Conclusions: As early as wk14, IV GLM demonstrated clinically meaningful improvements in skin PsO irrespective of MTX use and nail PsO. Improvement in DLQI was seen as early as wk8, w/continued improvement at wks14 and 24.

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SAT0347 BASELINE CHARACTERISTICS OF PATIENTS WITH PSORIATIC ARTHRITIS INITIATED ON APREMILAST IN THE CORONA PSORIATIC ARTHRITIS/SPONDYLOARTHRITIS (PSA/SPA) REGISTRY

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Background: Apremilast (APR) is an oral phosphodiesterase 4 inhibitor approved for the treatment of adult patients with active psoriatic arthritis (PsA) and psoriasis.

Objectives: To characterise demographics, disease activity and duration, concomitant therapy, quality of life, and prior comorbidities among patients with PsA who initiated APR in the Corona Psoriatic Arthritis/Spondyloarthritis (PsA/SpA) registry, an independent, prospective, US observational cohort.

Methods: Adult patients ≥18 years of age with PsA who were reported initiating APR in the Corona PsA/SpA registry between May 2014 and September 2017 were included in the analysis. Descriptive statistics were calculated for patients' clinical characteristics and disease assessments at the index visit. The index visit was defined as the Corona visit when APR initiation was reported. If the patient started a drug between 2 Corona visits, the measures/outcomes from a prior visit were imputed to replace the missing values.

Characteristic	n*	Mean (SD)
Swollen joint count (0-66)	136	2.7 (4.43)
Tender joint count (0-66)	136	7.2 (11.56)
PhGA (VAS 0-100 mm)	135	22.1 (18.82)
PIGA (VAS 0-100 mm)	134	54.2 (26.45)
Dactylitis count (1-20)	14/138	2.6 (2.21) [‡]
SPARCC/Leeds Enthesitis Index (1-16)	34/138	4.2 (3.05) [‡]
DAS-28 (CRP) (0-10)	67	3.1 (1.04)
CDAI (0-76)	128	13.9 (9.57)
cDAPSA (0-154)	128	20.7 (15.07)
HAQ-S (0-3)	135	0.95 (0.69)
BASDAI (0-10)	126	5.4 (2.53)
Morning stiffness (VAS 0-100 mm)	134	54.4 (28.26)

*Number of patients with data for the given assessment. [‡]Assessed among patients with dactylitis (n=14) or enthesitis (n=34) at baseline.
PhGA=Physician's Global Assessment of Disease Activity; PIGA=Patient's Global Assessment of Disease Activity; VAS=visual analog scale; SPARCC=Spondyloarthritis Research Consortium of Canada; DAS-28=28-joint count Disease Activity Score; CRP=C-reactive protein; CDAI=Clinical Disease Activity Index; cDAPSA=Clinical Disease Activity Index for Psoriatic Arthritis; HAQ-S=Health Assessment Questionnaire for Spondyloarthropathies; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index.

Results: Among 138 patients included in the analysis, mean (SD) age was 56¹² years, mean (SD) BMI was 33.⁷ 62% were female, 66% were previously on a non-biologic DMARD (nbDMARD) and 79% had prior biologic use; 62% were on APR monotherapy. Of the APR initiators, the number of patients receiving concomitant methotrexate, nbDMARD, TNF inhibitor, and non-TNF inhibitor were 32 (23%), 41 (30%), 6 (4%), and 4 (3%), respectively. Pertinent comorbidities included diabetes mellitus (22%), metabolic syndrome (22%), cancer (18%), cardiovascular disease (17%), and congestive heart failure (0.7%). Patients reported a mean (SD) of 13¹⁰ years for PsA symptoms and a mean (SD) of 10⁹ years since PsA diagnosis. Of the 94 patients with data available for evaluation, 14% met criteria for minimal disease activity while 1% met criteria for very low disease activity. Most patients had moderate or low levels of disease activity, respectively: CDAI (48% and 35%), cDAPSA (47% and 34%), and DAS-28 (CRP) (37% and 21%). Of note, 82% of patients had <5 swollen joints and 63% had <5 tender joints. Mean HAQ-S (0-3) was 0.95 and BASDAI (0-10) was 5.4 (Table). Patients demonstrated a substantial burden of disease with a mean fatigue score (0-100) of 55 and mean overall pain score (0-100) of 55, and 81% reported stiffness lasting >30 min. Additionally, mean baseline work productivity and activity impairment (WPAI) subscale scores

indicated limitations on absenteeism (8%), presenteeism (25%), work productivity loss (26%), and activity impairment (40%).

Conclusions: The population of patients with PsA treated with APR in the Corona PsA/SpA registry exhibited low to moderate disease activity and were substantially impacted, as evidenced by patient-reported outcomes (pain, fatigue, stiffness, and productivity). Future analyses on this cohort will provide more insight into patient characteristics and treatment patterns in this population, as well as long-term efficacy and safety information for PsA patients treated with APR.

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SAT0348 SAFETY OF IXEKIZUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS: RESULTS FROM A POOLED ANALYSIS OF THREE CLINICAL TRIALS

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Background: Ixekizumab (IXE), a high affinity monoclonal antibody that selectively targets interleukin-17A, has been shown to be superior to placebo (PBO) in improving signs and symptoms of psoriatic arthritis (PsA) in Phase 3 trials^{1,2}.

Objectives: To assess the safety of IXE in patients with active PsA using data pooled from 3 (SPIRIT-P1, -P2, and -P3) Phase 3 trials.

Methods: SPIRIT-P1¹ and -P2² are double-blind trials; patients were randomised to PBO, adalimumab (ADA; active reference arm; SPIRIT-P1 only),¹ or 80 mg IXE every 4 (Q4W) or 2 (Q2W) weeks. PBO and ADA patients were re-randomised to either IXEQ4W or IXEQ2W for the open-label extension period (Weeks 24–156); patients who initially received IXE remained on their original dose. SPIRIT-P3 is an open-label (Week 36–64) trial where patients received IXEQ2W followed by a randomised withdrawal period. In all the 3 trials, patients received a 160 mg loading dose of IXE. Safety data were integrated from all IXE-treated patients (defined as all patients receiving ≥1 dose of IXE) included in SPIRIT-P1, -P2, and -P3. Exposure-adjusted incidence rates (IRs) per 100 patient-years (PY) were reported for adverse events (AEs).

Results: Overall, 1118 patients received IXE (total exposure=1373.4 PY). Four deaths (0.3/100PY) were reported (cerebrovascular accident, cardio-respiratory arrest, drowning, and pneumonia) (Table). The most common treatment-emergent AEs (TEAEs) were injection-site reaction (ISRs), upper respiratory tract infection, and nasopharyngitis; IRs for TEAEs, including ISRs, decreased over-time. There was no clinically meaningful increase in IRs of serious AEs, infections, serious infections, hypersensitivity, and major adverse cardiovascular events (MACE) with longer IXE exposure (Table). IR for serious infections was low (1.2/100PY). Serious infections included pneumonia (0.2/100PY), lower respiratory tract infection, and esophageal candidiasis (0.1/100PY each). No case of active tuberculosis (TB) was reported, but 1 case of latent TB was deemed as serious due to hospitalisation for testing to exclude active TB. Opportunistic infections were limited to oral and esophageal *Candida* and localised herpes zoster. There were no reports of deep organ or bloodstream *Candida* infections. No anaphylaxis was reported, but 1 patient (0.1/100PY) experienced angioedema. No patient had infections temporally associated with Grade ≥2 neutropenia. Nine patients (0.7/100PY) had MACE. One case (0.1/100PY) each of Crohn's disease (with prior history of irritable bowel syndrome) and ulcerative colitis were reported. However, none of the 12 patients with pre-existing inflammatory bowel disease experienced an exacerbation with IXE.