Conclusion: Subjects with low or moderate disease activity at baseline exhibited the highest likelihood of achieving and maintaining an improvement in LDA or REM with continued APR treatment to Week 52. In these patients, a partial response with apremilast by Week 16 was associated with higher achievement or maintenance of cDAPSA LDA or REM by Week 52.

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SECUKINUMAB PROVIDES SUSTAINED IMPROVEMENTS IN THE SIGNS AND SYMPTOMS IN PSORIATIC ARTHRITIS: FINAL 5 YEAR EFFICACY AND SAFETY RESULTS FROM A PHASE 3 TRIAL

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Background: Secukinumab (SEC) provided rapid and significant improvements in all key clinical domains of psoriatic arthritis (PsA) in the FUTURE 1 study (NCT01392326) with improvements sustained through 3 years.¹

Objectives: We present the final 5 year efficacy and safety results of the study.

Methods: Overall, 606 adults with active PsA were randomised to SEC 10 mg/kg intravenously at baseline, and at weeks (wks) 2 and 4, followed by 150 mg or 75 mg subcutaneously (SC) every 4 wks, or matching placebo. Placebo patients (pts) were re-randomised to SEC 150 mg or 75 mg SC from Wk 16 or 24, depending on clinical response.¹ At Wk 104, 460 pts entered the 3-year extension study. Pts could have SEC dose escalated from 150 to 300 mg and from 75 mg to 150/300 mg starting from Wk 156, based on physician's judgement. Assessments at Wk 260 included ACR20/50/70, PASI 90, HAQ-DI, SF-36 PCS, and

resolution of dactylitis and enthesitis and are reported for pts originally randomised to the SEC 150 mg and 75 mg groups (observed data). Safety is reported as exposure adjusted incidence rate/100 patient-years (EAIR) for all pts (n = 587) who received ≥1 dose of study treatment.

Results: Overall, 132/161 (82%) and 124/147 (84.4%) pts originally randomised to SEC 150/75 mg, respectively, who entered the extension study, completed 260 Wks of treatment. A total of 86/236 (36.4%) pts on SEC 150 mg were escalated to 300 mg, while 180/221 (81.4%) pts on SEC 75 mg were escalated to 150/300 mg. Clinical responses were sustained or further improved through 5 years treatment (Table 1). Over the entire study period (SEC mean exposure of 2320 patient-years), the safety profile of SEC was consistent with previous reports.¹ EAIR of selected adverse events for SEC were serious infections (1.8), ulcerative colitis (0.04), Crohn's disease (0.1), and MACE (0.5). Six deaths (3 in each dose group) were reported in any SEC group through 5 years.

Conclusion: SEC provided sustained improvements in the signs and symptoms in the major clinical domains of PsA through 5 years. SEC was well tolerated with a safety profile consistent with that previously reported.

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Table 1. Summary of Efficacy Results at Week 260

Efficacy endpoints (n/N (%) unless otherwise stated)	SEC 150 mg Group (N=161) ¹	SEC 75 mg Group (N=147) ¹
ACR20	89/131 (67.9)	98/127 (77.2)
ACR50	69/131 (52.7)	65/127 (51.2)
ACR70	49/131 (37.4)	43/127 (33.9)
PASI90 ²	48/72 (66.7)	47/71 (66.2)
HAQ-DI, mean change from baseline (SD)	-0.4 (0.58) n=131	-0.5 (0.61) n=126
SF-36 PCS, mean change from baseline (SD)	6.6 (8.33) n=131	5.9 (9.36) n=123
Resolution of enthesitis ³	67/81 (82.7)	60/77 (77.9)
Resolution of dactylitis ⁴	63/67 (94.0)	63/70 (90.0)

¹Secukinumab 150 and 75 mg arms include 60 and 121 pts, respectively, who were dose escalated to 150 and/or 300 mg at Wk 156 or later

²Pts with psoriasis affecting ≥3% body surface area at baseline (150 mg: N = 89; 75 mg: N = 82)

³Pts (N = 99 [150 mg], and 91 [75 mg]) with enthesitis at baseline

⁴Pts (N = 83 [150 mg], and 77 [75 mg]) with dactylitis at baselineM, number of evaluable pts; N, total number of randomised pts; n, number of responders

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