Figure 1. (A) OR for changes in FL prevalence vs presence or absence of inflammation at BL; (B) OR of FL for VEs with vs without inflammation at Week 12.

A: An OR >1 represents an increase in FL from BL. A logistic regression with fixed effects for BL inflammation status by visit (including BL) and random effects for patient and VE (within patient). B: An OR >1 represents increased FL in VEs with vs without inflammation at Week 12, adjusted for BL VE status with respect to inflammation and FL. A logistic regression with fixed effects for Week 12 inflammation by visit (excluding BL) and BL inflammation by BL FL, and random effects for patient and VE (within patient). BL: baseline; FL: fatty lesion; OR: odds ratio; VE: vertebral edge.

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OP0105

EFFICACY AND SAFETY OF BIMEKIZUMAB IN ANKYLOSING SPONDYLITIS: 48-WEEK PATIENT-REPORTED OUTCOMES FROM A PHASE 2B, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED, DOSE-RANGING STUDY

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Background: Bimekizumab (BKZ), a monoclonal antibody that selectively neutralises interleukin (IL)-17A and IL-17F, is a potential therapeutic option in ankylosing spondylitis (AS).

Objectives: To report 48-week (wk) patient-reported outcomes (PROs) in patients (pts) with AS treated with BKZ in a phase 2b dose-ranging study (BE-AGILE; NCT02963506).

Methods: Pts with active AS (Bath AS Disease Activity Index [BASDAI] ≥4; spinal pain ≥4 [0–10]), fulfilling modified New York criteria (central reading), and inadequate response/intolerance to NSAIDs were randomised according to the study design (Figure 1). PROs included spinal pain, fatigue (BASDAI Q1), morning stiffness (mean of BASDAI Q5+6), Bath AS Functional Index (BASFI), Medical Outcomes Study (MOS) Sleep Problems Index II and AS Quality of Life questionnaire (ASQoL). Efficacy is reported for pts initially randomised to placebo (PBO) or BKZ 160/320 mg every 4 weeks (Q4W); treatment-emergent adverse events (TEAEs) are reported for pts who received ≥1 dose of study drug (Safety Set).

Results: Of 303 pts, 181 were randomised to PBO or BKZ 160/320 mg at Wk 0; 179/181 completed Wk 12 and 161/181 completed Wk 48. At Wk 12, improvements in pain, fatigue, morning stiffness, BASFI, sleep and ASQoL were greater in BKZ pts vs PBO pts. Responses were further improved or maintained to Wk 48, with no meaningful differences between BKZ 160 mg and 320 mg (Table 1). Serious TEAEs occurred in 13/303 (4.3%) pts (Table 2), which included 2 major adverse cardiac events considered not related to study drug. Oral candidiasis occurred in 16 (5.3%) pts.

Figure 1. Study design

ASAS40: Assessment of SpondyloArthritis international Society improvement of ≥40%; Q4W: every 4 weeks; SFU: safety follow-up.

Table 1. PRO efficacy endpoints to Week 48 (multiple imputation)

Mean (SD)	Wk	PBO – BKZ 160 mg (n=24)	PBO – BKZ 320 mg (n=36)	BKZ 160 mg (n=58)	BKZ 320 mg (n=61)
Spinal pain	0	6.9 (1.4)	7.0 (1.9)	6.6 (2.0)	7.3 (1.5)
CfB	12	-1.5 (1.6)	-0.7 (1.7)	-2.6 (2.2)	-3.6 (2.4)
	48	-3.7 (2.0)	-3.7 (2.6)	-3.8 (2.4)	-4.7 (2.1)
Fatigue	0	6.4 (1.7)	6.8 (1.6)	6.4 (1.7)	6.4 (1.9)
CfB	12	-0.7 (2.5)	-1.0 (1.7)	-2.1 (2.2)	-2.1 (2.5)
	48	-2.7 (2.2)	-2.8 (2.4)	-3.1 (2.1)	-3.3 (2.4)
Morning stiffness	0	6.9 (1.7)	6.7 (2.0)	6.5 (1.8)	6.6 (2.1)
CfB	12	-1.5 (1.7)	-1.1 (1.5)	-2.8 (2.0)	-3.4 (2.7)
	48	-3.9 (2.2)	-3.6 (2.4)	-3.9 (2.2)	-4.4 (2.4)
BASFI	0	5.8 (1.8)	5.5 (2.2)	5.5 (2.2)	5.9 (2.0)
CfB	12	-1.0 (2.1)	-0.3 (1.7)	-1.7 (1.8)	-2.2 (2.0)
	48	-2.9 (2.2)	-2.4 (2.2)	-2.5 (2.0)	-2.9 (2.2)
MOS Sleep Problems Index II	0	45.5 (8.1)	45.3 (7.9)	46.9 (7.5)	47.2 (9.4)
CfB	12	2.1 (8.3)	1.8 (6.8)	5.6 (6.7)	6.8 (7.5)
	48	7.6 (8.7)	8.0 (9.1)	6.5 (6.1)	8.0 (7.9)
ASQoL	0	8.4 (4.7)	9.2 (4.7)	8.4 (4.3)	8.7 (4.3)
CfB	12	-1.3 (5.5)	-1.3 (3.7)	-3.5 (4.3)	-4.6 (4.8)
	48	-4.2 (5.6)	-5.3 (5.6)	-4.9 (4.1)	-5.4 (4.8)

CfB: change from baseline

Conclusion: Pts with active AS demonstrated rapid and sustained improvements in PROs, sleep and quality of life over 48 wks of BKZ treatment. BKZ was generally well tolerated with no unexpected safety findings versus previous studies.

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Table 2. Overview of TEAEs to Week 48 (Safety Set; N=303)

n (%)	BKZ 160 mg (n=149)	BKZ 320 mg (n=150)	All BKZ [a] (N=303)
Any TEAE	103 (69.1)	122 (81.3)	235 (77.6)
Drug-related TEAEs	48 (32.2)	54 (36.0)	110 (36.3)
Serious TEAEs	5 (3.4)	6 (4.0)	13 (4.3)
Discontinuations due to TEAEs	7 (4.7)	10 (6.7)	20 (6.6)

[a] Includes TEAEs for 16 and 64 mg BKZ

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OP0106

SECUKINUMAB 150 MG SIGNIFICANTLY IMPROVED SIGNS AND SYMPTOMS OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 52-WEEK RESULTS FROM THE PHASE III PREVENT STUDY

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Background: Axial spondyloarthritis (axSpA) spectrum covers radiographic axSpA and non-radiographic axSpA (nr-axSpA). PREVENT (NCT02696031) is the first phase III, placebo (PBO) controlled study evaluating secukinumab (SEC) 150 mg with (LD) or without loading (NL) dose, in patients (pts) with nr-axSpA.¹ The study had 2 independent analysis plans as per EU (Wk 16) and US (Wk 52) regulatory requirements.

Objectives: To report efficacy through Wk 52 and safety up to two years for the PREVENT study.

Methods: 555 pts fulfilling ASAS criteria for axSpA plus abnormal CRP and/or MRI, without evidence of radiographic changes in sacroiliac (SI) joints according to modified New York Criteria for AS were enrolled. All images were assessed centrally before inclusion. Pts were randomised (1:1:1) to SEC 150 mg with LD, NL, or PBO at baseline (BL). LD pts received SEC 150 mg at Wks 1, 2, 3, and 4, and then every 4 wks (q4wk) starting at Wk 4. NL pts received SEC 150 mg at BL and PBO at Wks 1, 2, and 3, and then 150 mg q4wk. Switch to open-label

(OL) SEC 150 mg or standard of care (SoC) was permitted after Wk 20. Primary endpoint was ASAS40 at Wk 16 (LD) and at Wk 52 (NL) in anti-TNF-naïve pts. Secondary endpoints (overall population) included ASAS40, BASDAI50, SI joint bone marrow edema (BME) score by MRI at Wks 16 and 52 and ASDAS-CRP inactive disease (ID) at Wk 52. Endpoints were analysed according to statistical hierarchy. Analysis used non responder imputation through Wk 52. Safety analyses included all pts who received ≥1 dose of study treatment.

Results: Overall, 481 pts completed 52 wks with no major differences in retention across groups: 84.3% (156/185; LD), 89.7% (165/184; NL) and 86.0% (160/186; PBO). BL characteristics were similar across groups; 90% pts were anti-TNF-naïve, 56-58% pts had elevated CRP, 71-75% pts had evidence of SI joint inflammation by MRI. Proportion of pts who switched to OL or SoC between Wks 20 and 48 was 52.1% (LD), 49.2% (NL), and 67.4% (PBO). Primary endpoints at Wk 16 and Wk 52 were met (Table). SEC 150 mg LD or NL significantly improved secondary endpoints at Wk 16 and 52 vs PBO (Table). SEC significantly reduced SI joint MRI BME score vs PBO at Wk 16 (-1.68 and -1.03 vs -0.39; $P = 0.0197$ and 0.026 , LD and NL respectively). No unexpected safety signals were reported.

Conclusion: SEC 150 mg provided significant and sustained improvement in signs and symptoms of pts with nr-axSpA through Wk 52. MRI BME scores were reduced accordingly. There was no major difference between LD and NL. Safety of SEC was consistent with previous reports.²

References:

- [1] Deodhar A, et al. *Arthritis Rheumatol.* 2019;71(suppl 10).
- [2] Deodhar A, et al. *Arth Res Ther.* 2019;21:111.

Table

Endpoints, % responders	Wk	SEC 150 mg LD (N = 185)	SEC 150 mg NL (N = 184)	PBO (N = 186)
Primary				
ASAS40 in anti-TNF-naïve pts	16	41.5 [‡]	42.2 [‡]	29.2
	52	35.4 [‡]	39.8 [‡]	19.9
Secondary				
ASAS40	16	40.0 [‡]	40.8 [‡]	28.0
	52	33.5 [‡]	38.0 [‡]	19.4
BASDAI50	16	37.3 [‡]	37.5 [‡]	21.0
	52	30.8 [‡]	35.3 [‡]	19.9
ASDAS-CRP ID	16	20.5 [†]	21.7 [†]	8.1
	52	15.7	23.9 [‡]	10.2

[†] $P < 0.001$; [‡] $P < 0.05$ vs PBO (P values are adjusted for multiplicity of testing at Wks 16 and 52. Unadjusted P value for ASDAS-CRP ID at Wk 16). Missing values were imputed as non-response.

N, number of randomised pts

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