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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OP0107 ETANERCEPT WITHDRAWAL AND RE-TREATMENT IN PATIENTS WITH INACTIVE NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS AT 24 WEEKS: RESULTS OF RE-EMBARK, AN OPEN-LABEL, PHASE IV TRIAL

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Background: In the RE-EMBARK trial (NCT02509026), etanercept (ETN)-treated patients with non-radiographic axial spondyloarthritis (nr-axSpA) who achieved inactive disease (defined as Ankylosing Spondylitis Disease Activity Score with C-reactive protein [ASDAS CRP] <1.3) in Period 1 (P1)[1] discontinued ETN for ≤40 weeks.

Objectives: To assess the proportion of patients with inactive disease after P1 who experienced disease flare (ASDAS with erythrocyte sedimentation rate [ASDAS ESR] ≥2.1) within 40 weeks of ETN withdrawal and to estimate time to flare following ETN withdrawal.

Methods: RE-EMBARK was a multicenter, open-label, Phase IV trial of ETN in patients with active nr-axSpA (meeting Assessment in SpondyloArthritis international Society criteria and with ASDAS CRP ≥2.1) and an inadequate response to ≥2 nonsteroidal anti-inflammatory drugs (NSAIDs) while taking a stable dose of 1 NSAID for ≥2 weeks before the first ETN dose. All patients received ETN (50 mg/week) plus NSAID for the first 24 weeks (P1). At week 24, patients with inactive disease discontinued ETN for ≤40 weeks (Period 2 [P2]). Those who experienced flare during P2 were re-treated with ETN for 12 weeks in Period 3 (P3). Kaplan-Meier (KM) analysis and Cox proportional hazard models were used to 1) estimate the probability of experiencing flare within a given time period, and 2) compare data between RE-EMBARK and the EMBARK trial (NCT01258738) of patients with nr-axSpA who met RE-EMBARK P2 entry criteria (achieved inactive disease after 24 weeks of ETN treatment) and continued treatment for a further ≤40 weeks.

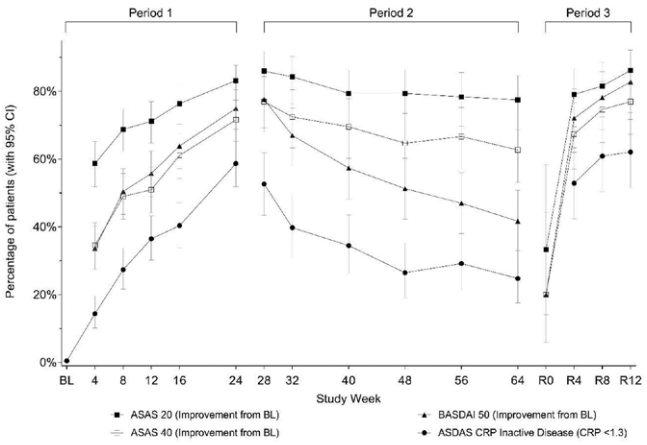
Results: Of the 209 patients in P1 (mean age, 33 years; women, 46%; white, 89%), 119 (57%) entered P2. The proportion of patients experiencing ≥1 flare increased from 22% (25/112) at P2 week 4 to 67% (77/115) at P2 week 40. Overall, 75% (86/115) of patients in P2 experienced flare and 50% experienced flare within 16 weeks (95% CI: 13-24 weeks, KM analysis). Conversely, data from the comparator EMBARK trial suggested that <25% of patients receiving continuous ETN treatment over 40 weeks experienced flare. Cox proportional hazard model analysis showed an 85% relative risk reduction of experiencing flare during P2 in patients with inactive disease who continued ETN treatment vs those who discontinued. By P3 end 62% (54/87) of patients re-treated with ETN re-achieved inactive disease; 50% of patients who re-achieved inactive disease in P3 did so within 5 weeks (95% CI: 4-8 weeks, KM analysis). The observed trend of clinical improvement (P1), worsening (P2), and improvement (P3) was reflected in other clinical measures (Figure) plus measures of joint damage (Spondyloarthritis Research Consortium of Canada Sacroiliac Joint magnetic resonance imaging score) and quality of life (EQ-5D visual analog scale score); mean (standard deviation) score changes from each study period baseline–end were –6.1 (11.7) [P1], +1.5 (4.4) [P2], –2.0 (8.8) [P3] and +27.7 (26.7) [P1], –26.4 (30.5) [P2], +32.1 (26.3) [P3], respectively. There were no unexpected safety signals.

Conclusion: For patients with nr-axSpA who achieved inactive disease with ETN and then discontinued treatment, a quarter maintained treatment-free inactive disease for 40 weeks and 50% maintained an ASDAS ESR score of <2.1 for ≥16 weeks. Re-starting ETN allowed 62% of patients who flared to re-achieve inactive disease within 12 weeks.

References:

[1] Van den Bosch F, et al. *Ann Rheum Dis* 2019;78:896-7

Figure: Clinical Assessments by RE-EMBARK Study Period



ASAS, Assessment of SpondyloArthritis International Society; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BL, baseline; CI, confidence interval; CRP, C-reactive protein; R, re-treatment

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OP0108 RANDOMIZED CONTROLLED TRIAL OF ORAL CORTICOSTEROIDS IN AXIAL SPONDYLOARTHROPATHY: MODIFIED COBRA REGIME

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Background: There is an unmet need of anti-inflammatory agents in AxSpA after NSAID failure. This is especially true for patients with persisting high disease activity and not having access to anti-TNFα. In this regard, corticosteroids may be helpful as a short-term measure. However, current guidelines recommend against oral corticosteroids citing insufficient evidence of efficacy. [1]. Also, there is an assumption that the dose required for benefit is much higher than RA, and thus untenable. It is unclear whether starting with a high dose followed by rapid taper would be effective (like the COBRA regime in RA)[2].

Objectives: To study the efficacy of the COBRA regime of oral corticosteroids in axial SpA over 24 weeks.

Methods: This was a double blind placebo controlled randomized trial. Patients with active axial SpA (BASDAI ≥ 4) despite NSAIDs were randomized to either