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POS0900

SECUKINUMAB 150 MG PROVIDES SUSTAINED IMPROVEMENT IN SIGNS AND SYMPTOMS OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 2-YEAR RESULTS FROM THE PREVENT STUDY

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Background: Axial spondyloarthritis (axSpA) is an inflammatory disease characterised by chronic back pain, and it comprises radiographic axSpA and non-radiographic axSpA (nr-axSpA).¹ Secukinumab (SEC) 150 mg, with (LD) or without loading (NL), dose significantly improved the signs and symptoms of patients with nr-axSpA in the PREVENT (NCT02696031) study through Week 52.²

Objectives: To report the long-term clinical efficacy and safety of secukinumab from the PREVENT study through 2 years.

Methods: A detailed study design, key primary and secondary endpoints have been reported previously.² In total, 555 patients fulfilling ASAS criteria for axSpA plus abnormal C-reactive protein (CRP) and/or MRI, without evidence of radiographic changes in sacroiliac (SI) joints according to modified New York Criteria for AS were randomised (1:1:1) to receive SEC 150 mg with LD, NL, or placebo (PBO) at baseline. LD patients received SEC 150 mg at Weeks 1, 2, 3, and 4, and then every 4 weeks (q4wk) starting at Week 4. NL patients received SEC 150 mg at baseline and PBO at weeks 1, 2, and 3, and then 150 mg q4wk. 90% patients were anti-tumour necrosis factor (anti-TNF) naïve, 57% had elevated CRP and 73% had evidence of SI joint inflammation on MRI. All images were assessed centrally before inclusion. All patients continued to receive open-label SEC 150 mg treatment after Week 52. Efficacy assessments through Week 104 included ASAS40 in anti-TNF-naïve patients, ASAS40, BASDAI change from baseline, BASDAI50, ASAS partial remission, and ASDAS-CRP inactive disease in the overall population. The safety analyses included all patients who received ≥1 dose of study treatment for the entire treatment period up to Week 104. Data are presented as observed.

Results: Overall, 438 patients completed 104 weeks of study: 78.9% (146/185; LD), 77.7% (143/184; NL) and 80.1% (149/186; PBO). Efficacy results at Week 52 were sustained through Week 104 and are reported in the Table 1. The safety profile was consistent with the previous reports with no deaths reported during the entire treatment period up to Week 104.²

Conclusion: Secukinumab 150 mg demonstrated sustained improvement in the signs and symptoms of patients with nr-axSpA through 2 years. Secukinumab was well tolerated with no new or unexpected safety signals.

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§p<0.01 and †p<0.05 vs placebo (unadjusted p-values at Week 16). Data presented as non-responder imputation till week 16 and as observed from Week 24 to Week 104. At Week 52 all patients remaining on blinded treatment switched to open-label secukinumab.

ASAS, Assessment of SpondyloArthritis International Society; N, total number of patients randomised; n, number of evaluable patients including those who switched to open label secukinumab or standard of care after Week 20. After Week 52, only patients who continued to receive open-label secukinumab are presented; s.c., subcutaneous

Figure 1. ASAS40 response was maintained through Week 104 in the overall population

Table 1. Summary of clinical efficacy (Observed data)

Endpoints	Week	SEC 150 mg LD (N=185)	SEC 150 mg NL (N=184)	PBO-SEC 150 mg (N=186)
*ASAS40 in anti-TNF-naïve patients, n/M (%)	52 ^a	90/137 (65.7)	95/145 (65.5)	85/151 (56.3)
	104	78/123 (63.4)	83/123 (67.5)	83/134 (61.9)
BASDAI change from baseline, mean±SD	52 ^a	-3.7±2.8	-3.7±2.6	-3.3±2.4
	104	-4.1±2.6	-3.9±2.6	-3.7±2.5
BASDAI50, n/M (%)	52 ^a	90/153 (58.8)	92/163 (56.4)	90/161 (55.9)
	104	88/137 (64.2)	84/136 (61.8)	87/142 (61.3)
ASAS partial remission, n/M (%)	52 ^a	46/152 (30.3)	56/163 (34.4)	46/161 (28.6)
	104	51/137 (37.2)	50/135 (37.0)	50/142 (35.2)
ASDAS CRP inactive disease, n/M (%)	52 ^a	49/152 (32.2)	58/163 (35.6)	48/160 (30.0)
	104	50/132 (37.9)	53/133 (39.8)	53/142 (37.3)

*For anti-TNF-naïve patients, N=164, LD; 166, NL; 171, PBO-SEC.^a total number of evaluable patients including open-label SEC and standard of care (SOC; 2 patients in LD, 1 patient in NL continued on SOC). After Week 52, only patients who continued to receive open-label SEC are presented. ASAS, Assessment of SpondyloArthritis International Society; ASDAS, Ankylosing Spondylitis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; M, number of patients with evaluation; N, total randomised patients; n, number of patients who are responders; SD, standard deviation

Disclosure of Interests: Denis Poddubnyy Speakers bureau: AbbVie, BMS, Eli Lilly, MSD, Novartis, Pfizer, UCB, Consultant of: AbbVie, Biocad, BMS, Eli Lilly, Gilead, MSD, Novartis, Pfizer, Samsung Bioepis, UCB, Grant/research support from: AbbVie, MSD, Novartis, Pfizer, Atul Deodhar Speakers bureau: AbbVie, Amgen, Boehringer Ingelheim, Bristol Myer Squibb (BMS), Eli Lilly, GSK, Janssen, Novartis, Pfizer, and UCB, Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, GSK, Janssen, Novartis, Pfizer, and UCB, Grant/research support from: AbbVie, Eli Lilly, GSK, Novartis, Pfizer, and UCB, Xenofon Baraliakos Speakers bureau: AbbVie, BMS, Celgene, Chugai, MSD, Novartis, Pfizer, and UCB, Consultant of: AbbVie, BMS, Celgene, Chugai, Galapagos, Gilead, MSD, Novartis, Pfizer, and UCB, Grant/research support from: AbbVie and Novartis, Ricardo Blanco Speakers bureau: AbbVie, Pfizer, Roche, Bristol-Myers, Janssen, UCB pharma and MSD and Eli Lilly, Consultant of: AbbVie, Pfizer, Roche, Bristol-Myers, Janssen, UCB pharma and MSD, Grant/research support from: AbbVie, MSD, and Roche, Eva Dokoupilova Grant/research support from: AbbVie, Affibody AB, Eli Lilly, Galapagos, Gilead, GSK, Hexal AG, MSD, Novartis, Pfizer, R-Pharm, Sanofi-Aventis, and UCB, Stephen Hall Speakers bureau: Novartis, Merck, Janssen, Pfizer, Eli Lilly, and UCB, Consultant of: Novartis, Merck, Janssen, Pfizer, Eli Lilly, and UCB, Grant/research support from: AbbVie, UCB, Janssen, and Merck, Alan Kivitz Shareholder of: Pfizer, Sanofi, Novartis, Amgen, GlaxoSmithKline, Gilead Sciences, Inc., Speakers bureau: Celgene, GlaxoSmithKline, Eli Lilly, Merck, Novartis, Pfizer, Sanofi, Genzyme, Flexion, AbbVie, UCB, Consultant of: AbbVie, Boehringer Ingelheim, Flexion, Janssen, Pfizer, Sanofi, Regeneron, SUN Pharma Advanced Research, Gilead Sciences, Inc., Marleen G.H. van de Sande Speakers bureau: Novartis, MSD, Consultant of: AbbVie, Novartis, Eli Lilly, Grant/research support from: Novartis, Eli Lilly, Janssen, UCB, Anna Stefanska Shareholder of: Novartis, Employee of: Novartis, Patricia Pertel Shareholder of: Novartis, Employee of: Novartis, Hanno Richards Shareholder of: Novartis, Employee of: Novartis, Juergen Braun Speakers bureau: AbbVie (Abbott), Amgen, BMS, Boehringer, Celgene, Celltrion, Centocor, Chugai, EBEWE Pharma, Medac, MSD (Schering-Plough), Mundipharma, Novartis, Pfizer (Wyeth), Roche, Sanofi-Aventis and UCB pharma, Eli Lilly, Consultant of: AbbVie (Abbott), Amgen, BMS, Boehringer, Celgene, Celltrion, Centocor, Chugai, EBEWE Pharma, Medac, MSD (Schering-Plough), Mundipharma, Novartis, Pfizer (Wyeth), Roche, Sanofi-Aventis and UCB, Eli Lilly, Grant/research support from: AbbVie (Abbott), Amgen, BMS, Boehringer, Celgene, Celltrion, Centocor, Chugai, Medac, MSD (Schering-Plough), Mundipharma, Novartis, Pfizer (Wyeth), Roche, Sanofi-Aventis and UCB, Eli Lilly

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IXEKIZUMAB SHOWS A DISTINCT PATTERN OF PAIN IMPROVEMENT BEYOND INFLAMMATION IN RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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Background: The efficacy of ixekizumab (IXE) in biologic-naïve patients with radiographic axial spondyloarthritis (r-axSpA) has been previously presented using traditional axSpA outcome measures, such as BASDAI and ASAS.