Table of Contents

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SUPPLEMENTARY METHODS

Inclusion criteria

The study population for Study COAST-Y included patients from any of the originating studies (COAST-V, COAST-W, or COAST-X), and therefore included patients with rad-axSpA and patients with nonrad-axSpA, with or without prior use of TNF inhibitors.

For most patients, Week 52 of the originating study (COAST-V, COAST-W, or COAST-X) coincided with Week 0 (Visit 1) for Study COAST-Y. Study investigator(s) reviewed patient data from Week 52 in the respective originating study to determine if the patient met all inclusion and none of the exclusion criteria to qualify for participation in Study COAST-Y. If, at Week 52 in the originating study, a patient was not able to enter Study COAST-Y (e.g., due to unresolved safety concerns), investigational product was temporarily interrupted and the patient was evaluated in the originating study for up to 12 weeks beyond Week 52 to determine whether treatment with investigational product could resume. If, in the opinion of the investigator, restarting ixekizumab did not pose an unacceptable risk, the patient could begin participation in Study COAST-Y (Visit 1 [Week 0]).

Patients were eligible to be included in the study only if they met the following criteria:

1) Have completed the final study visit in Study COAST-V, COAST-W, or COAST-X. (Note: Patients from Study COAST-X are not eligible if they permanently discontinued ixekizumab and were receiving a TNF inhibitor).
2) Must agree to use a reliable method of birth control.
    a. If the patient is male, the patient must agree to use a reliable method of birth control during the study and for at least 12 weeks following the last dose of investigational product, whichever is longer. Methods of birth control include, but are not limited to, condoms with spermicide and male sterilization.
    b. If the patient is female and is a woman of childbearing potential who tests negative for pregnancy, the patient must agree to use a reliable method of birth control or remain abstinent during the study and for at least 12 weeks following the last dose of investigational product, whichever is longer. Methods of birth control include, but are not limited to, oral contraceptives, contraceptive patch, injectable or implantable contraceptives, intrauterine device, vaginal ring, or diaphragm with contraceptive gel. (Note: Where required by regulation, a highly effective method of birth control is required. A highly effective method of birth control is defined as one that results in a low failure rate [that is, <1% per year] when used consistently and correctly, such as male sterilization, oral contraceptives, contraceptive patch, injectable or implantable contraceptives, intrauterine device, or vaginal ring).
    c. If a female patient is a woman of nonchildbearing potential she is not required to use any method of birth control. Nonchildbearing potential is defined as:
        i. Women who have had surgical sterilization (hysterectomy, bilateral oophorectomy, or tubal ligation).
        ii. Or, women who are ≥60 years of age.
        iii. Or, women ≥40 and <60 years of age who have had a cessation of menses for ≥12 months and a follicle stimulating hormone test confirming nonchildbearing potential (≥40 mIU/mL or ≥40 IU/L).

3) Have given written informed consent approved by Lilly or its designee, and the Investigational Review Board/Ethical Review Board governing the site.

Exclusion criteria

Patients were excluded from study enrollment if they met any of the following criteria:

1) Have significant uncontrolled cerebrocardiovascular (e.g., myocardial infarction, unstable angina, unstable arterial hypertension, severe heart failure, or cerebrovascular accident), respiratory, hepatic, renal, gastrointestinal, endocrine, hematologic, neuropsychiatric disorders, or abnormal laboratory values that developed during the originating ixekizumab study (COAST-V, COAST-W, or COAST-X) that, in the opinion of the investigator, pose an unacceptable risk to the patient if investigational product continues to be administered.
2) Have a known hypersensitivity to ixekizumab or any component of this investigational product.
3) Had investigational product permanently discontinued during a previous ixekizumab study.
4) Had temporary investigational product interruption at any time during or at the final study visit of the originating ixekizumab study (COAST-V, COAST-W, or COAST-X) and, in the opinion of the investigator, restarting ixekizumab poses an unacceptable risk for the patient's participation in the study.
5) Have any other condition that, in the opinion of the investigator, renders the patient unable to understand the nature, scope, and possible consequences of the study or precludes the patient from following and completing the protocol.
6) Are currently enrolled in any other clinical trial involving an investigational product or any other type of medical research judged not to be scientifically or medically compatible with this study.

Study design

Patient enrollment for COAST-Y occurred between May 9, 2017 and March 1, 2019. Patients eligible for the RWRP were assigned to treatment groups in the RWRP using a computer-generated random sequence and an interactive web-response system. Randomization was stratified by region and originating study. Patients, study site personnel, and study team members were blinded to treatment assignment during the RWRP. Patients who entered the RWRP were requested to not have any changes to concomitant medications during the RWRP except for the defined retreatment medication or changes needing to be made for an AE or safety reasons.

Patients who were not eligible for participation in the RWRP continued the ixekizumab treatment regimen received during the lead-in period through Week 64, and during the long-term extension period. During the long-term extension period, patients who were receiving IXE Q4W could have their dose escalated to IXE Q2W if the investigator determined the patient may benefit from an increase in dosing frequency to achieve adequate disease control.

During the long-term extension period, patients who participated in the randomized withdrawal-retreatment period continued receiving the treatment they were receiving at Week 64. Patients who had not experienced a flare through Week 64 and experienced a flare during the long-term extension period were retreated with the ixekizumab dosing regimen received during the lead-in period. Patients who had been retreated with ixekizumab Q4W following a flare could have their dose escalated to IXE

Q2W if they had received retreatment for at least 12 Weeks and if the investigator determined that the patient may benefit from an increase in dosing frequency to achieve adequate disease control.

Ixekizumab and matching placebo were supplied as an injectable solution in 1-mL, single-dose, prefilled, disposable manual syringes with study specific labels. Each syringe of ixekizumab was designed to deliver 80 mg ixekizumab. The syringes and contents of ixekizumab and matching placebo were visibly indistinguishable from each other.

Outcomes

ASDAS

Flare was defined as an ASDAS≥2.1 at two consecutive visits or >3.5 at any visit during the randomized withdrawal-retreatment period. The ASDAS is a composite index that assesses disease activity in axSpA.[1-3] The components of the ASDAS are total back pain as measured by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) question 2, the patient global assessment of disease activity, peripheral pain/swelling as measured by BASDAI question 3, duration of morning stiffness as measured by BASDAI question 6, and high sensitivity C-reactive protein in mg/L.

The ASDAS CRP is calculated using the following equation: 0.121 X total back pain + 0.110 X patient global + 0.073 X peripheral pain/swelling + 0.058 X duration of morning stiffness + 0.579 X Ln(CRP+1).[4] CRP was calculated in mg/L, the range of other variables was from 0 to 10. Ln represents the natural logarithm. ASDAS and all ASDAS components were measured at each study visit.

ASDAS inactive disease and low disease activity are defined as an ASDAS<1.3 or <2.1 respectively.[5]

ASAS

The following ASAS domains were used to determine ASAS20, ASAS40, ASAS 5/6, and ASAS Partial Remission: Patient Global (Assessment of Disease Activity), Spinal Pain, Function (BASFI), Inflammation (mean of BASDAI questions 5 and 6), CRP, and Spinal mobility (lateral spinal flexion from the Bath Ankylosing Spondylitis Metrology Index [BASMI]).[6] The ASAS20, ASAS40, and ASAS Partial Remission responses were derived from the patient-reported domains of Patient Global, Spinal Pain, Function, and Inflammation. ASAS 5/6 included assessment of all 6 ASAS domains.

An ASAS20 response is defined as a ≥20% improvement and an absolute improvement from baseline (from originating study) of ≥1 units (range 0 to 10) in ≥3 of the 4 patient-reported domains and no worsening of ≥20% and ≥1 unit (range 0 to 10) in the remaining domain. The ASAS40 is defined as a ≥40% improvement and an absolute improvement from baseline (from originating study) of ≥2 units (range 0 to 10) in ≥3 of the 4 patient-reported domains without any worsening in the remaining domain.[6-8] ASAS 5/6 represents improvement of ≥20% in at least 5 of the 6 ASAS domains. An ASAS partial remission is defined as a value not above 2 units (range 0 to 10, numeric rating scale in each of the 4 patient-reported ASAS domains.

BASDAI

The BASDAI is a patient-reported assessment consisting of 6 questions that relate to 5 major symptoms relevant to axSpA, including fatigue, spinal pain, peripheral arthritis enthesitis, intensity of morning stiffness, and duration of morning stiffness.[6,9] Each question was scored on a numerical rating scale ranging from 0 to 10 with higher score representing worse disease activity. BASDAI 50 represents an improvement of ≥50% improvement from baseline in the BASDAI. BASDAI was assessed at each study visit.

Patient Global Assessment of Disease Activity

The patient is asked to the following question: "How active was your spondylitis on average during the last week?".[6] The answer is recorded on a numerical rating scale ranging from "0" (not active) to "10" (very active). The patient Global Assessment of Disease activity was assessed at each study visit.

High sensitivity C-Reactive Protein

High sensitivity C-Reactive Protein was the measure of acute phase reactant. It was measured using a high sensitivity assay at a central laboratory to assess the effect of ixekizumab on disease activity. High sensitivity CRP was assessed at each study visit.

Spinal Pain

The patient is asked to respond to the following 2 questions (on average during the last week):

1. "How much pain of your spine due to ankylosing spondylitis do you have?"
2. "How much pain of your spine due to ankylosing spondylitis do you have at night?"

The answers are recorded on an numeric rating scale and are each rated between "0" (no pain) and "10" (most severe pain). The first question was used to derive ASAS responses. Spinal pain was assessed at each study visit.

BASFI

The BASFI is a patient-reported assessment that establishes a patient's functional baseline and subsequent response to treatment.[10] To complete the BASFI, a patient is asked to rate the difficulty associated with 10 individual basic functional activities. Patients respond to each question using an NRS (range 0 to 10), with a higher score indicating worse functioning. The patient's final BASFI score is the mean of the 10 item scores completed on an NRS. The BASFI was assessed at each study visit.

BASMI

The BASMI is a combined index comprising the following 5 clinical measurements of spinal mobility in patients with axSpA: lateral spinal flexion, tragus-to-wall distance, lumbar flexion (modified Schrober), maximal intermalleolar distance, and cervical rotation.[11] Each measurement is scaled to a score of 0 to 10 depending on the result of the assessment (BASMI linear function). The average score of the 5 assessments gives the BASMI linear result.[6,12] The BASMI was assessed by a rheumatologist or health care provider who met qualifications for study assessment. The BASMI was assessed at study visits at Weeks 0, 16, 24, 40, 56, 64, 88, and 104, and at an early termination visit when applicable.

SF-36

The SF-36 is a 36-item, patient-reported measure designed to be a short, multipurpose assessment of health in the areas of physical functioning, role – physical, role - emotional, bodily pain, vitality, social functioning, mental health, and general health. The 2 overarching domains of mental well-being and physical well-being are captured by the Mental Component Summary and Physical Component Summary scores. The summary scores range from 0 to 100; higher scores indicate better levels of function and/or better health. Items are answered on Likert scales of varying lengths. The SF-36 version 2 (acute

version), which uses a 1-week recall period, was used.[13] The SF-36 was assessed at Weeks 0, 24, 40, 64, 88, and 104, and at an early termination visit when applicable.

Safety outcomes

TEAEs were any untoward medical occurrence that either occurred or worsened at any time after treatment baseline, regardless of whether it had a causal relationship with treatment. AEs of special interest included cytopenia, clinically significant hepatic events and/or significant elevations in liver function tests/enzyme elevations, infections, injection-site reactions, allergic reactions/hypersensitivities, cerebrocardiovascular events, malignancies, inflammatory bowel disease, or depression. Data on preferred terms associated with cerebrocardiovascular events were collected and were adjudicated by an external clinical events committee which included a chairman, two cardiologists, and a neurologist. Data on suspected inflammatory bowel disease, including events possibly indicative of ulcerative colitis and Crohn's disease, were collected and adjudicated by an external clinical events committee with expertise in inflammatory bowel disease.

Statistical analysis

Approximately 750 patients were predicted to enter COAST-Y after completion of the originating studies based on the 1-year retention rates from ixekizumab psoriasis studies and from a study of secukinumab in patients with r-axSpA, which had a retention rate of approximately 85%.[14] Approximately 30% of the 750 patients were estimated to be eligible for entry into the RWRP.[15] Approximately 100 patients in each IXE treatment group (Q2W and Q4W) were anticipated for randomization in a 2:1 ratio to IXE or placebo. This sample size of 200 was determined to provide over 99% power to detect a difference between the combined ixekizumab treatment group and placebo in the proportion of flare-free patients using a 2-sided Fisher's exact test at the 0.05 level, assuming the flare rates would be 10% for ixekizumab and 70% for placebo.

Descriptive statistics were summarized as observed for the flare population with retreatment, defined as all patients who were randomly assigned at Week 24, experienced a flare after randomization, and received at least one injection of IXE retreatment after flare. Patients were retreated at the next scheduled visit after they had flared. For analyses of recapture of response after flare within 16 weeks of retreatment, patients who flared but recaptured response at the next scheduled visit (i.e. patients who regained response prior to retreatment) were excluded from the analysis so that recapture of response was not incorrectly attributed to retreatment with IXE.

Post-hoc analyses were conducted to evaluate potential predictors of flare. Variables with p-values <0.2 were entered into the multivariate logistic model for stepwise selection, with a p-value of 0.1 as a criterion for removal and stay. Interaction of each of the variables of interest with ixekizumab treatment withdrawal was also evaluated in an individual logistic regression model. Variables and their corresponding interaction were entered into the multivariate logistic regression model for variables found in the stepwise selection procedure; a backward selection was used to build the final model. Results from the univariate model and final model are presented in Supplementary Tables 1, 2, and 3.

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SUPPLEMENTARY TABLES

Supplementary Table 1. Proportion of flare-free patients at Week 64 in patient subgroups.

	Withdrawn to Placebo N=53	IXE Q4W N=48	IXE Q2W N=54	Combined IXE N=102
Radiographic diagnosis				
r-axSpA	17/33 (51.5%)	28/34 (82.4%)	25/30 (83.3%)	53/64 (82.8%)
nr-axSpA	12/20 (60.0%)	12/14 (85.7%)	20/24 (83.3%)	32/38 (84.2%)
Prior TNFi experience				
No (bDMARD-naïve)	24/44 (54.5%)	33/39 (84.6%)	39/46 (84.8%)	72/85 (84.7%)
Yes (bDMARD-experienced)	5/9 (55.6%)	7/9 (77.8%)	6/8 (75.0%)	13/17 (76.5%)
Concomitant NSAID[a] use				
No	2/6 (33.3%)	8/9 (88.9%)	4/5 (80%)	12/14 (85.7%)
Yes	28/47 (59.6%)	33/39 (84.6%)	44/49 (89.8%)	77/88 (87.5%)
Concomitant csDMARDs use				
No	19/32 (59.4%)	26/30 (86.7%)	27/30 (90%)	53/60 (88.3%)
Yes	11/21 (52.4%)	15/18 (83.3%)	21/24 (87.5%)	36/42 (85.7%)

The proportion of flare-free patients is presented as the number of responders divided by the number of patients within the subgroup.
[a]Includes COX-2 inhibitors
Abbreviations: bDMARD, biologic disease-modifying anti-rheumatic drug; COX-2, cyclooxygenase 2; csDMARDs, conventional synthetic disease-modifying anti-rheumatic drug; IXE, ixekizumab; nr-axSpA, non-radiographic axial spondyloarthrits; NSAID, non-steroidal anti-inflammatory drug; Q2W, every two weeks; Q4W, every four weeks; r-axSpA, radiographic axial spondyloarthritis; TNFi, tumor necrosis factor inhibitor

Supplementary Table 2. Patient characteristics associated with flare during the randomized withdrawal-retreatment period of COAST-Y (univariate logistic regression model)

Variable	Category	Odds ratio (95% CI)	p-value
Categorical variables			
Treatment	Placebo (n=53), IXE (n=102)	4.14 (1.95 to 8.77)	<0.001
Residual inflammation by MRI at Week 24 of COAST-Y	Yes (n=55), No (n=84)	2.43 (1.14 to 5.21)	0.022
Anti-drug antibody positive at any time between Week 0 of the originating study and Week 24 of COAST-Y	Yes (n=32), No (n=123)	2.32 (1.02 to 5.28)	0.045
BMI group at Week 0 of COAST-Y	Non-normal (n=86), Normal (n=69)[a]	2.08 (0.98 to 4.42)	0.057*
Length of IXE treatment at Week 24 of COAST-Y	24-60 weeks (n=69), 76 weeks (n=86)	1.65 (0.80 to 3.39)	0.171
Geographic region	Non-Europe (n=97), Europe (n=58)	1.63 (0.76 to 3.53)	0.211
Sustained low CRP[b]	Yes (n=136), No (n=19)	0.57 (0.21 to 1.57)	0.277
Anti-drug antibody positive at Week 24 of COAST-Y	Yes (n=10), No (n=143)	1.98 (0.53 to 7.42)	0.31
CRP group at baseline of originating study	>5 mg/L (n=96), ≤5 mg/L (n=59)	1.46 (0.68 to 3.11)	0.33
HLA-B27 status at baseline of originating study	Positive (n=137), Negative (n=18)	0.69 (0.24 to 1.97)	0.483
Symptom duration group at Week 0 of COAST-Y	≥5 years (n=123), <5 years (n=32)	1.36 (0.54 to 3.45)	0.511
Age group at Week 0 of COAST-Y	≥35 years (n=88), <35 years (n=67)	1.26 (0.61 to 2.62)	0.527
CRP group at Week 24 of COAST-Y	>5 mg/L (n=22), ≤5 mg/L (n=133)	1.36 (0.51 to 3.61)	0.539
Prior TNFi experience	Yes (n=26), No (n=129)	1.29 (0.51 to 3.25)	0.585
Symptom duration group at Week 0 of COAST-Y	≥10 years (n=85), <10 years (n=70)	0.82 (0.40 to 1.68)	0.587
AxSpA classification	r-axSpA (n=97), nr-axSpA (n=58)	1.21 (0.57 to 2.56)	0.614
Concomitant DMARD use at Week 0 of COAST-Y	Yes (n=63), No (n=92)	1.20 (0.58 to 2.47)	0.621
Sex	Male (n=116), Female (n=39)	0.89 (0.39 to 2.00)	0.774
Tobacco use group	Ever used (n=63), Never used (n=92)	1.05 (0.51 to 2.16)	0.901
Tobacco use group	Current use (n=45), Former or never used (n=110)	1.02 (0.46 to 2.23)	0.969
Continuous variables			
CRP at baseline of originating study	Continuous	1.03 (1.01 to 1.04)	0.005
ASDAS at baseline of originating study	Continuous	1.63 (1.07 to 2.49)	0.024
ASDAS area under the curve[c]	Continuous	1.06 (1.01 to 1.12)	0.024*
BASFI at baseline of originating study	Continuous	1.16 (0.97 to 1.39)	0.109
BASDAI inflammation at Week 24 of COAST-Y	Continuous	1.29 (0.93 to 1.80)	0.125*
Total back pain at Week 24 of COAST-Y	Continuous	1.19 (0.94 to 1.50)	0.146*
BASDAI at Week 24 of COAST-Y	Continuous	1.26 (0.92 to 1.73)	0.154*
Total back pain at baseline of originating study	Continuous	1.17 (0.94 to 1.46)	0.166
ASDAS at Week 24 of COAST-Y	Continuous	1.67 (0.80 to 3.51)	0.174*

BASDAI at baseline of originating study	Continuous	1.17 (0.92 to 1.49)	0.213
CRP at Week 24 of COAST-Y	Continuous	1.06 (0.95 to 1.19)	0.309
BASDAI inflammation at baseline of originating study	Continuous	1.10 (0.90 to 1.35)	0.36
PatGA at baseline of originating study	Continuous	1.10 (0.89 to 1.36)	0.383
CRP area under the curve[c]	Continuous	1.00 (1.00 to 1.01)	0.411
BASFI at Week 24 of COAST-Y	Continuous	1.10 (0.82 to 1.49)	0.52*
PatGA at Week 24 of COAST-Y	Continuous	1.02 (0.78 to 1.32)	0.895

*Indicates treatment interaction p-value of <0.05

[a]Normal BMI category is defined as ≥18.5 and <25 kg/m^2. Non-normal BMI category includes underweight (<18.5 kg/m^2), overweight (≥25 and <30 kg/m^2), obese (≥30 and <40 kg/m^2), or extremely obese (≥40 kg/m^2).

[b]Sustained low CRP is defined as CRP≤10 mg/L for all visits from Week 0 to Week 24 of COAST-Y.

[c]Area under the curve for CRP and ASDAS are defined as the area under the curve across time from Week 0 to Week 24 in COAST-Y

Abbreviations: ASDAS, Ankylosing Spondylitis Disease Activity Score; axSpA, axial spondyloarthritis; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; BMI, body mass index; CI, confidence interval; CRP, C-reactive protein; DMARD, disease-modifying anti-rheumatic drug; HLA-B27, human leukocyte antigen B27; IXE, ixekizumab; MRI, magnetic resonance imaging; nr-axSpA, non-radiographic axSpA; PatGA, Patient Global Assessment of disease activity; r-axSpA, radiographic axSpA; TNFi, tumor necrosis factor inhibitor

Supplementary Table 3. Patient characteristics associated with flare during the randomized withdrawal-retreatment period of COAST-Y (multivariate model after stepwise selection)

Variable	Category	Odds ratio (95% CI)	p-value
Categorical Variables			
Treatment	Placebo, IXE	5.12 (2.18 to 12.05)	<0.001
BMI group at Week 0 of COAST-Y	Non-normal, Normal[a]	2.46 (1.03 to 5.86)	0.043
Anti-drug antibody positive status at any time between Week 0 of originating study and Week 24 of COAST-Y	Yes, No	2.63 (1.02 to 6.79)	0.046
Continuous Variables			
CRP at baseline of originating study	Continuous	1.03 (1.01 to 1.05)	0.006
ASDAS area under the curve[b]	Continuous	1.07 (1.01 to 1.14)	0.019

[a]Normal BMI category is defined as ≥18.5 and <25 kg/m^2. Non-normal BMI category includes underweight (<18.5 kg/m^2), overweight (≥25 and <30 kg/m^2), obese (≥30 and <40 kg/m^2), or extremely obese (≥40 kg/m^2).
[b]Area under the curve for ASDAS is defined as the area under the curve across time from Week 0 to Week 24 in COAST-Y
Abbreviations: ASDAS, Ankylosing Spondylitis Disease Activity Score; BMI, body mass index; CI, Confidence interval, CRP, C-reactive protein; IXE, ixekizumab.

Supplementary Table 4. Patient characteristics associated with flare during the randomized withdrawal-retreatment period of COAST-Y (final model with interaction effect)

Variable	Estimate (SE)	p-value
Intercept	-1.9620 (0.3856)	<0.0001
IXE treatment (continued IXE versus withdrawn to placebo)	-1.3937 (0.3209)	<0.0001
CRP at baseline of originating study	0.0312 (0.0101)	0.0021
Non-normal BMI group at Week 0 of COAST-Y (non-normal versus normal)[a]	0.5215 (0.2238)	0.0198
BASDAI Pain score at Week 24 of COAST-Y	0.2649 (0.1362)	0.0517
Interaction of BASDAI Pain score at Week 24 of COAST-Y with IXE treatment (continued IXE versus withdrawal to placebo)	0.3717 (0.1358)	0.0062

[a]Normal BMI category is defined as ≥18.5 and <25 kg/m^2. Non-normal BMI category includes underweight (<18.5 kg/m^2), overweight (≥25 and <30 kg/m^2), obese (≥30 and <40 kg/m^2), or extremely obese (≥40 kg/m^2).

Abbreviations: BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BMI, body mass index; CRP, C-reactive protein; IXE, ixekizumab; SE, standard error

Supplementary Table 5. Summary of efficacy outcomes at the time of flare during the randomized withdrawal-retreatment Period of COAST-Y.

	Placebo N=23	IXE Q4W N=7	IXE Q2W N=6	Combined IXE N=13
ASDAS, mean (SD)	3.5 (0.9)	2.9 (1.1)	2.8 (0.6)	2.8 (0.9)
High disease activity[a]	12 (52%)	5 (71%)	5 (83%)	10 (77%)
Very high disease activity[b]	11 (48%)	2 (29%)	1 (17%)	3 (23%)
CRP (mg/L), mean (SD)	12.2 (12.7)	6.9 (5.5)	3.6 (2.2)	5.4 (4.5)

Values are presented as n (%) unless otherwise indicated.

[a]ASDAS high disease activity is a score of ≥2.1 and ≤3.5

[b]ASDAS very high disease activity is a score of >3.5

Abbreviations: ASDAS, Ankylosing Spondylitis Disease Activity Score; CRP, C-reactive protein; IXE, ixekizumab; Q2W, every two weeks; Q4W, every four weeks; SD, standard deviation.