Objectives: To evaluate the efficacy of UPA 15mg once daily (QD) in selected subgroups of patients with AS based on different baseline characteristics.

Methods: In SELECT-AXIS 1, patients were randomized to 14 weeks of blinded treatment with UPA 15mg QD or placebo (PBO). This post hoc analysis evaluated the proportions of patients achieving $\geq 40\%$ improvement in Assessment of SpondyloArthritis International Society criteria (ASAS40), $\geq 50\%$ improvement in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI50), and change from baseline in Ankylosing Spondylitis Disease Activity Score with C-reactive protein (ASDAS[CRP]) at Week 14 across subgroups based on the following baseline patient characteristics: gender, age, body mass index, AS symptom duration, C-reactive protein (CRP) levels, Spondyloarthritis Research Consortium of Canada Magnetic Resonance Imaging index, and human leukocyte antigen B27 status. For missing data, non-responder imputation analysis was used for ASAS40 and BASDAI50, and mixed model repeated measures analysis was used for ASDAS[CRP].

Results: Baseline disease characteristics were balanced between the treatment groups at randomization, as previously reported.¹ ASAS40 and BASDAI50 response rates at Week 14 were numerically higher with UPA 15mg versus PBO across the demographic and disease characteristic subgroups evaluated (Figure 1), including some subgroups with small sample sizes, such as patients with disease duration < 5 years and female patients. Improvements from baseline in ASDAS[CRP] were also consistently greater with UPA 15mg versus PBO across the subgroups evaluated (Table 1).

Conclusion: Within subgroups evaluated, most patients with active AS receiving UPA 15mg demonstrated greater improvements versus PBO in disease activity measures assessed by ASAS40, BASDAI50, and change from baseline in ASDAS[CRP]. There was some evidence that gender, AS symptom duration, and baseline CRP levels seemed to influence outcomes, though results should be interpreted with caution due to small sample sizes for some subgroups.

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Table 1. PBO-corrected mean change from baseline (95% CI) in ASDAS[CRP] at Week 14 in patients receiving UPA 15 mg by baseline subgroups (MMRM)

Subgroup		n		ASDAS[CRP]
		UPA 15 mg	PBO	
Gender	Male	58	62	-1.11 (-1.37, -0.84)
	Female	26	22	-0.44 (-0.92, 0.03)
Age	< 40 years	24	36	-1.00 (-1.42, -0.58)
	40– < 65 years	51	46	-0.88 (-1.17, -0.59)
Body mass index	< 25 kg/m ²	32	37	-0.92 (-1.30, -0.55)
	≥ 25 kg/m ²	52	47	-0.89 (-1.20, -0.59)
AS symptom duration	< 5 years	16	17	-0.90 (-1.46, -0.34)
	≥ 5 years	68	67	-0.92 (-1.18, -0.66)
Baseline hsCRP	≤ 2.8 mg/L	23	19	-0.59 (-1.02, -0.15)
	> 2.8 – < 10 mg/L	39	34	-0.59 (-0.95, -0.23)
	≥ 10 mg/L	22	31	-1.64 (-2.01, -1.27)
Inflammation based on SPARCC MRI scores	Positive ^a	56	57	-0.98 (-1.27, -0.69)
	Negative ^b	21	16	-0.60 (-1.08, -0.12)
HLA-B27 status	Positive	62	66	-0.97 (-1.24, -0.71)
	Negative	20	17	-0.73 (-1.28, -0.17)

^aSpine SPARCC score ≥ 2 or sacroiliac joint SPARCC score ≥ 2 . ^bSpine SPARCC score < 2 and sacroiliac joint SPARCC score < 2 . ASDAS[CRP], Ankylosing Spondylitis Disease Activity Score with C-reactive protein; CI, confidence interval; HLA-B27, human leukocyte antigen B27; hsCRP, high-sensitivity C-reactive protein; MMRM, mixed model repeated measures; MRI, magnetic resonance imaging; PBO, placebo; SPARCC, Spondyloarthritis Research Consortium of Canada; UPA, upadacitinib.

Figure Response rate difference for UPA versus PBO (95% CI) for ASAS40 and BASDAI50 responses at Week 14 in patients receiving UPA 15 mg by baseline subgroups (non-responder imputation)

^aSpine SPARCC score ≥ 2 or sacroiliac joint SPARCC score ≥ 2 . ^bSpine SPARCC score < 2 and sacroiliac joint SPARCC score < 2 . AS, ankylosing spondylitis; ASAS40, $\geq 40\%$ improvement in Assessment of SpondyloArthritis International Society criteria; BASDAI50, $\geq 50\%$ improvement in Bath Ankylosing Spondylitis Disease Activity Index; BMI, body mass index; CI, confidence interval; HLA-B27, human leukocyte antigen B27; hsCRP, high-sensitivity C-reactive protein; MRI, magnetic resonance imaging; PBO, placebo; SPARCC, Spondyloarthritis Research Consortium of Canada; UPA, upadacitinib.

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POS0924

PREDICTORS OF 1-YEAR TREATMENT RESPONSE AMONG UPADACITINIB-TREATED PATIENTS WITH ANKYLOSING SPONDYLITIS: A POST HOC ANALYSIS OF SELECT-AXIS 1

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Background: Upadacitinib (UPA) is an oral Janus kinase inhibitor that has demonstrated efficacy and safety among patients with ankylosing spondylitis (AS) in the phase 2/3 SELECT-AXIS 1 study.¹ If identified, early predictors of treatment response may inform treat-to-target strategies and optimize patient outcomes in AS.

Objectives: To determine whether baseline (BL) characteristics or early responses predict clinical response at 1 year in UPA-treated patients with AS.

Methods: In the double-blind, randomized, placebo (PBO)-controlled SELECT-AXIS 1 study, patients received UPA 15 mg once daily or PBO until Week 14.¹ At Week 14, PBO-treated patients switched to UPA 15 mg; patients originally randomized to UPA continued UPA therapy. Data from patients in the PBO and UPA arms were combined based on overall exposure to UPA; in the switch arm, exposure was defined as current visit minus 14 weeks (time of switch). The following outcomes were assessed at 1 year: Ankylosing Spondylitis Disease Activity Score with C-reactive protein (ASDAS[CRP]) inactive disease (ID; <1.3) and low disease activity (LDA; <2.1), Assessment of SpondyloArthritis International Society (ASAS) partial remission (PR), and ≥40% improvement in ASAS criteria (ASAS40) response. The ability of BL characteristics, efficacy at Week 12, and back pain at Week 12 to predict 1-year outcomes was assessed using a univariable logistic regression model generating odds ratios (ORs; 95% confidence intervals). LASSO regression was used to select the best-fitted multivariable model at Week 12 for each outcome measure.

Results: Among 187 patients who received or switched to UPA 15 mg, 70 (37.4%), 134 (71.7%), 73 (39.0%), and 131 (70.1%) achieved ASDAS(CRP) ID, ASDAS(CRP) LDA, ASAS PR, and ASAS40, respectively, following 1 year of UPA treatment. No meaningful predictors of 1-year efficacy outcomes were identified based on BL demographics (including disease duration, gender, and human leukocyte antigen B27 status) or BL disease characteristics (including ASDAS, Bath Ankylosing Spondylitis Disease Activity Index, and CRP levels). In univariable analyses, Week 12 responses based on several disease activity measures and patient-reported outcomes (PROs), including reductions (much better improvement [MBI], ≥30/≥50/≥70% reduction, or improvement) in back pain score, along with lower scores for back pain at Week 12, were associated with the achievement of ASDAS(CRP) ID, ASDAS(CRP) LDA, ASAS PR, and ASAS40 at 1 year (Figure 1). In a multivariable analysis, improvement from BL to Week 12 in back pain score consistently predicted several efficacy outcomes at 1 year.

Conclusion: In upadacitinib-treated patients with AS, improvement in PROs and reduction in back pain score at 12 weeks predicted clinical outcomes at 1 year.

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Figure 1. Association between Week 12 response or back pain at Week 12 and achievement of efficacy outcomes at 1 year (univariable analysis)

All ASDAS scores are calculated using C-reactive protein

ASDAS CII: change from BL ≥1.1; ASDAS MI: change from BL ≥2.0; MBI back pain: ≥2-point reduction in absolute score and ≥33% reduction from BL on a 0–10 NRS

ASAS, Assessment of SpondyloArthritis International Society; ASAS40, ≥40% improvement in ASAS criteria; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI50, ≥50% improvement in the Bath Ankylosing Spondylitis Disease Activity Index; BL, baseline; CI, confidence interval; CII, clinically important improvement; ID, inactive disease; LDA, low disease activity; MBI, much better improvement; MI, major improvement; NRS, numeric rating scale; OR, odds ratio; PR, partial remission

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POS0925

EFFICACY OF SECUKINUMAB IN TNFI-NAÏVE PATIENTS ACROSS THE AXIAL SPONDYLOARTHRITIS SPECTRUM OVER 52 WEEKS: A POST HOC ANALYSIS OF THE MEASURE AND PREVENT CLINICAL TRIALS

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Background: Secukinumab (SEC) has demonstrated significant efficacy in patients (pts) with ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA).¹⁻⁵ However, evidence regarding the efficacy of SEC across the axSpA disease spectrum is limited.

Objectives: To assess the efficacy of SEC on key efficacy endpoints in pts with axSpA (nr-axSpA and AS) over 52 weeks from 6 pooled phase 3 clinical trials.

Methods: This post hoc analysis included pooled data from tumour necrosis factor inhibitors (TNFI)-naïve pts in the MEASURE 1-5 (AS) and PREVENT (nr-axSpA) phase 3 trials. Assessments included proportion of patients achieving ASAS40, ASAS 5/6, ASAS partial remission (ASAS-PR), ASDAS-CRP major improvement, ASDAS-CRP inactive disease (ASDAS-CRP ID), BASDAI50 and mean change from baseline in nocturnal back pain and morning stiffness with any SEC 150 mg or SEC 300 mg or placebo (PBO) at Week 16, and sustainability was measured in pts treated with SEC at Week 52. Data are reported as non-responder imputation.

Results: A total of 1558 TNFI-naïve pts (SEC 150 mg, N=932; SEC 300 mg, N=57 and PBO, N=569) with a mean age of 39.3 ± 11.58 years were included in the study. At Week 16, significantly higher improvements in pts treated with SEC versus PBO were observed in all efficacy endpoints (Table 1) with improvements sustained up to Week 52.

Conclusion: SEC 300 mg and 150 mg provided significant and sustained improvement in the signs and symptoms of TNFI-naïve pts with axSpA regardless of radiographic status.

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