46.3% of GLM pts and 40.6% of PBO pts had ≥1 AE; 2.9% vs. 3.3% of pts, respectively, had ≥1 serious AE. Two deaths, 2 malignancies, and 1 demyelinating event were reported. The most common treatment-emergent type of AE was infection (20.0% of GLM pts vs. 13.8% of PBO pts). No opportunistic infection or tuberculosis was reported through wk24. The rate of infusion reactions was low at <2%; none was serious or severe.

Table. Clinical Response

| | Placebo | Golimumab 2 mg/kg | P-values |
|---|---|---|---|
| Patients randomized, n | 239 | 241 | |
| **Clinical efficacy at wk14** | | | |
| ACR20/50/70, (%) | 21.8/6.3/2.1 | 75.1/43.6/24.5 | p<0.001 |
| PASI 75, n (%)* | 27/198 (13.6%) | 116/196 (59.2%) | p<0.001 |
| Change from BL in HAQ-DI (n) Mean (SD) | 222 -0.12 (0.47) | 233 -0.60 (0.53) | p<0.001 |
| Change from BL in enthesitis** (n) Mean (SD) | 173 -0.8 (1.98) | 182 -1.87 (1.75) | p<0.001 |
| Change from BL in dactylitis** (n) Mean (SD) | 115 -2.8 (7.03) | 130 -7.8 (8.57) | p<0.001 |
| Minimal Disease Activity, n/N (%) | 10/239 (4.2%) | 65/241 (27.0%) | p<0.001 |
| Number Needed to Treat (95% CI) | | 1.9 (1.64, 2.18) | |
| **Clinical efficacy at Week 24** | | | |
| ACR50, n (%) | 15 (6.3%) | 129 (53.5%) | |
| **Imaging data at Week 24** | | | |
| Change from BL in vdH-S score (N) Mean (SE) | 237 1.95 (0.264) | 237 -0.36 (0.144) | p<0.001 |
| **HRQoL at wk14** | | | |
| Change from BL in SF-36 PCS score (n) Mean (SD) | 222 2.69 (5.92) | 233 8.65 (7.60) | p<0.001 |
| Change from BL in SF-36 MCS score (n) Mean (SD) | 222 0.97 (7.64) | 233 5.33 (9.95) | p<0.001 |

*Among pts with ≥3% BSA involvement, **Among pts with finding at baseline, BL:baseline

**Conclusions:** In pts with active PsA, IV GLM demonstrated significant and clinically meaningful improvements of disease activity and physical function, skin psoriasis clearance, HRQoL, reduction in dactylitis and enthesitis, and inhibition of structural damage progression. GLM was well-tolerated through wk24; the safety profile was consistent with other anti-TNF therapies, including SC GLM.

**Disclosure of Interest:** A. Kavanaugh Consultant for: Janssen, M. E. Husni Consultant for: Janssen, UCB, Amgen, Novartis, Lilly, Regeneron, D. Harrison Employee of: Janssen Research & Development, LLC, L. Kim Employee of: Janssen Research & Development, LLC, K. H. Lo Employee of: Janssen Research & Development, LLC, E. Hsia Employee of: Janssen Research & Development, LLC

**DOI:** 10.1136/annrheumdis-2017-eular.1165

## FRI0487 APREMILAST IS ASSOCIATED WITH LONG-TERM (4-YEAR) DAS-28 (CRP) REMISSION AND IMPROVEMENTS IN SKIN DISEASE: RESULTS FROM A PHASE III STUDY IN DMARD/BIOLOGIC-EXPERIENCED PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

C.J. Edwards[1], F.J. Blanco[2], J. Crowley[3], M. McIlraith[4], M. Paris[4], N. Delev[4], L. Teng[4], C.A. Birbara[5]. *[1]University Hospital Southampton, Southampton, United Kingdom; [2]INIBIC-Hospital Universitario A Coruña, Galicia, Spain; [3]Bakersfield Dermatology, Bakersfield; [4]Celgene Corporation, Summit; [5]University of Massachusetts Medical School, Worcester, United States*

**Background:** Treatment goals for long-term control of skin and joint symptoms in active psoriatic arthritis (PsA) include clinically important changes in DAS-28 (CRP), achievement of remission in DAS-28 (CRP), reduction in swollen joint count (SJC), and decrease in skin disease.[1] PALACE 3 included PsA patients with active joint disease and an active skin lesion at the time of enrollment.

**Objectives:** Report the impact of apremilast (APR) on PsA manifestations over 4 years.

**Methods:** Patients were stratified by baseline (BL) DMARD use (yes/no) and psoriasis involvement of the body surface area (<3%/≥3%) and randomized (1:1:1) to placebo (PBO), APR 30 mg BID (APR30), or APR 20 mg BID (APR20). After the 24-week PBO-controlled phase, all patients were treated with APR30 or APR20 and could enroll in the long-term extension. Efficacy assessments were conducted through Week 208.

**Results:** 505 patients were randomized and received ≥1 dose of study medication (PBO: n=169; APR30: n=167; APR20: n=169). A total of 91% (227/249) of patients starting the fourth year of APR therapy completed the Week 208 visit. Patients treated with APR30 demonstrated sustained decreases in disease activity at Week 208, as shown by mean change from BL in DAS-28 (CRP) of –1.66; 80.3% achieved good/moderate EULAR response and 50.4% achieved DAS-28 (CRP) remission. Sustained effect on inflammation at Week 208 was also demonstrated by mean/median percent changes in SJC, a marker of inflammatory activity, of –77.4%/–100.0% (Table); 64.8% of patients had an SJC of 0 or 1. Decreases in disability and maintenance of functionality were shown by sustained improvements in Health Assessment Questionnaire-Disability Index (HAQ-DI) scores (Table). A continued effect on skin disease was shown by decreases in skin involvement, as measured by the Psoriasis Area and Severity Index (PASI); 54.7% of APR30 patients had BL PASI >5 and 27.3% had BL PASI >10; at Week 208, 64.5% had PASI <3 and 77.4% had PASI ≤5. PASI-75 and PASI-50 response rates also demonstrated clinically significant relief (Table). In patients treated with APR20, similar findings were observed at Week 208. No new safety concerns were identified through 208 weeks of APR30 therapy. During Weeks >156 to ≤208 of APR30 exposure, the only adverse event (AE) occurring in ≥5% of patients was nasopharyngitis; most AEs were mild or moderate in severity. Serious AEs occurred in 7.2% of APR30 patients over Weeks >156 to ≤208, similar to rates in earlier study periods. Few discontinuations due to AEs (0.7%) occurred over Weeks >156 to ≤208. The APR20 safety profile was similar to that of APR30.

| Outcomes at Week 208 | |
|---|---|
| | **APR30 n=129*** |
| DAS-28 (CRP), mean change | −1.66 |
| DAS-28 (CRP) <2.6, n/m (%) | 64/127 (50.4) |
| SJC, mean/median % change | −77.4/−100.0 |
| TJC, mean/median % change | −64.4/−86.6 |
| HAQ-DI (0-3), mean change | −0.42 |
| HAQ-DI MCID ≥0.30/≥0.35, n/m (%) | 63/129 (48.8) |
| ACR20, n/m (%) | 85/128 (66.4) |
| ACR50, n/m (%) | 51/128 (39.8) |
| ACR70, n/m (%) | 31/127 (24.4) |
| PASI-75, n/m (%)§ | 28/62 (45.2) |
| PASI-50, n/m (%)§ | 42/62 (67.7) |

Data as observed. *The n reflects the number of patients treated with APR30, regardless of when APR was started (BL, Week 16, or Week 24) and who had data available at Week 208; actual number of patients available for each end point may vary. §Examined among patients with psoriasis involvement of the body surface area ≥3% at BL. APR30=apremilast 30 mg BID; DAS-28=28-joint count Disease Activity Score; CRP=C-reactive protein; SJC=swollen joint count; TJC=tender joint count; HAQ-DI=Health Assessment Questionnaire-Disability Index; MCID=minimal clinically important differences; ACR20/50/70=20%/50%/70% improvement in modified American College of Rheumatology response criteria; n/m=number of responders/number of patients with sufficient data for evaluation; PASI-75/50=≥75%/≥50% reduction from BL Psoriasis Area and Severity Index score; BL=baseline.

**Conclusions:** Over 208 weeks, APR demonstrated sustained and clinically important improvements in PsA signs and symptoms, including physical function and associated psoriasis, among patients continuing the study. APR was generally well tolerated with an acceptable safety profile.

**References:**

[1] Gossec L, et al. Ann Rheum Dis. 2016;75:499–510.

**Disclosure of Interest:** C. Edwards Grant/research support from: Celgene Corporation, Pfizer, Roche, Samsung, Consultant for: Celgene Corporation, Pfizer, Roche, Samsung, Speakers bureau: Abbott, GSK, Pfizer, Roche, F. Blanco Consultant for: Bioibérica, Gebro Pharma, Pfizer, J. Crowley Grant/research support from: AbbVie, Amgen, Celgene Corporation, Janssen, Merck, Pfizer, Consultant for: AbbVie, Amgen, Speakers bureau: AbbVie, M. McIlraith Employee of: Celgene Corporation, M. Paris Employee of: Celgene Corporation, N. Delev Employee of: Celgene Corporation, L. Teng Employee of: Celgene Corporation, C. Birbara Grant/research support from: Amgen, BMS, Incyte, Eli Lilly, Merck, Pfizer

**DOI:** 10.1136/annrheumdis-2017-eular.3563

## FRI0488 PSORIATIC ARTHRITIS IN THE UNITED STATES: INCREASING ALL-CAUSE HOSPITALIZATIONS 1993–2014

G. Singh[1], C. Moise[2], A. Mithal[3], R. Ionescu[2], A. Mithal[4]. *[1]Gastroenterology and Hepatology, Stanford University, Palo Alto, United States; [2]Disciplina Medicina Interna si Reumatologie, Spitalul Clinic "Sf. Maria", Bucharest, Romania; [3]Student; [4]Epidemiology, ICORE, Woodside, United States*

**Background:** Psoriatic arthritis (PsA) is a rare disease, with an estimated prevalence of 0.02 – 0.42% in Europe and US (1). PsA is often regarded as a mild disease, but recent data suggest an increase in comorbidities and mortality, possibly related to systemic inflammation (1).

**Objectives:** To study all-cause hospitalizations in patients with PsA in the United States (US) from 1993 to 2014.

**Methods:** The Nationwide Inpatient Sample (NIS) is a stratified random sample of all US community hospitals. It is the only US national hospital database with information on all patients, regardless of payer, including persons covered by Medicare, Medicaid, private insurance, and the uninsured. We examined all inpatient hospitalizations in NIS from 1993 to 2014 with a primary or secondary diagnosis of PsA, and compared them to total all-cause US hospitalizations during the same period. US population estimates and projections for the resident US population were obtained from the US Census Bureau.

**Results:** There were 789.8 million all-cause hospitalizations in 6.4 billion person-years of observation from 1993 to 2014 (123.4 hospitalizations per 1,000 person-years). During this time-period, 332,496 hospitalizations occurred in patients with PsA (5.2 per 100,000 person-years). All-cause US hospitalizations increased from 33.7 million in 1993 to 35.4 million in 2014, an increase of 4.8% over 22 years (Figure, dotted blue line). All-cause hospitalizations in PsA patients have increased from 6,866 in 1993 (2.6 per 100,000 person-year) to 33,875 in 2014 (10.6 per 100,000 person-years, a dramatic increase of over 393% (p<0.0001, Figure solid red line). In 2014, hospitalizations in PsA patients accounted for 163,630 hospital days at a total national cost of over US$1.66 billion.

**Conclusions:** All-cause hospitalizations in patients with PsA in the US have significantly increased by 393% in the last 22 years, almost 80-fold of the 4.8% increase in US population all-cause hospitalization rate in the same time-period. This calls for an increase need for identification and management of serious co-morbid conditions in patients with PsA.