of identifying disease's or patient's related characteristics to drive the optimal choice is still under investigation.

Objectives: We aimed at evaluating the effectiveness and drug survival of the biological drugs (bDMARDs) and apremilast indicated for the treatment of PsA patients with inadequate response to cDMARDs. To this purpose, PsA patients on treatment with bDMARDs or Apremilast recorded into the Apulian BIOPURE registry have been retrospectively analyzed.

Methods: We retrospectively assessed PsA patients, fulfilling CASPAR criteria, starting a biologic drug or apremilast from June 2016 through December 2017. At baseline and at last observation within the time frame of the study, DAPSA, PASI, ASDAS-CRP, the presence of enthesitis and dactylitis were collected. Rate of patients achieving DAPSA based remission was assessed at last observation. The persistence on the first treatment was evaluated by Kaplan-Meier survival curves. Estimated hazard ratios (HRs) of discontinuing therapy or achieving remission were assessed by multivariate stepwise backward Cox regression models, adjusting for patient demographics (gender, age) and disease characteristics (disease duration, number of prior bDMARDs, baseline DAPSA, PASI, presence of enthesitis and dactylitis, type of current drug).

Results: We recruited 450 PsA patients (268, 60% female) with mean age 53 (± 11) years, disease duration 19 (± 13) months, 337 (75%) naïve to bDMARDs. At baseline, 404 had peripheral joint involvement and 46 axial disease, DAPSA was 18 (± 10), PASI 1.6 (± 3), ASDAS-CRP 2.5 (± 1), 48/355 (13.5) had dactylitis and 78/231 (33%) showed enthesitis. Table 1 shows the type of drugs. At last observation, the rate of patients who achieved the DAPSA remission was significantly higher in naïve patients (25%) than in those bDMARDs experienced (14%, $p=0.02$). The rate of drug survival was not significantly different among drugs (Figure 1). Cox-regression multivariate models showed that independent baseline factors negatively associated to drug persistence were prior bDMARD treatment (HR 0.70, 0.50-0.97 (95% CI), $p=0.03$) and the absence of axial disease (HR 0.56, 0.35-0.91 (95% CI), $p=0.02$). Negative predictors of DAPSA remission were prior bDMARD treatment (HR 0.40, 0.19-0.83 (95% CI), $p=0.01$), gender female (HR 0.51, 0.29-0.91 (95% CI), $p=0.02$), and the absence of dactylitis (HR 0.36, 0.19-0.68 (95% CI), $p=0.002$).

Conclusion: A good rate of DAPSA remission is achievable with all the current available drugs in PsA in settings of real life. Predictors of remission and persistence on treatment were being male and naïve to prior bDMARDs. No difference among drugs was detected.

Table 1. Treatments

	Frequency	Percentage
Adalimumab	80	17.8
Certolizumab	56	12.4
Golimumab	61	13.6
Etanercept	65	14.4
Secukinumab	104	23.1
Ustekinumab	43	9.6
Apremilast	41	9.1
All	450	100

Figure 1. Kaplan-Meier curves of drug survival of PsA patients on different therapies.

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Pfizer, Sanofi, MSD, BMS, Carmelo Zuccaro Consultant for: C Zuccaro has received consultancy fees and/or speaker honoraria from MSD, AbbVie, Novartis, Pfizer, Janssen outside this work, Speakers bureau: C Zuccaro has received consultancy fees and/or speaker honoraria from MSD, AbbVie, Novartis, Pfizer, Janssen outside this work, Angelo Semeraro Speakers bureau: A Semeraro has received speaker honoraria from Sanofi, Roche, AbbVie, BMS, MSD, Novartis, Antonio Marsico: None declared, Daniela Mazzotta: None declared, Paola Chiara Francesca Falappone Consultant for: PC Falappone had received consultancy fees and/or speaker honoraria from Amgen, Abbott, MSD, BMS, outside this work, Speakers bureau: PC Falappone had received consultancy fees and/or speaker honoraria from Amgen, Abbott, MSD, BMS, outside this work, Lorenzo Iannone Consultant for: F Iannone has received consultancy fees and/or speaker honoraria from Pfizer, AbbVie, MSD, BMS, Novartis, Lilly, UCB outside this work, Speakers bureau: F Iannone has received consultancy fees and/or speaker honoraria from Pfizer, AbbVie, MSD, BMS, Novartis, Lilly, UCB outside this work

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FRI0450

PROBABILITY OF ACHIEVING LOW DISEASE ACTIVITY OR REMISSION IN SUBJECTS WITH ACTIVE PSORIATIC ARTHRITIS TREATED WITH APREMILAST

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Background: Therapeutic targets for long-term control of psoriatic arthritis (PsA) include the achievement of remission (REM) or low disease activity (LDA), as measured by the Clinical Disease Activity Index for Psoriatic Arthritis (cDAPSA).¹

Objectives: This post hoc analysis was conducted to (1) assess the predictive values of baseline clinical disease status on achieving long-term Clinical Disease Activity for Psoriatic Arthritis (cDAPSA) targets at Week 52 and (2) examine the association between early response to APR at Week 16 and the achievement of cDAPSA targets at Week 52.

Methods: Pooled analyses of 3 phase III trials (PALACE 1-3) were performed among subjects assigned to receive APR 30 mg twice daily at baseline. Data were analyzed using multiple imputation to account for subjects who discontinued or had missing values, using all available cDAPSA scores. The probabilities of shifting across different cDAPSA categories from baseline or Week 16 responses to Week 52 were calculated within these subjects. Binary logistic regression was also performed to confirm the results. We also analyzed mean cDAPSA from baseline to Week 52 by cDAPSA category at Week 52 among subjects with moderate or high disease activity (HDA) at baseline.

Results: A total of 494 subjects who received APR were included in the analyses; at baseline, 74.3% were in HDA, 24.5% in moderate disease activity, and 1.2% in LDA. Most subjects had ≥ 1 of the following conditions at baseline: affected body surface area $\geq 3\%$, dactylitis >0 based on the dactylitis severity score, enthesitis >0 based on the Maastricht Ankylosing Spondylitis Enthesitis Score or pre-existing axial PsA (physician determined) (HDA: 93.5%; moderate disease activity: 82.6%; LDA: 100%). The estimated probabilities of achieving either cDAPSA LDA or REM at Week 52 were 46.9% in subjects with baseline moderate disease activity (cDAPSA >13 to ≤ 27) and 71.1% in subjects with baseline LDA (cDAPSA >4 to ≤ 13) (Figure). In subjects with baseline HDA (cDAPSA >27), the probability of achieving LDA or REM by Week 52 was 24.9%. Subjects with moderate disease activity at baseline and improved to LDA or REM by Week 16 had high probabilities (58.9% and 88.5%) of remaining in target at Week 52. Among the subjects with moderate disease activity at baseline, a mean cDAPSA improvement of $\geq 30\%$ by Week 16 was associated with achievement of LDA or REM at Week 52.

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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FRI0451

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 $\geq 3\%$ 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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