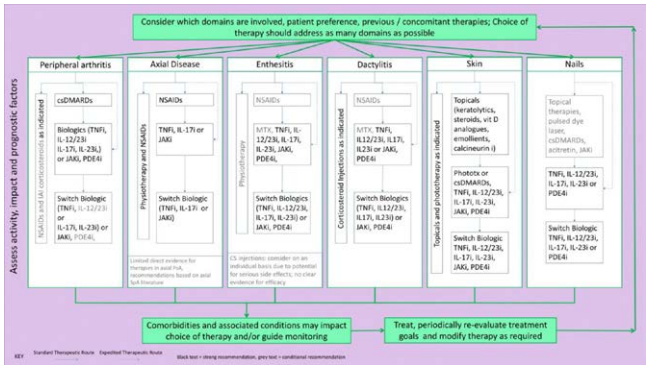

Disclosure of Interests: Laura C Coates Speakers bureau: AbbVie, Amgen, Biogen, Celgene, Gilead, Eli Lilly, Janssen, Medac, Novartis, Pfizer, and UCB, Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB, Grant/research support from: AbbVie, Amgen, Celgene, Eli Lilly, Pfizer, and Novartis, Enrique Soriano Speakers bureau: AbbVie, Amgen, Bristol-Myers Squibb,GSK, Genzyme, Janssen, Lilly, Novartis, Pfizer, Roche, Sandoz, Sanofi, UCB, Consultant of: AbbVie, Amgen, Bristol-Myers Squibb,GSK, Genzyme, Janssen, Lilly, Novartis, Pfizer, Roche, Sandoz, Sanofi, UCB, Grant/research support from: AbbVie, Janssen, Novartis Pharma, Pfizer, Roche, and UCB, Nadia Corp: None declared, Heidi Bertheussen Consultant of: Pfizer, Kristina Callis-Duffin Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Lilly, Janssen, Novartis, Pfizer, Sienna Biopharmaceuticals, Stiefel Laboratories, UCB, Ortho Dermatologics, Inc, Regeneron Pharmaceuticals, Inc., Anaptys Bio, Boehringer Ingelheim., Cristiano Barbosa Campanholo Speakers bureau: AbbVie, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, Consultant of: AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB, Jeffrey Chau: None declared, Lihi Eder Consultant of: Abbvie, UCB, Janssen, Eli Lily, Pfizer, Novartis, Grant/research support from: Abbvie, UCB, Janssen, Eli Lily, Pfizer, Novartis, Daniel Fernandez Consultant of: Abbvie, UCB, Roche, Janssen, Pfizer, Amgen and Brystol, Grant/research support from: Abbvie, UCB, Roche, Janssen, Pfizer, Amgen and Brystol, Oliver FitzGerald Speakers bureau: AbbVie, Janssen and Pfizer Inc, Consultant of: BMS, Celgene, Eli Lilly, Janssen and Pfizer Inc, Grant/research support from: AbbVie, BMS, Eli Lilly, Novartis and Pfizer Inc, Amit Garg Consultant of: Abbvie, Amgen, Asana Biosciences, Bristol Myers Squibb, Boehringer Ingelheim, Incyte, InflaRx, Janssen, Pfizer, UCB, Viela Biosciences, Grant/research support from: Abbvie, Dafna D Gladman Consultant of: Abbvie, Amgen, BMS, Eli Lilly, Galapagos, Gilead, Jansen, Novartis, Pfizer and UCB, Grant/research support from: Abbvie, Amgen, Eli Lilly, Jansen, Novartis, Pfizer and UCB, Niti Goel: None declared, Suzanne Grieb: None declared, Philip Helliwell Speakers bureau: Janssen, Novartis, Pfizer, Consultant of: Eli Lilly, M Elaine Husni Consultant of: Abbvie, Amgen, Janssen, Novartis, Lilly, UCB, Regeneron, and Pfizer, Deepak Jadon Speakers bureau: AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Healthcare Celltrion, Janssen, MSD, Novartis, Pfizer, Roche, Sandoz, UCB, Consultant of: AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Healthcare Celltrion, Janssen, MSD, Novartis, Pfizer, Roche, Sandoz, UCB, Grant/research support from: AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Healthcare Celltrion, Janssen, MSD, Novartis, Pfizer, Roche, Sandoz, UCB, Arnon Katz: None declared, Dhruvkumar Laheru: None declared, John Latella: None declared, Ying Ying Leung Speakers bureau: Novartis, AbbVie, Eli Lilly, Janssen, Consultant of: Pfizer and Boehringer Ingelheim, Grant/research support from: Pfizer and conference support from AbbVie, Christine Lindsay Shareholder of: Amgen, Employee of: Aurinia pharmaceuticals, Ennio Lubrano Speakers bureau: Alfa-Sigma, Abbvie, Galapagos, Janssen Cilag, Lilly., Consultant of: Alfa-Sigma, Abbvie, Galapagos, Janssen Cilag, Lilly., Luis Mazzuoccolo Speakers bureau: Abbvie, Amgen, Novartis, Elli Lilly, Jansen, Consultant of: Abbvie, Amgen, Novartis, Elli Lilly, Jansen, Roland McDonald: None declared, Philip J Mease Speakers bureau: AbbVie, Amgen, Eli Lilly, Janssen, Novartis, Pfizer and UCB, Consultant of: AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Galapagos, Gilead Sciences, GlaxoSmithKline, Janssen, Novartis, Pfizer, SUN and UCB, Grant/research support from: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Eli Lilly, Galapagos, Gilead Sciences, Janssen, Novartis, Pfizer, SUN and UCB, Denis O'Sullivan: None declared, Alexis Ogdie Consultant of: AbbVie, Amgen, BMS, Celgene, Corrona, Gilead, Janssen, Lilly, Novartis, and Pfizer, Grant/research support from: Novartis and Pfizer and Amgen, Wendy Olsder: None declared, Lori Schick: None declared, Ingrid Steinkoenig: None declared, Maarten de Wit Consultant of: AbbVie, BMS, Celgene, Janssen, Lilly, Novartis, Pfizer, Roche, Danielle van der Windt: None declared, Arthur Kavanaugh Speakers bureau: AbbVie, Amgen, BMS, Eli Lilly, Gilead Janssen, Novartis, Pfizer, UCB, Consultant of: AbbVie, Amgen, BMS, Eli Lilly, Gilead Janssen, Novartis, Pfizer, UCB

DOI: 10.1136/annrheumdis-2021-eular.4091

OP0230

EFFICACY AND SAFETY OF GUSELKUMAB IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS WHO DEMONSTRATED INADEQUATE RESPONSE TO TUMOR NECROSIS FACTOR INHIBITION: WEEK 24 RESULTS OF A PHASE 3B, RANDOMIZED, CONTROLLED STUDY

L. C. Coates[1], L. Gossec[2], E. Theander[3], P. Bergmans[4], M. Neuhold[5], C. Karyekar[6], M. Shawi[6], W. Noel[5], G. Schett[7], I. Mcinnes[8]. [1]*University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, United Kingdom*; [2]*Sorbonne Université, Professor of Rheumatology, Paris, France*; [3]*Janssen Scientific Affairs, LLC, Immunology, Solna, Sweden*; [4]*Janssen, Biostatistics, Breda, Netherlands*; [5]*Janssen Scientific Affairs, LLC, Immunology, Brussels, Belgium*; [6]*Janssen Global Services, LLC, Immunology, Horsham, United States of America*; [7]*University of Erlangen-Nuremberg, Internal Medicine 3, Erlangen, Germany*; [8]*University of Glasgow, Institute of Infection, Immunity and Inflammation, Glasgow, United Kingdom*

Background: Guselkumab (GUS), a selective monoclonal antibody targeting the interleukin-23p19 subunit, has demonstrated efficacy in 2 pivotal Ph3 psoriatic arthritis (PsA) studies (DISCOVER-1,[1] DISCOVER-2[2]).

Objectives: Evaluate GUS efficacy and safety in PsA patients (pts) with inadequate response (IR) to tumor-necrosis-factor inhibition (TNFi) through Week24 (W24) of the Ph3b COSMOS study.

Methods: In this randomized, double-blind, placebo (PBO)-controlled trial, 285 pts with active PsA (≥3 swollen & ≥3 tender joints) who demonstrated lack of benefit or intolerance to 1-2 TNFi were randomized 2:1 to subcutaneous GUS 100mg (n=189) or PBO (n=96) at W0, W4, then every 8 weeks (Q8W) through W44 (with PBO crossover to GUS at W24). At W16, pts who met early escape (EE) criteria (<5% improvement in both tender & swollen joint counts) also could switch from PBO to GUS. The primary efficacy endpoint was ACR20 response at W24 among randomized, treated pts. Pts missing ACR20 data at W24 or who met treatment failure criteria (including meeting EE criteria at W16) were considered nonresponders (NRs). Subgroup analyses were performed to assess consistency of primary treatment effect based on demographics, disease characteristics, and medication use at baseline. Prespecified sensitivity analyses included 'Per-Protocol' (PP) (excluded pts with major protocol deviations) and 'EE-Correction' (included pts incorrectly routed to EE) analyses. Adverse events (AEs) were summarized by treatment received.

Results: Baseline characteristics were similar across GUS and PBO pts, though a higher proportion of females and more severe joint symptoms were seen in the GUS group. At W24, 44.4% of GUS vs 19.8% of PBO pts achieved ACR20 (p<0.001) (Figure). GUS was superior to PBO for all major secondary endpoints. Efficacy was consistent across subgroups defined by baseline characteristics, including in pts who discontinued prior TNFi use due to inadequate efficacy (84% GUS vs 81% PBO) and safety (16% GUS vs 19% PBO) (Table). 20 pts (12 GUS, 8 PBO) were incorrectly routed to EE. Results of PP (48.8% vs 23.8%) and EE-correction (48.1% vs 19.8%) sensitivity analyses were consistent with the primary analysis (Figure). AEs were similar between GUS- and PBO-treated pts (Table).

Table 1. Baseline characteristics of, and adverse events reported by, randomized and treated COSMOS pts

	GUS 100 mg Q8W (N=189)	PBO (N=96)
Age, y	49	49
Sex, Female	54%	46%
Duration of PsA, y	8.3	8.7
Body mass index, kg/m^2	29	31[a]
Swollen (0-66) / tender (0-68) joint count	10 / 21	9 / 18
Pt pain / Pt global arthritis / Physician global disease, 0-10 cm VAS	6.5 / 6.5 / 6.9	6.0 / 6.2 / 6.4
Health Assessment Questionnaire-Disability Index, 0-3	1.3[b]	1.2
C-reactive protein, mg/dL	1.2[b]	1.2
Methotrexate use at baseline	56%	53%
Psoriatic body surface area, %	17.9	13.4
Number of prior TNFi: 1 / 2	88% / 12%	89% / 11%
Reason for prior TNFi discontinuation: Efficacy / Safety	84% / 16%*	81% / 19%*
Pts with ≥1 AE / SAE	37% / 3%	48% / 3%
Pts with ≥1 infection / serious infection	18% / 0%	20% / 0%
Pts with ≥1 AE leading to study agent discontinuation	2%	2%
Pts with ≥1 malignancy	0.4%	0
Pts with ≥1 injection-site reaction	2%	1%

Data shown are mean or %. [a]N=95; [b]N=188. *Missing for 1 pt. *SAE – serious adverse events*; *VAS – visual analog scale*

Conclusion: In this Ph3b, placebo-controlled study of PsA pts with IR to 1-2 TNFi, GUS 100 mg Q8W elicited a significantly higher ACR20 response rate vs.

PBO at W24; results of prespecified sensitivity and subgroup analyses were consistent. GUS safety in TNF-IR PsA pts through W24 is consistent with the favorable GUS safety profile in psoriasis and biologic-naïve PsA pts.[3]

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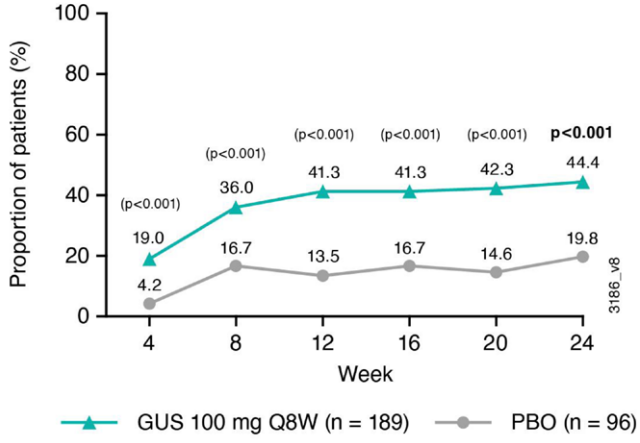
Disclosure of Interests: Laura C Coates Consultant of: AbbVie, Amgen, Biogen, BMS, Boehringer Ingelehim, Celgene, Domain, Eli Lilly, Gilead, Janssen, Medac, Novartis, Pfizer and UCB, Grant/research support from: AbbVie, Amgen, Celgene, Eli Lilly, Gilead, Novartis, Pfizer, Laure Gossec Consultant of: AbbVie, Amgen, BMS, Biogen, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, Samsung Bioepis, Sanofi-Aventis, UCB, Grant/research support from: Amgen, Eli Lilly, Galapagos, Janssen, Pfizer, Sandoz, Sanofi, Elke Theander Shareholder of: Johnson & Johnson, Employee of: Janssen Scientific Affairs, LLC, Paul Bergmans Shareholder of: Johnson & Johnson, Employee of: Janssen, Marlies Neuhold Shareholder of: Johnson & Johnson, Employee of: Janssen Scientific Affairs, LLC, Chetan Karyekar Shareholder of: Johnson & Johnson, Employee of: Janssen Global Services, LLC, May Shawi Shareholder of: Johnson & Johnson, Employee of: Janssen Global Services, LLC, Wim Noel Shareholder of: Johnson & Johnson, Employee of: Janssen Scientific Affairs, LLC, Georg Schett: None declared, Iain McInnes Consultant of: AbbVie, Bristol-Myers Squibb, Celgene, Eli Lilly, Gilead, Janssen, Novartis, Pfizer, and UCB, Grant/research support from: Bristol-Myers Squibb, Celgene, Eli Lilly, Janssen, Novartis, and UCB

Figure. ACR 20 Response through Week 24 of COSMOS.



Bolded p values are adjusted for multiplicity of testing; p values shown in parentheses are not adjusted for multiplicity of testing

DOI: 10.1136/annrheumdis-2021-eular.42

OP0231

DIFFERENCES IN REAL-WORLD PATIENT CHARACTERISTICS OF 8921 PSORIASIS PATIENTS WITH AND WITHOUT COMORBID PSORIATIC ARTHRITIS USING THE UK BADBIR DATABASE

W. Tillett[1], A. Ogdie[2], P. Gorecki[3], A. Passey[4]. [1]*Royal National Hospital for Rheumatic Diseases, Rheumatology, Bath, United Kingdom*; [2]*University of Pennsylvania, Perelman School of Medicine, Philadelphia, United States of America*; [3]*Janssen, Medical Affairs, High Wycombe, United Kingdom*; [4]*Janssen Real World Evidence, HEMAR EMEA, High Wycombe, United Kingdom*

Background: Psoriatic arthritis (PsA) is a chronic inflammatory arthritis associated with psoriasis (PsO) and multiple comorbidities.[1] Approximately one-third of PsO patients develop PsA during the course of their disease.[2] As patient cohorts included in randomised clinical trials are not necessarily representative of the real world, registry data can complement any information gained on patient characteristics and disease outcomes.[3] The British Association of Dermatologists Biologic and Immunomodulators Register (BADBIR) is one such registry for patients with plaque PsO, with PsA being one of the recorded comorbidities at time of patient enrolment into the database.

Objectives: The primary objective of this study was to evaluate baseline characteristics and comorbidities in PsO patients with and without a PsA diagnosis using the BADBIR database. The hypothesis was that patients with both diseases show a higher likelihood of being diagnosed with additional comorbid conditions vs. PsO alone.

Methods: This was a retrospective observational study using two cohorts of BADBIR data (i.e. adult PsO patients either receiving ustekinumab [UST] as their biologic treatment or receiving conventional systemic anti-psoriatic medication [conventional systemic]). Comparisons were made between PsA and PsO alone in each cohort at baseline, additionally stratifying by biologic experience in the UST treatment group. Baseline characteristics of interest were evaluated, including body mass index, smoking and employment status, as well as comorbidities (i.e. diabetes, hypertension, myocardial infarction and depression). Effect sizes and 95% confidence intervals were generated via matching with a two-sided Fisher's exact test.

Results: Cohort patient counts were as follows: 2697 UST treated without PsA; 590 UST treated with PsA; 5105 conventional systemic without PsA; 529 conventional systemic with PsA. PsO patients with a PsA diagnosis had a higher prevalence of diabetes, obesity and hypertension across both conventional systemic and UST cohorts vs. PsO alone (Table 1). Similarly, inability to work was notably higher in PsO patients with PsA vs. PsO alone (Figure 1). Patients with PsO and comorbid PsA who were receiving UST were more likely to have a diagnosis of depression than those receiving conventional systemic treatment (Table 1).

Table 1. Prevalence odds ratio of baseline characteristics of patients with PsO treated with either UST or a conventional systemic agent.

Baseline variable	Treatment cohort	Odds ratio	95% CI
Ability to work	UST	0.27	0.21–0.35
	Conventional systemic	0.49	0.37–0.65
Smoking	UST	0.94	0.76–1.17
	Conventional systemic	0.72	0.58–0.89
Depression	UST	1.54	1.25–1.88
	Conventional systemic	1.14	0.91–1.42
Obesity*	UST	1.34	1.11–1.62
	Conventional systemic	1.21	1.01–1.46
Diabetes	UST	1.45	1.10–1.89
	Conventional systemic	1.51	1.11–2.04
Hypertension	UST	1.54	1.26–1.87
	Conventional systemic	1.30	1.03–1.62
Myocardial infarction	UST	1.67	0.98–2.76
	Conventional systemic	1.17	0.56–2.21

Odds ratios and 95% CIs are shown for the prevalence of each patient baseline characteristic in the PsO with comorbid PsA group vs. the prevalence in the PsO group. *Obesity is defined as a BMI ≥30 kg/m^2. BMI, body mass index; CI, confidence interval; PsA, psoriatic arthritis; PsO, psoriasis; UST, ustekinumab.

Conclusion: These results indicate that PsO patients with PsA had a higher prevalence of obesity, diabetes, hypertension and inability to work vs. PsO alone. Depression also seems to be more prevalent in PsO patients with comorbid PsA receiving biologic treatment vs. those receiving conventional systemics. These results potentially indicate a higher inflammatory and quality-of-life burden in PsO patients with a PsA diagnosis, highlighting the need for adequate patient assessment and follow-up to ensure a best possible holistic patient management approach.

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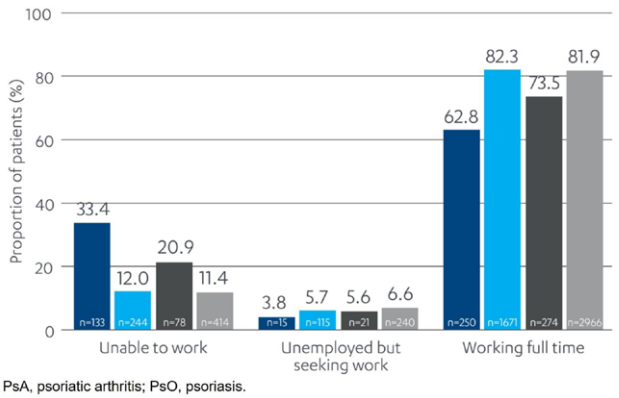
Disclosure of Interests: William Tillett Speakers bureau: AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, Pfizer and UCB, Consultant of: AbbVie, Amgen, Celgene, Eli Lilly, Janssen, Novartis, MSD, Pfizer and UCB, Grant/research support from: AbbVie, Celgene, Eli Lilly, Janssen and UCB, Alexis Ogdie Consultant of: AbbVie, Amgen, Bristol-Myers Squibb, Celgene, Corrona, Janssen, Eli Lilly, Novartis and Pfizer, Grant/research support from: Pfizer to Penn, Novartis to Penn, Amgen to Forward/NDB, Patricia Gorecki Employee of: Janssen-Cilag Ltd, Alun Passey Employee of: Janssen-Cilag Ltd

Figure 1: Employment status of patients with PsO by presence of comorbid PsA and treatment type



PsA, psoriatic arthritis; PsO, psoriasis.

DOI: 10.1136/annrheumdis-2021-eular.1018