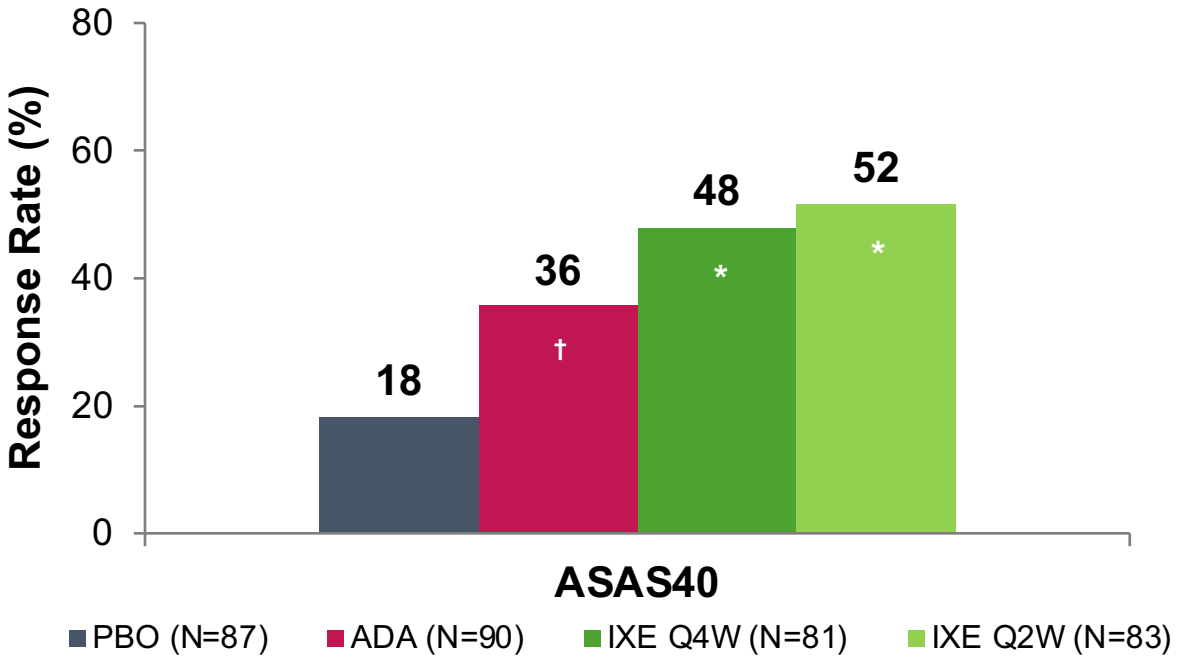
*Obiettivo primario a 16 settimane, periodo di estensione dello studio fino a 52 settimane, seguito dallo studio a lungo termine COAST-Y.
§Obiettivo primario a 52 settimane per gli USA, a 16 settimane per gli altri Paesi, seguito dallo studio a lungo termine COAST-Y.
ADA represents an active reference; the study was not powered to test equivalence or noninferiority of active treatment groups to each other, including IXE vs. ADA.
van der Heijde D, et al. Lancet 2018;392:2441-51. Deodhar A, et al. Arthritis Rheumatol 2019;71:599-611. Deodhar A, et al. Lancet 2020;395:53-64

Primary Endpoint: ASAS40 Response at Week 16, NRI

Blinded Dosing Period, ITT Population

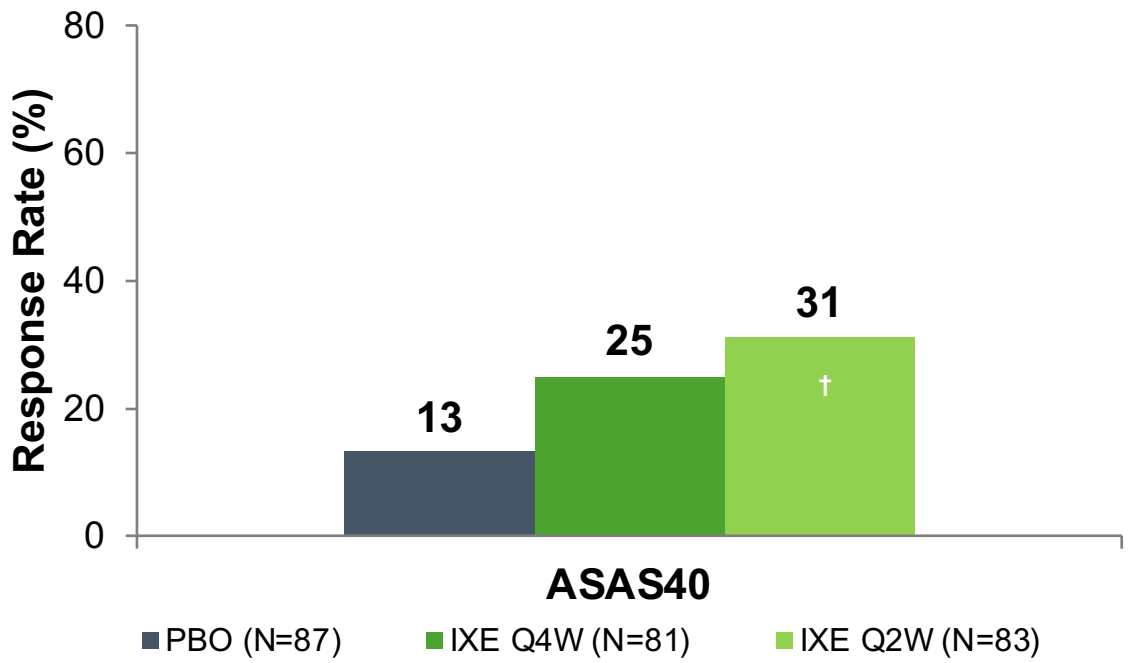
COAST-V

(bDMARD-naïve, AS/r-axSpA)



COAST-W

(TNFi-Experienced, AS/r-axSpA)

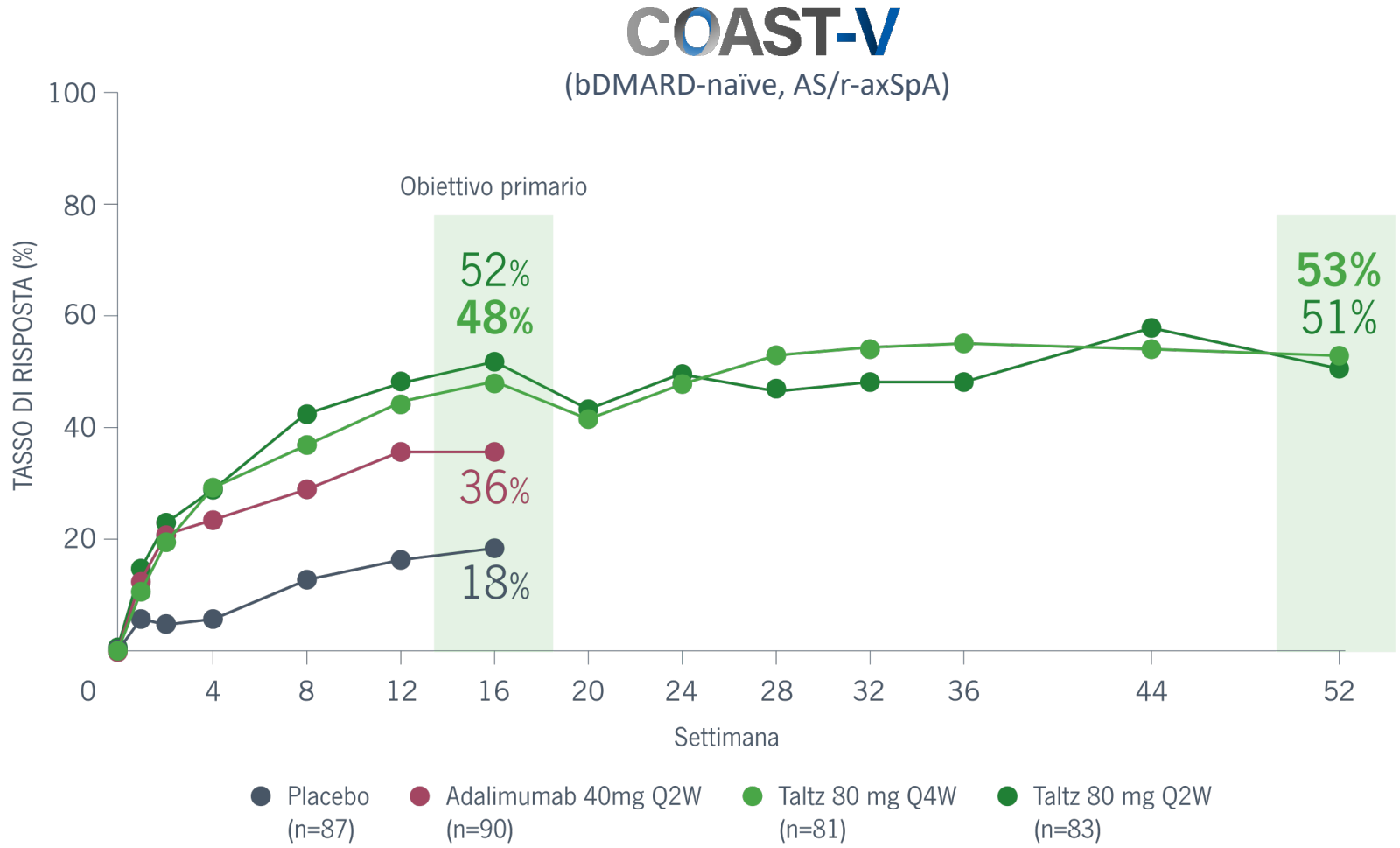


*p≤.001 vs. PBO; †p≤.01 vs. PBO.

ADA represents an active reference; the study was not powered to test equivalence or noninferiority of active treatment groups to each other, including IXE vs. ADA.

van der Heijde D, et al. *Lancet.* 2018;392:2441-2451. Deodhar A, et al. *Arthritis Rheumatol.* 2019;71:599-611.

ASAS40 Response Rates Through Week 52, NRI



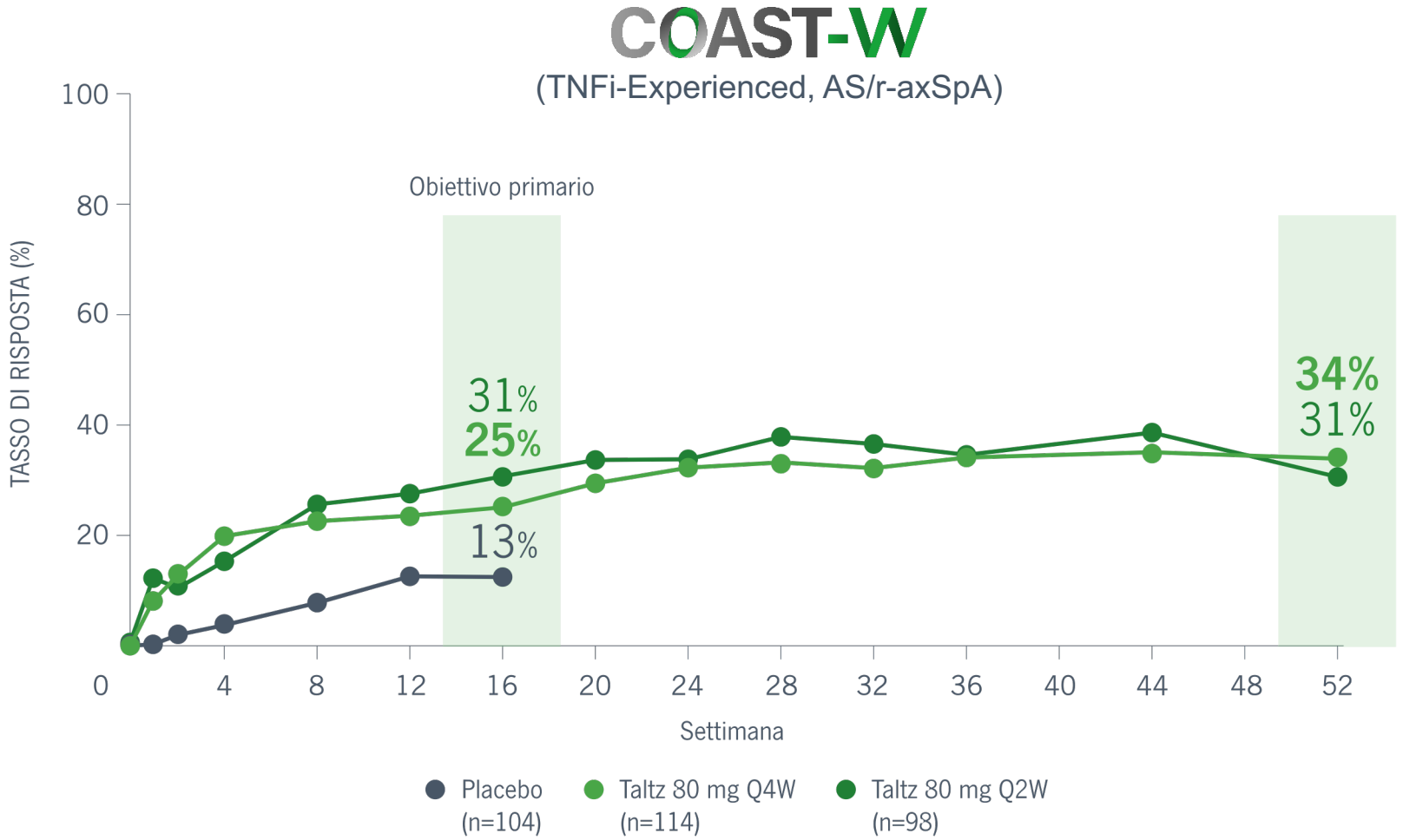
Statistically significant improvements in ASAS40 response rate vs. PBO were seen as early as Week 2 in COAST-V. Responses were maintained through Week 52.

*p≤.001 vs. PBO; †p<.01 vs. PBO; ‡p<.05 vs. PBO.

Note: ADA represents an active reference; COAST-V was not powered to test equivalence or noninferiority of active treatment groups to each other, including IXE vs. ADA.

1. van der Heijde D, et al. *Lancet.* 2018;392:2441-2451. 2. Dougados M, et al. *Ann Rheum Dis.* 2020;79:176-185.

ASAS40 Response Rates Through Week 52, NRI



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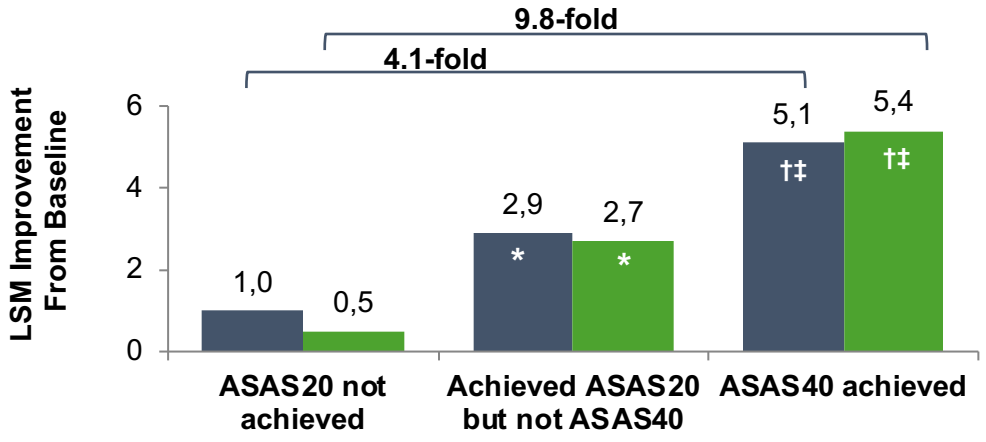
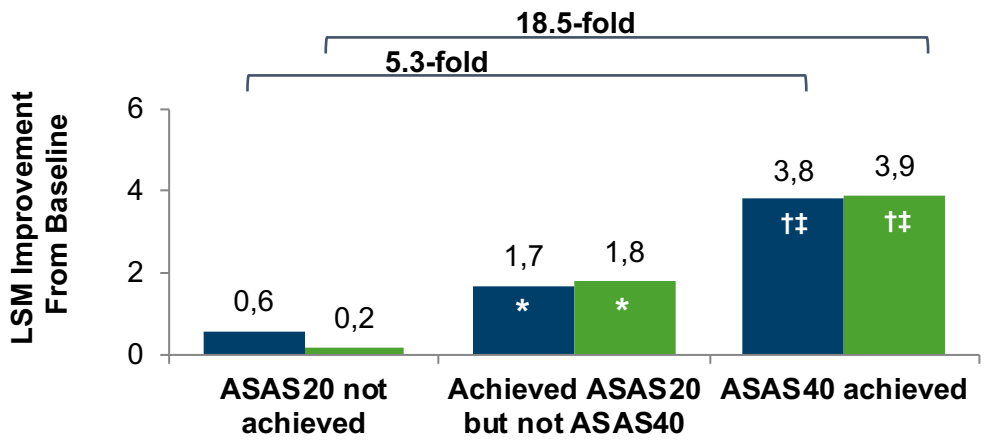
1. van der Heijde D, et al. *Lancet.* 2018;392:2441-2451. 2. Dougados M, et al. *Ann Rheum Dis.* 2020;79:176-185.

ASAS40 Response is Associated With Significantly Better Patient Reported Outcomes Thus Representing a Higher Clinical Standard

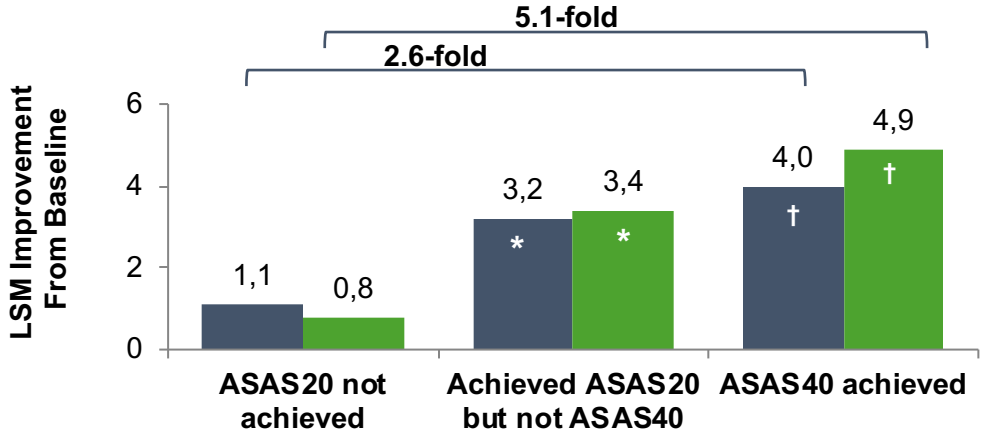
Spinal Pain at Night at Week 16, mBOCF



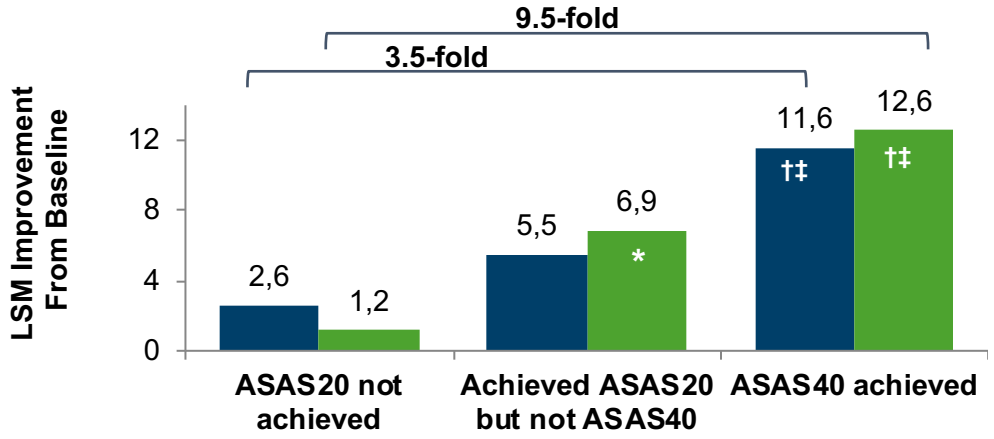
Fatigue NRS at Week 16, mBOCF



Sleep Quality (JESQ) at Week 16, mBOCF



SF-36 PCS at Week 16, mBOCF



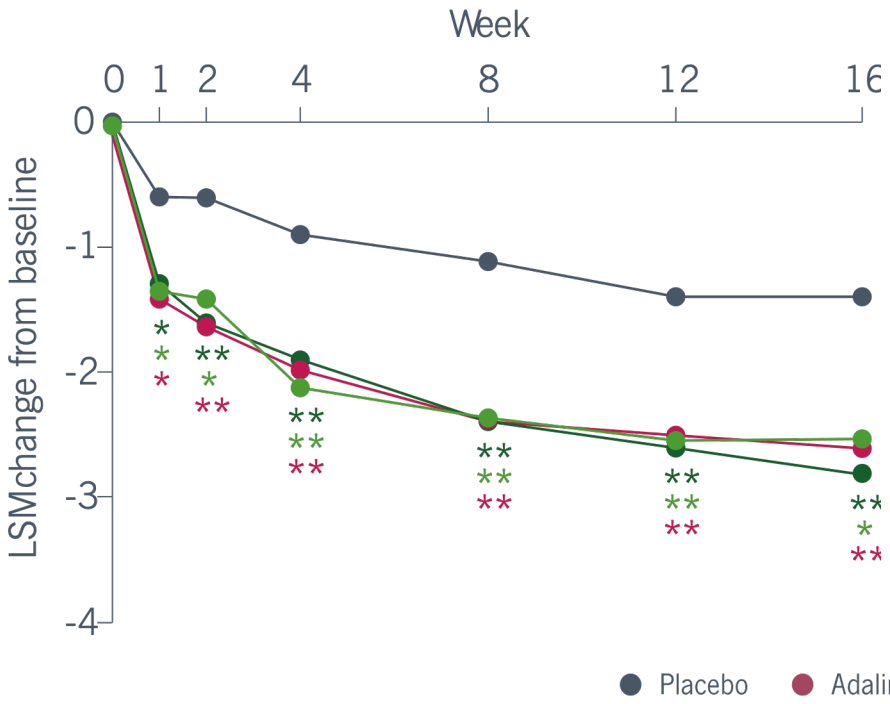
bDMARD-naïve (COAST-V) (N=341) TNFi-experienced (COAST-W) (N=316)

*p<.001 achieved ASAS20 but not ASAS40 vs. ASAS20 not achieved; †p<.0001, ASAS40 achieved vs. ASAS20 not achieved; ‡p<.0001 ASAS40 achieved vs. achieved ASAS20 but not ASAS40.

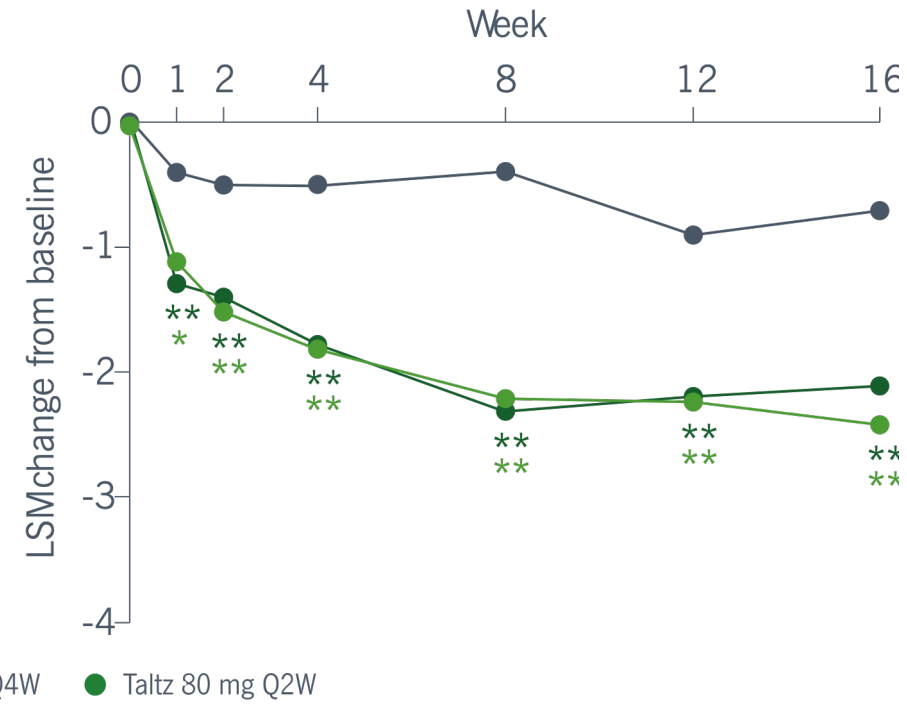
Mease P, et al. *Rheumatol Ther*. 2019;6:435-450.

SF-36 physical component score through week 52, mBOCF

COAST-V
(bDMARD-naïve, AS/r-axSpA)



COAST-W
(TNFi-Experienced, AS/r-axSpA)

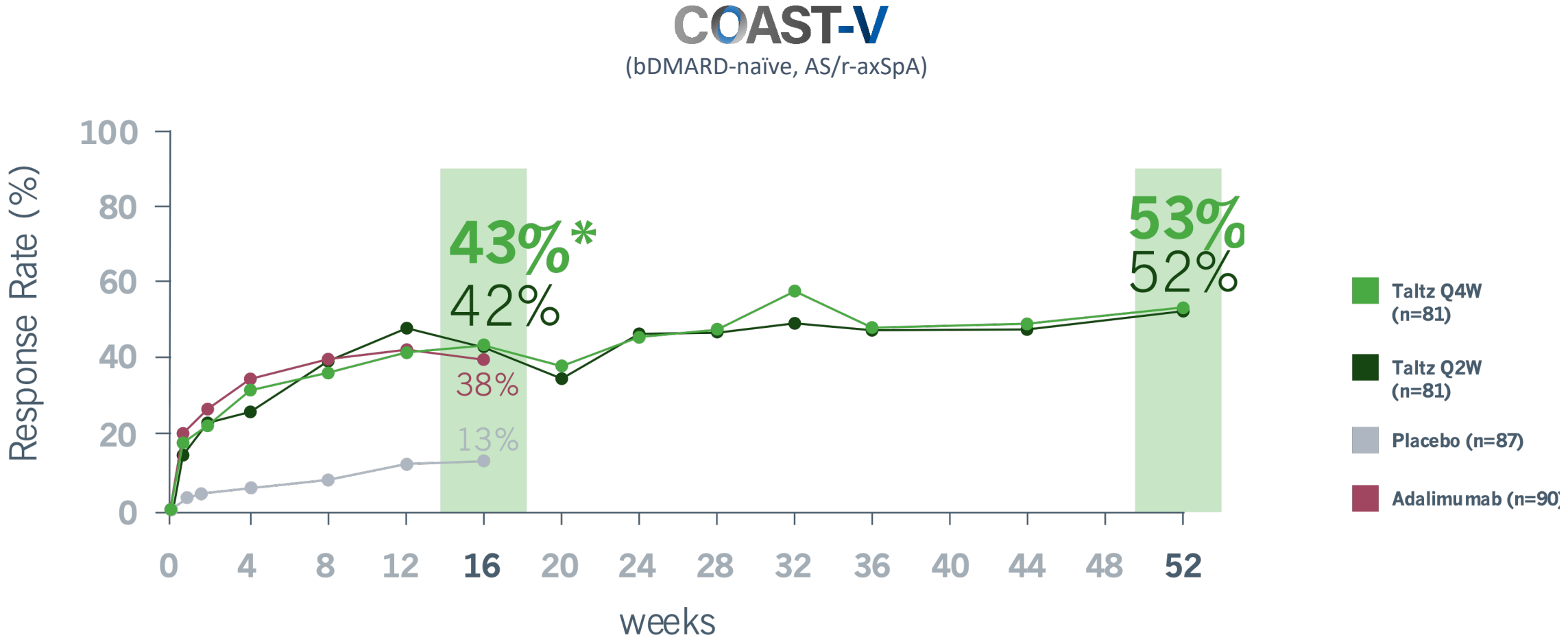


Placebo · Adalimumab 40mg Q2W · Taltz 80 mg Q4W · Taltz 80 mg Q2W

Improvements in SF-36 PCG scores were observed as early as week 4 and were sustained trough week 52

*p≤0.001 vs. PBO; †p≤0.01 vs. PBO.
ADA represents an active reference; the study was not powered to test equivalence or noninferiority of active treatment groups to each other, including IXE vs. ADA.
van der Heijde D, et al. *Lancet.* 2018;392:2441-2451

ASDAS<2.1 (LDA) Response Rates Through Week 52, NRI



The proportion of IXE-treated patients achieving ASDAS Low Disease Activity at week 16 was significantly higher than PBO. Reponses were maintained trough week 52.

*p≤.0,01 vs. PBO; †p<0,05 vs. PBO; ‡p≤0,001 vs. PBO.
ASDAS Low Disease Activity/Inactive Disease = ASDAS score of <2,1
Dougados M, et al. Ann Rheum Dis 2020;79:176-185 Deodhar A, et al. Arthritis Rheumatol. 2019;71:599-611

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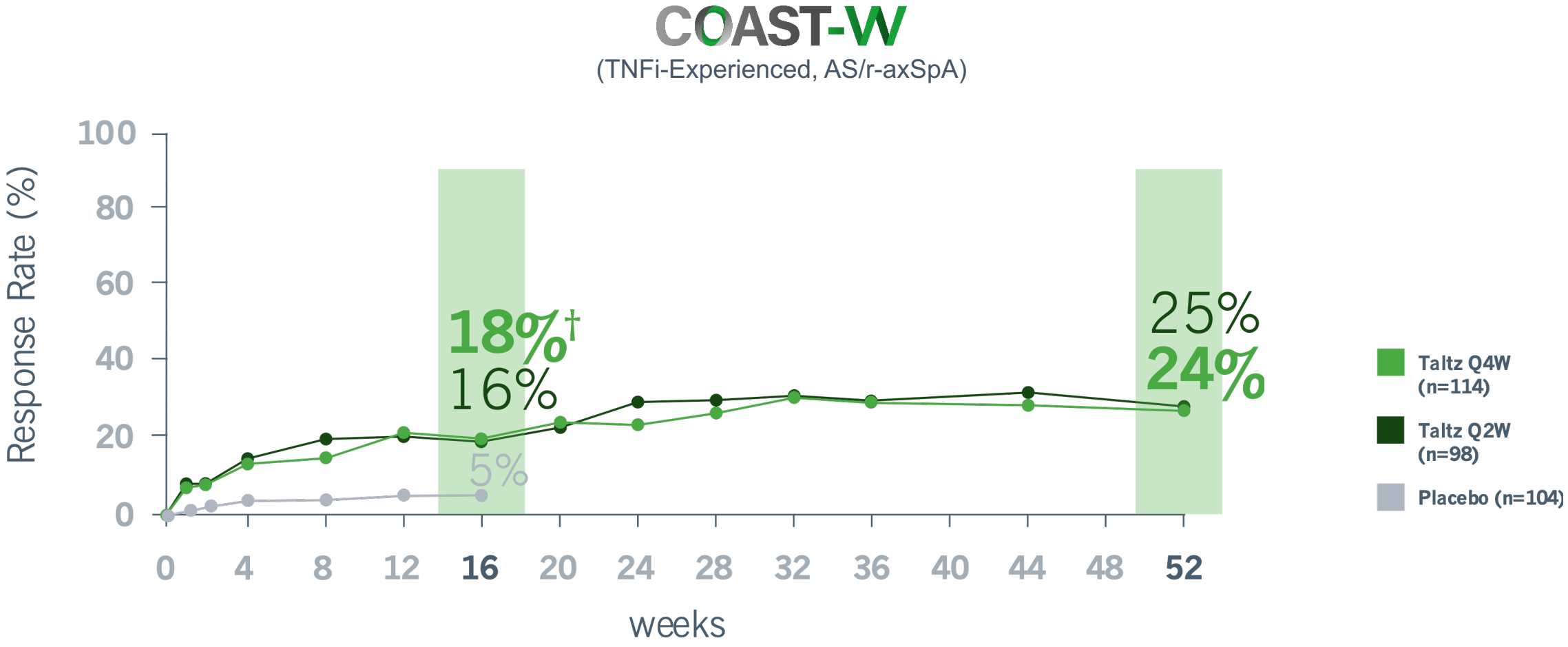

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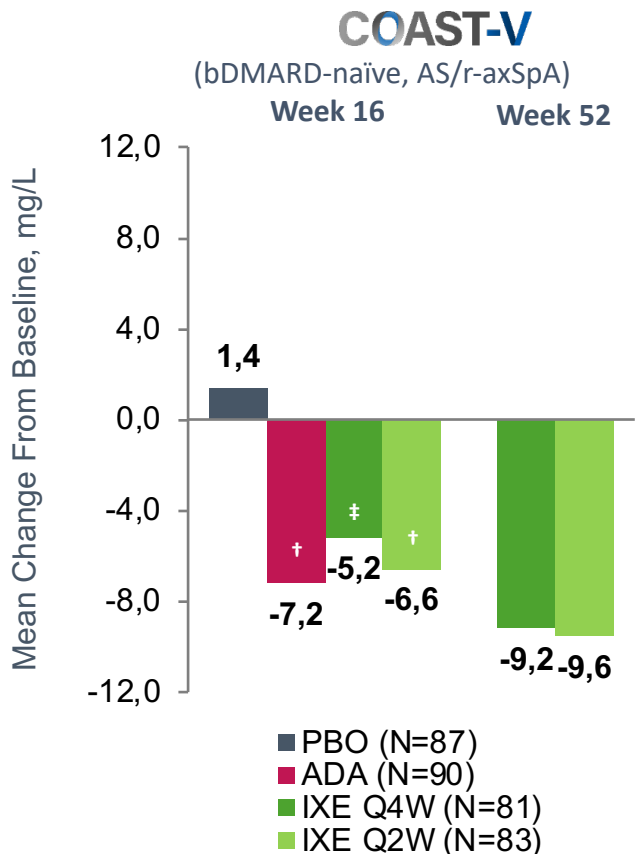
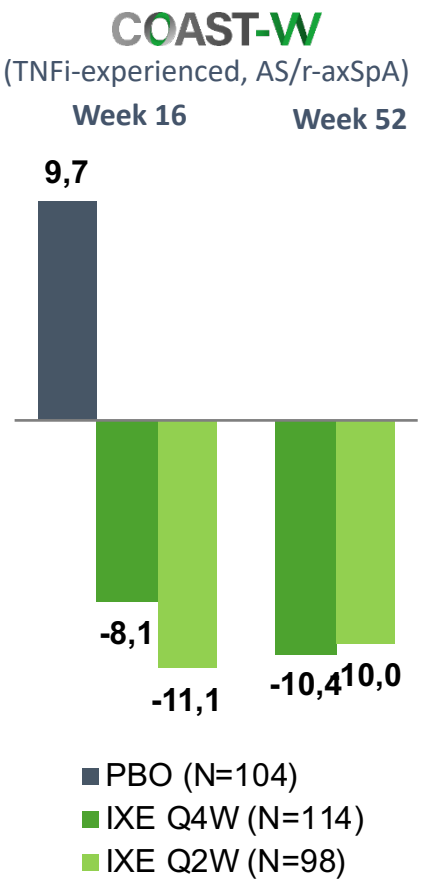
Significant Treatment Effect on Inflammation, as Assessed by CRP Concentrations

CRP Change From Baseline at Weeks 16 (MMRM) and 52 (mBOCF), ITT Population



Baseline mean: PBO=16.0, ADA=12.5; IXE Q4W=12.2, IXE Q2W=13.4

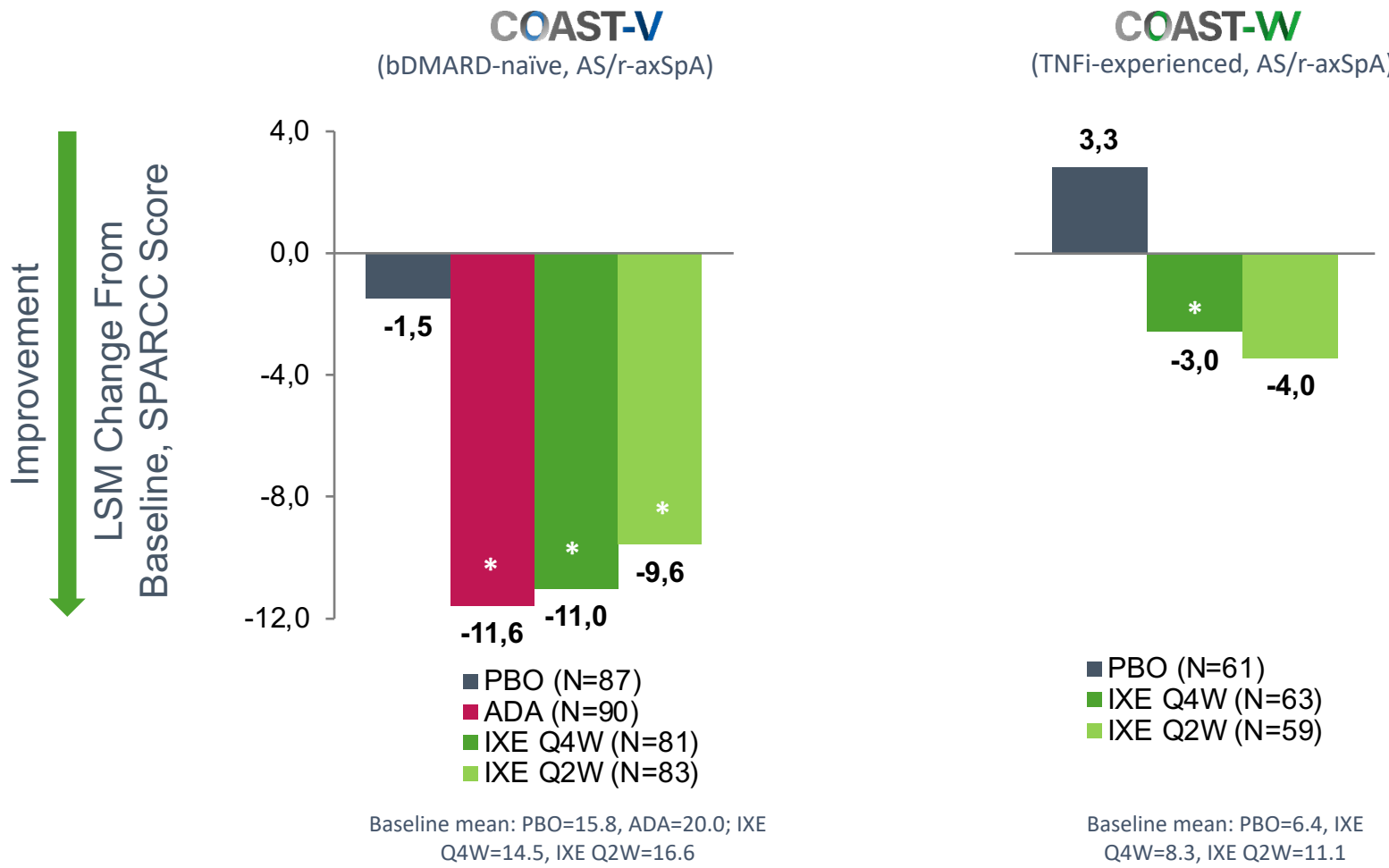


Baseline mean: PBO=16.0, IXE Q4W=20.2, IXE Q2W=16.9

*p≤.001 vs. PBO; †p<.01 vs. PBO; ‡p<.05 vs. PBO.
[a]Only patients who participated in the MRI addendum.
Notes: ADA represents an active reference arm; the study was not powered to test equivalence or noninferiority of active treatment groups to each other, including IXE vs. ADA. SPARCC maximum score=414 (23 DVU).[1]
van der Heijde D, et al. *Lancet*. 2018;392:2441-2451. Deodhar A, et al. *Arthritis Rheumatol*. 2019;71:599-611. Dougados M, et al. *Ann Rheum Dis*. 2020;79:176-185.

MRI Spine (SPARCC), Change From Baseline at week 16, Observed Case Analysis (ANCOVA)

MRI Spine (SPARCC) Change From Baseline at Week 16, ITT Population



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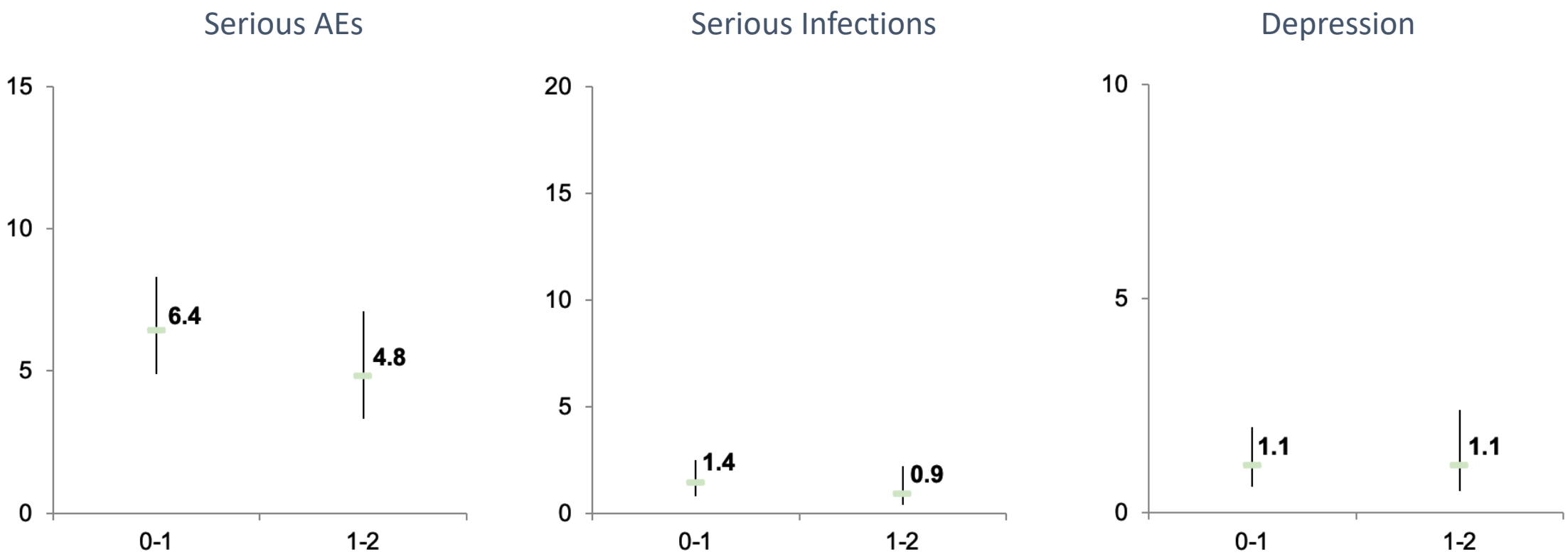
Safety profile of ixekizumab in axSpA (n=929)



Note: CIs are from likehood ratio test of treatment from the Poisson regression model.
Genovese MC, et al. Rheumatology (Oxford) 2020; doi:10.1093/rheumatology/keaa189 (ahead of print)

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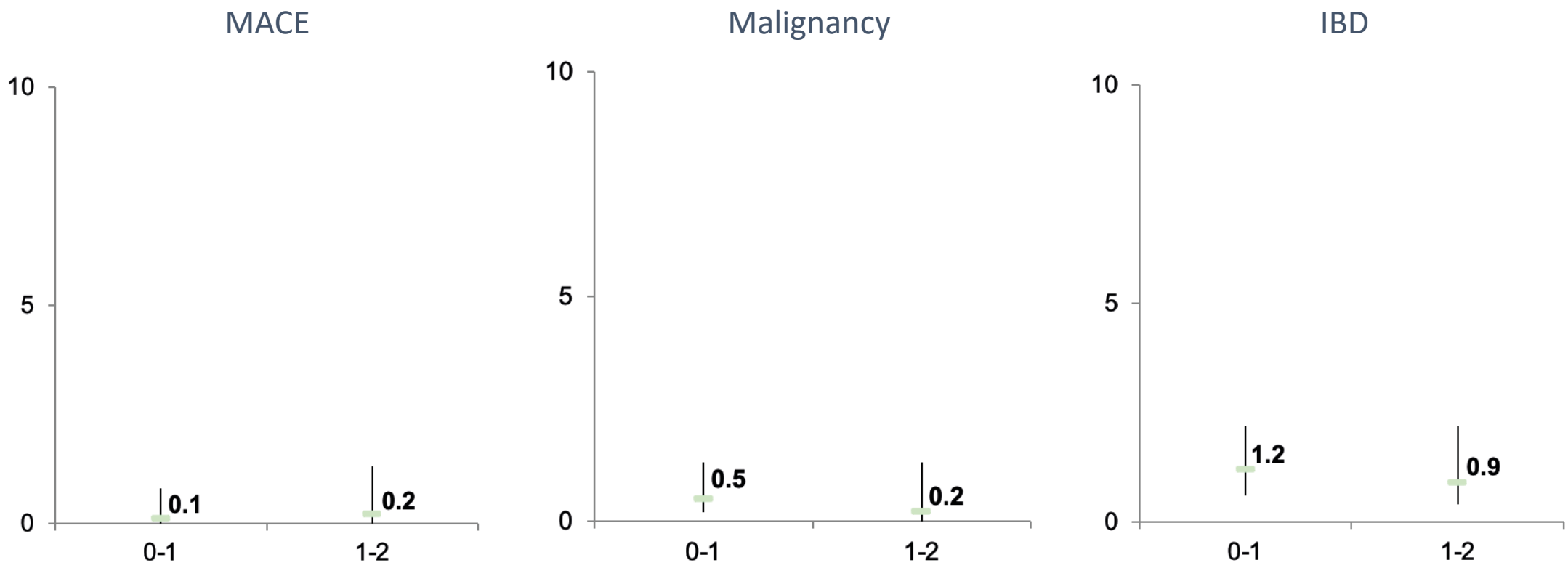

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Product information

Classe H - Medicinale soggetto a prescrizione medica limitativa, vendibile al pubblico su prescrizione di centri ospedalieri o di specialisti - internista, reumatologo, dermatologo (RRL).

TALTZ 80 mg soluzione iniettabile in penna preriempita – 2 penne preriempite - AIC n° 044863025/E
Prezzo al pubblico: € 3.518,73 Prezzo ex-factory: € 2.132,00

TALTZ 80 mg soluzione iniettabile in siringa preriempita – 2 siringhe preriempite - AIC n° 044863052/E
Prezzo al pubblico: € 3.518,73 Prezzo ex-factory: € 2.132,00

Clicchi qui per RCP Taltz