Real-world evidence for guselkumab treatment of severe psoriasis: A sub-group analysis of efficacy and drug survival from the Australasian Psoriasis Registry

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BACKGROUND AND OBJECTIVE

- Guselkumab, a monoclonal antibody targeting interleukin-23, was listed on the Australian Pharmaceutical Benefits Scheme (PBS) in 2019 for the treatment of severe plaque psoriasis.
- The primary objective of this retrospective study was to examine real-world effectiveness and drug survival of guselkumab in specific subgroups of interest, including smoking categories, body mass index (BMI) categories, weight quartiles, alcohol consumption categories, biologic experience, presence of psoriatic arthritis, and number of comorbidities.

METHODOLOGY

- De-identified data were derived from patients in the Australasian Psoriasis Registry (APR) who met PBS requirements for whole body psoriasis and were prescribed guselkumab.
- APR was established in 2008 to collect valid and reliable clinical data on people with psoriasis. The registry is in the process of being re-purposed as the Australasian Dermatology Registry (ADR).
- The aim of this registry is to collect detailed information about the diagnosis, treatment, efficacy, safety and comorbidities of patients with psoriasis in order to improve our understanding of local real-world outcomes of treatment response, safety, patient health status and quality of life.
- Demographic and treatment data (including Psoriasis Area and Severity Index [PASI]) at specific timepoints until 1st October 2022 were included in the analysis.
- Baseline PASI was determined to be the score at the time of commencement of first biologic.
- Drug survival was defined as the time to drug cessation or dose increase (except for the drug induction period)
- Cox proportional hazards regression and Kaplan-Meier curves were used to evaluate the relationship between participants' characteristics and time to drug cessation or dose increase, PASI90, PASI100, PASI≤3, ≤2 and ≤1.

RESULTS

Table 1: Baseline demographics and disease characteristics

Characteristic		Value
Age at commencement of guselkumab (years), median (IQR)		48.7 (39.8, 60.7)
Weight (kg), median (IQR)		90.3 (78.0, 108.2)
BMI (kg/m2), median (IQR)		31.3 (26.1, 36.2)
Disease duration (years), median (IQR)		26.0 (17.0, 34.0)
Presence of psoriatic arthritis, n (%)		28 (27.5%)
Baseline PASI, median (IQR)		24.0 (17.9, 32.2)
Gender, n (%)	Male	62 (60.8%)
	Female	40 (39.2%)
Biologic experience, n (%)	Previous biologic	89 (87.3%)
	Biologic naïve	13 (12.7%)
Smoking status, n (%)	Non-smoker	50 (49.0%)
	Current	34 (33.3%)
	Former	5 (4.9%)
	Not recorded	13 (12.7%)
Alcohol consumption*, n (%)	Infrequent	35 (34.3%)
	Intermediate	37 (36.3%)
	Frequent	16 (15.7%)
	Not recorded	14 (13.7%)
Number of comorbidities, n (%)	0	8 (7.8%)
	1	37 (36.3%)
	2	17 (16.7%)
	3+	25 (24.5%)
	Not recorded	15 (14.7%)

*Infrequent: ≤6 times per year; Intermediate: <3 days per week to 1-2 times per month; Frequent: ≥3 days per week

Table 2: Univariable associations with achieving PASI90

Variable		HR (95% CI)	P-value
Gender	Male	Ref	
	Female	1.56 (1.02, 2.40)	0.041
BMI categories	18.5-24.9	Ref	
	25-29.9	1.53 (0.77, 3.04)	0.224
	30-34.9	0.93 (0.47, 1.85)	0.839
	35-39.9	1.05 (0.51-2.19)	0.894
	>40	0.61 (0.25, 1.47)	0.270
Smoking status	Non-smokers	Ref	
	Current	1.02 (0.64, 1.63)	0.940
	Former	1.11 (0.43, 2.86)	0.827
Alcohol consumption*	Infrequent	Ref	
	Intermediate	0.96 (0.58, 1.58)	0.878
	Frequent	0.71 (0.37, 1.37)	0.309
Number of comorbidities	0	Ref	
	1	0.70 (0.31, 1.60)	0.397
	2	0.86 (0.35, 2.11)	0.748
	3+	0.66 (0.28, 1.58)	0.355
Presence of psoriatic arthritis		0.91 (0.56, 1.48)	0.702
Biologic naïve		0.81 (0.44, 1.49)	0.496
Baseline PASI		0.98 (0.96, 1.01)	0.220

*Infrequent: ≤6 times per year; Intermediate: <3 days per week to 1-2 times per month; Frequent: ≥3 days per week

RESULTS CONT.

Table 3: Univariable associations with drug survival

Variable		HR (95% CI)	P-value
Gender	Male	Ref	
	Female	0.49 (0.19, 1.23)	0.128
BMI categories	18.5-24.9	Ref	
	25-29.9	1.19 (0.33, 4.21)	0.791
	30-34.9	1.18 (0.33, 4.18)	0.798
	35-39.9	1.03 (0.26, 4.14)	0.962
	>40	1.20 (0.27, 5.38)	0.808
Smoking status	Non-smokers	Ref	
	Current	0.73 (0.31, 1.73)	0.475
	Former	0.63 (0.08, 4.79)	0.657
Alcohol consumption*	Infrequent	Ref	
	Intermediate	1.21 (0.48, 3.06)	0.691
	Frequent	1.79 (0.62, 5.17)	0.281
Number of comorbidities	0	Ref	
	1	0.14 (0.04, 0.53)	0.004
	2	0.55 (0.17, 1.81)	0.323
	3+	0.46 (0.15, 1.41)	0.175
Presence of psoriatic arthritis		0.88 (0.36, 2.12)	0.767
Biologic naïve		n/a	0.046
Baseline PASI		1.02 (0.98, 1.07)	0.388

*Infrequent: ≤6 times per year; Intermediate: <3 days per week to 1-2 times per month; Frequent: ≥3 days per week

Figure 1: Forest Plot showing univariable associations with achieving PASI90 across subgroups of interest

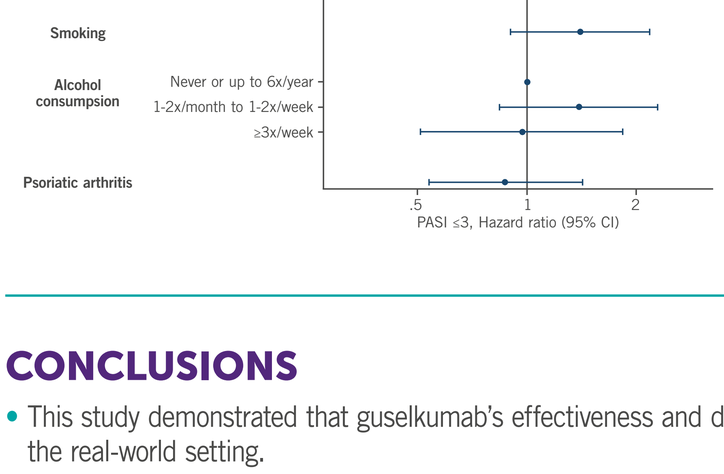


Figure 2: Forest Plot showing univariable associations with achieving absolute PASI ≤3 across subgroups of interest

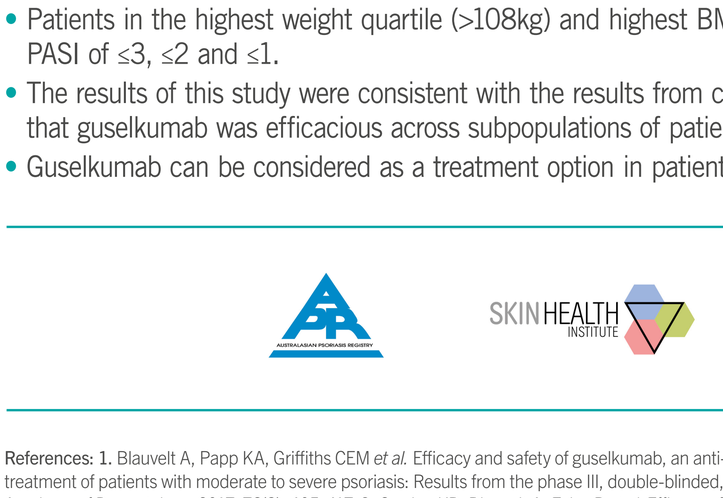


Figure 3: Kaplan-Meier curve showing PASI100 response in biologic naïve and biologic experienced patients

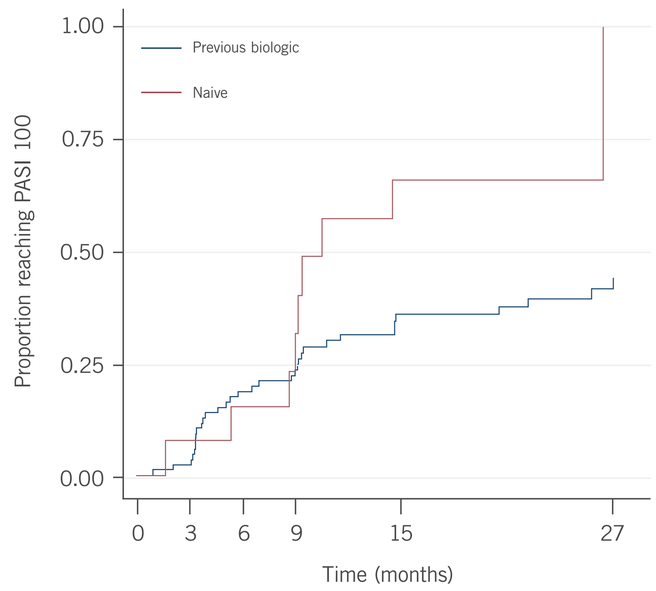


Figure 4: Kaplan-Meier curve showing PASI100 response in smokers and non-smokers

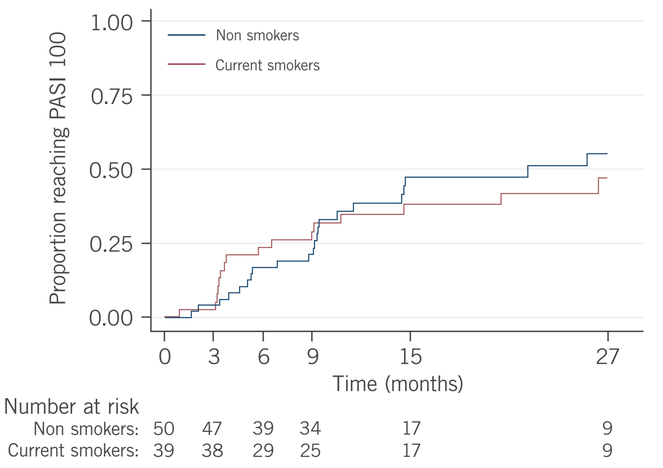
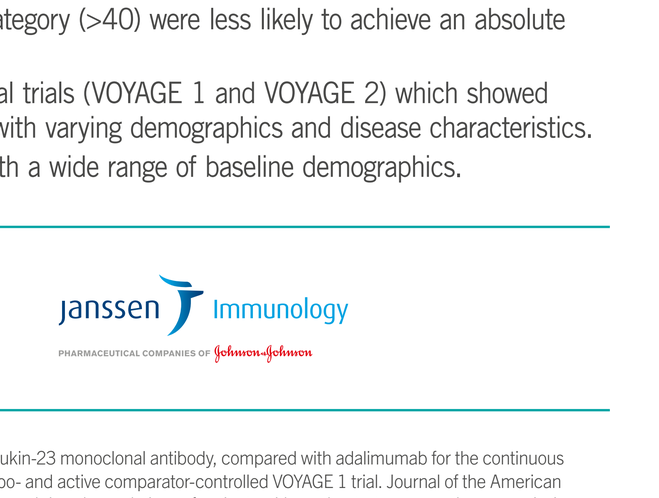


Figure 5: Kaplan-Meier curve showing drug survival in biologic naïve and biologic experienced patients



CONCLUSIONS

- This study demonstrated that guselkumab's effectiveness and drug survival is consistent across different populations in the real-world setting.
- Biologic naïve patients treated with guselkumab were more likely to remain on treatment and achieve PASI100 than bio-experienced patients.
- Patients in the highest weight quartile (>108kg) and highest BMI category (>40) were less likely to achieve an absolute PASI of ≤3, ≤2 and ≤1.
- The results of this study were consistent with the results from clinical trials (VOYAGE 1 and VOYAGE 2) which showed that guselkumab was efficacious across subpopulations of patients with varying demographics and disease characteristics.
- Guselkumab can be considered as a treatment option in patients with a wide range of baseline demographics.

References: 1. Blauvelt A, Papp KA, Griffiths CEM *et al.* Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. Journal of the American Academy of Dermatology. 2017; 76(3): 405-417. 2. Gordon KB, Blauvelt A, Foley P *et al.* Efficacy of guselkumab in subpopulations of patients with moderate-to-severe plaque psoriasis: a pooled analysis of the phase III VOYAGE 1 and VOYAGE 2 studies. British Journal of Dermatology. 2018;187(1):132-139.