DOI: 10.1111/ajd.14274

Australasian Journal of Dermatology

ABSTRACT

Biologics/Psoriasis

Drug survival of biological therapies in smokers and non-smokers with psoriasis: A retrospective cohort study using data from the Australasian Psoriasis Registry

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Aims: Smoking is an important modifiable risk factor which increases the likelihood of development of psoriasis and severity of disease. In recent years, biological therapies have transformed the management of severe psoriasis. There is conflicting evidence in the literature on whether smoking affects the efficacy of biologics in psoriasis. This study assessed drug survival and efficacy of first biologic for psoriasis in current and former smokers compared to non-smokers.
Methods: This was a non-interventional retrospective cohort study using data from the Australasian Psoriasis Registry (APR) from the Skin Health Institute and St Vincent's Hospital Melbourne. Participants with psoriasis who met Pharmaceutical Benefits Scheme eligibility criteria for treatment with a biologic ($n=395$) were included. Data were collected from the time of participant inclusion into the APR until 21st December 2022. Drug survival and Psoriasis Area and Severity Index (PASI) response were assessed using univariable and multivariable Cox Proportional Hazard regression.
Results: The prevalence of current smoking was 24.6%, with 18.5% of participants being former smokers and 57.0% being non-smokers. On univariable analysis, when compared with non-smokers, current and former smokers were 34% more likely to discontinue biologic ($p=0.039$), were 27% less likely to attain PASI90 ($p=0.037$) and 33% less likely to attain PASI100 ($p=0.038$). However, on multivariable analysis, when controlling for confounders including sex, obesity, psoriatic arthritis, biologic class, baseline PASI and time-varying PASI, there was a trend for shorter drug survival in current and former smokers, but this was no longer statistically significant.
Conclusions: This study demonstrated that current and former smokers treated with biological therapies for psoriasis were more likely to discontinue treatment than non-smokers, and less likely to achieve PASI90 and PASI100; however, this association was not statistically significant when controlling for confounding variables.

Bimekizumab safety and tolerability in moderate-to-severe plaque psoriasis: Pooled analysis from up to 4 years of treatment in 5 phase 3/3b clinical trials

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Aims: To evaluate safety data for bimekizumab (BKZ) through 4 years (yrs) of treatment and assess whether rates of treatment-emergent adverse events (TEAEs) changed with each yr of BKZ treatment in patients with moderate-to-severe plaque psoriasis, using the largest pool of phase 3/3b safety data available at the time of this report.
Methods: Data were pooled from BE SURE/BE VIVID/BE READY, their open-label extension (OLE) BE BRIGHT (4-yr data; cut-off 14 Nov 2022) and BE RADIANT (3-yr data; cut-off 6 May 2022).
Patients received BKZ 320 mg every 4 weeks (wks; Q4W) or Q8W; all received Q8W from Wk64 (BE RADIANT)/OLE Wk48 (BE BRIGHT) or next scheduled visit.
TEAEs are presented as exposure-adjusted incidence rates (EAIRs)/100 patient-yrs (PY) for all patients who received

≥1 BKZ dose and evaluated separately for Yr1/Yr2/Yr3/Yr4 (Wks0–52/52–104/104–156/156–208) of treatment.

Results: Total BKZ exposure was 6324.3PY ($N = 2186$) (Yr1: 2053.3PY [$n = 2186$]; Yr2: 1904.3PY [$n = 2013$]; Yr3: 1521.1PY [$n = 1803$]; Yr4: 819.5PY [$n = 1309$]).

Overall, TEAEs occurred at an EAIR of 170.5/100PY (Yr1, Yr2, Yr3, Yr4: 230.9/100PY, 137.7/100PY, 107.1/100PY, 99.9/100PY), serious TEAEs at 5.5/100PY (6.5/100PY, 5.9/100PY, 5.8/100PY; 5.6/100PY) and TEAEs leading to discontinuation at 2.9/100PY (4.6/100PY, 2.3/100PY, 2.3/100PY, 1.1/100PY).

The most common TEAEs were nasopharyngitis at 12.7/100PY (25.8/100PY, 13.2/100PY, 5.4/100PY, 5.9/100PY), oral candidiasis at 8.9/100PY (18.9/100PY, 10.7/100PY, 6.8/100PY, 5.4/100PY) and upper respiratory tract infection at 5.7/100PY (10.4/100PY, 5.7/100PY, 3.7/100PY, 3.9/100PY). Throughout, fewer TEAEs occurred with BKZ Q8W versus Q4W (115.4/100PY vs. 224.4/100PY), including for oral candidiasis (6.5/100PY vs. 16.7/100PY).

Conclusions: BKZ demonstrated good tolerability and a consistent safety profile over 4 yrs in patients with plaque psoriasis. EAIRs of TEAEs remained consistent/decreased with longer BKZ exposure; no new safety findings were identified.

Bimekizumab efficacy across subgroups of patients with moderate-to-severe plaque psoriasis: Pooled analysis from up to 3 years of treatment in 5 phase 3/3b clinical trials

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Aims: To evaluate efficacy outcomes across subgroups of age, weight and baseline disease characteristics in patients with moderate-to-severe plaque psoriasis treated with bimekizumab (BKZ), using the largest pool of phase 3/3b data over 3 years.

Methods: Data were pooled from the following trials: BE SURE, BE VIVID, BE READY, the first 96 weeks (wks) of their open-label extension (OLE) BE BRIGHT and BE RADIANT (48-wk double-blinded period, plus 96-wk OLE). Included patients received BKZ 320 mg every 4 wks (Q4W) or Q8W from baseline; all received Q8W from Wk64 (BE RADIANT)/OLE Wk48 (BE BRIGHT) or next scheduled visit.

Proportions of patients achieving absolute Psoriasis Area and Severity Index (PASI) ≤ 2 at Year 3 (OLE Wk96) were calculated across subgroups of: baseline age, weight, PASI and Investigator's Global Assessment (IGA), psoriasis disease duration prior to baseline and prior biologic exposure. Data are reported using modified non-responder imputation: patients discontinuing treatment due to lack of efficacy or treatment-related adverse events were considered non-responders at subsequent timepoints; multiple imputation was used for all other missing data.

Results: 1107 BKZ-randomized patients entered the OLEs. At Year 3, 91.3% achieved PASI≤2. PASI≤2 was achieved consistently at Year 3 across age (<40 years: 93.2%; 40–<65: 89.9%; ≥65: 92.4%), weight (≤100 kg: 92.6%; >100 kg: 88.1%), baseline PASI (≤15: 91.0%; >15: 91.4%), baseline IGA (3 [moderate]: 92.5%; 4 [severe]: 89.1%), psoriasis disease duration (<median [16.21 years]: 92.8%; ≥median: 89.9%) and biologic exposure (yes: 90.0%; no: 92.2%) subgroups.

Conclusions: Comparable and durable levels of near-complete skin clearance were achieved through 3 years of BKZ treatment across patient subgroups.

Drug survival of biologics in hidradenitis suppurativa: A systematic review and meta-analysis

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Introduction: Biologics inhibiting cytokines such as tumour necrosis factor (TNF)-α, interleukin(IL)-17 and IL-23 are frequently used to treat moderate-to-severe hidradenitis suppurativa (HS), with response rates of 40–50% across

clinical trials. However, durability of responses is poorly characterized. Drug survival (DS) is a metric reflecting both efficacy and tolerability of treatments in real-world settings, defined as the proportion of patients remaining on treatment over time.

Methods: A systematic review and meta-analysis was undertaken to benchmark DS of biologics in HS (PROSPERO registration CRD42023443159). Databases were searched using a combination of 'biologic' and 'HS' MeSH terms. Kaplan–Meier curves for DS were digitalised then pooled using a random-effects model and the inverse variance method. Subgroup differences in DS were evaluated, with $p < 0.05$ considered statistically significant. All analyses were conducted in R v4.3 using the RISCA package v1.0.4.

Results: Eight studies were identified, reporting on DS of biologics in 1170 HS patients. 91% of patients received TNF-α inhibitors, 63% were female and 58% were biologic-naïve. More patients treated with TNF-α than non-TNF-α inhibitors were biologic-naïve, 66% versus 13% ($p < 0.001$). Overall, median DS was 11.9 months (95%CI 9.6–16.6), while 12-month DS was 48% (95%CI 39–60). There was no significant difference in DS between patients receiving TNF-α than non-TNF- α inhibitors ($p = 0.35$), while DS was significantly longer for biologic-naïve patients ($p = 0.003$).

Discussion: Approximately half of HS patients treated with biologics will have ceased treatment after 12-months. This is markedly lower than DS benchmarks for biologics in other inflammatory dermatoses such as psoriasis or atopic dermatitis. Reasons for shorter DS in HS are unclear, but may include development of anti-drug antibodies or persistent B-cell, monocyte and complement activation not targeted by biologics. Future studies examining predictive factors for shorter DS will be essential in guiding optimal treatment selection and patient counselling in HS.

Bimekizumab efficacy and safety through 4 years in moderate-to-severe plaque psoriasis: Long-term results from the BE SURE trial and BE BRIGHT open-label extension

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Aims: To evaluate the efficacy, as measured by complete or near-complete skin clearance using the Psoriasis Area and Severity Index (PASI) and long-term safety of bimekizumab (BKZ) in patients with moderate-to-severe plaque psoriasis through 4 years of treatment.

Methods: In BE SURE, patients with moderate-to-severe plaque psoriasis were randomized 1:1:1 to either BKZ 320 mg every 4 weeks (wks; Q4W) to Wk16 then Q8W to Wk56 (BKZ Q4W/Q8W), BKZ Q4W to Wk56 (Q4W/Q4W), or adalimumab (ADA) 40 mg Q2W to Wk24 then BKZ Q4W to Wk56 (ADA/BKZ).

At Wk56, patients could enrol in BE BRIGHT to receive open-label BKZ Q4W or Q8W; all patients received BKZ Q8W from Wk104/next visit.

Efficacy data are reported through Wk200 by initial randomization group. Patients discontinuing due to lack of efficacy/treatment-related adverse events were considered non-responders; multiple imputation was used for other missing data (modified non-responder imputation).

Treatment-emergent adverse events (TEAEs) occurring whilst receiving BKZ (incidence/100 patient years [PY]) are reported through Wk0–200.

Results: In BE SURE, 478 patients were randomized to BKZ Q4W/Q8W (N = 161), BKZ Q4W/Q4W (N = 158) and ADA/BKZ (N = 159). At Wk200, absolute PASI ≤2 was achieved by 85.9% of BKZ Q4W/Q8W-randomized, 82.5% BKZ Q4W/Q4W-randomized and 89.6% ADA/BKZ-randomized patients. Absolute PASI = 0 was achieved by 58.5%, 61.9% and 69.5%, respectively.

Wk0–200 serious TEAE rate with BKZ was low (4.9/100PY). 5 deaths occurred (0 treatment-related). The most common TEAEs were: nasopharyngitis (12.3/100PY); oral candidiasis (8.3/100PY); upper respiratory tract infection

(6.0/100PY). Most (99.2%) oral candidiasis events were mild/moderate; none led to discontinuation.

Conclusions: Through 4 years, clinical improvements with BKZ were maintained and BKZ was well-tolerated with no unexpected safety findings.

Discontinuation rates of biologics in patients with psoriasis: 1 year (interim) follow-up of the psoriasis study of health outcomes (PSoHO)

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Introduction: The Psoriasis Study of Health Outcomes (PSoHO) is a 3-year, international, prospective, non-interventional, real-world, cohort study comparing the effectiveness of anti-interleukin (IL)-17A biologics to other biologics in patients with moderate-to-severe psoriasis initiating/switching biologics.

Aim: This study reports drug discontinuation rates up to 1 year in patients receiving anti-IL-17A or other biologics.

Methods: Discontinuation rates of biologics assigned at baseline for any reason, including lack of effectiveness and tolerability, was reported using Kaplan–Meier estimates. Patients were censored if they were lost-to-follow-up, died or completed 1 year. Analyses are presented by cohort (anti-IL-17A (ixekizumab, secukinumab) and other biologics (adalimumab, brodalumab, certolizumab, etanercept, guselkumab, infliximab, risankizumab and ustekinumab)) and by individual biologic. Hazard ratios (HR) adjusted for select key baseline characteristics with 95% CI, restricted at month 6, were calculated from frequentist model averaging to compare the cohorts and ixekizumab versus all other treatments (secukinumab, guselkumab and risankizumab).

Results: At baseline, 39.0% ($n=773/1981$) of patients received anti-IL-17A biologics and 61.0% ($n=1208$) other biologics. Overall, 11.9% ($n=92$) of patients amongst the anti-IL-17A cohort discontinued treatment for any reason vs. 15.8% ($n=191/1208$ [HR = 0.64; 95% CI 0.45, 0.86]) amongst those receiving other biologics.

The primary reasons for discontinuation were lack of drug effectiveness (anti-IL-17A: 4.5%, $n=35$) versus other biologics: 8.5% ($n=103$, [HR = 0.40 95% CI 0.17, 0.62]) and lack of tolerability (anti-IL-17A: 1.6%, $n=12$ vs. other biologics: 1.7% ($n=21$ [HR = 0.77; 95% CI 0.33, 1.59]).

Compared to ixekizumab (12.2%, $n=65/532$), treatment discontinuation due to all reasons was similar amongst patients receiving secukinumab (11.2%, $n=27/241$, [HR = 0.91; 95% CI 0.57, 7.79]), guselkumab (12.5%, $n=38/308$, [HR = 0.82; 95% CI 0.45, 14.87]) and risankizumab (6.6%, $n=17/259$, [HR = 1.81; 95% CI 0.92, 2.86]).

Conclusions: These real-world data from PSoHO show lower rates of drug discontinuation in patients with psoriasis treated with anti-IL-17A compared to a cohort including all other biologics collectively.

Herpes zoster infections in the biologic era in dermatology in Australia and the need for vaccination

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Aim: Herpes zoster (HZ), the reactivation of latent varicella zoster virus (VZV), can result in significant morbidity, associated with pain, permanent disfigurement and post herpetic neuralgia (PHN). The immunosuppression associated with biologic and small molecule agents can result in dermatomal and disseminated disease. We discuss the VZV vaccines currently available in Australia and the risk of HZ with immunosuppressive treatments.

Methods: A literature review was undertaken to compare the VZV vaccines and evaluate the risk of HZ with different types of immunosuppression.

Results: In Australia, the two zoster vaccines currently available are the live attenuated Zostavax (ZVL) and Shingrix (recombinant zoster vaccine (RZV)). ZVL is contraindicated in immunocompromised patients, but can be administered 1 month before commencing immunosuppression or 12 months after the last dose. RZV can be used in immunocompromised patients. It has superior effectiveness at preventing HZ and PHN, with minimal waning of efficacy over time compared to ZVL.

Janus kinase (JAK) inhibitors appear to carry the highest risk of HZ (RR 4.78, 95% CI: 1.79–12.75). Interleukin inhibitors have a lower risk of HZ than tumour necrosis factor inhibitors (HR 0.58; 95% CI, 0.41–0.82). Dupilumab

does not increase the risk, while cyclosporine (OR 1.29, 95% CI 0.09–17.53), azathioprine (OR 3.71, 95% CI 0.90–15.24), mycophenolate (OR 2.68, 95% CI 0.99–7.23) and methotrexate (adjusted hazard ratio 1.04 95% CI 0.20–5.41) have been shown to carry a non-statistically significant increased risk for HZ.

Conclusion: The risk of HZ varies between immunosuppressive agents. Of the 2 vaccines currently available in Australia, RZV appears more efficacious in preventing HZ and PHN. Its effect also lasts longer and it can be used in immunocompromised individuals. In Australia, dermatologists should be aware of HZ vaccines, their efficacy and the risks of developing HZ with biologics and JAK inhibitors and consider RZV in patients currently or soon to be immunocompromised.

Deucravacitinib efficacy in palmoplantar and fingernail psoriasis by baseline Psoriasis Area and Severity Index (PASI) and baseline body surface area (BSA) in the phase 3 POETYK PSO-1 and PSO-2 trials

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Aims: Deucravacitinib, an oral, selective, allosteric TYK2 inhibitor, is approved in the US, EU, Australia, and other countries for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. Deucravacitinib was effective and well-tolerated in the global, 52-week, phase 3 POETYK PSO-1 (NCT03624127) and PSO-2 (NCT03611751) trials. In the current analysis, efficacy in palmoplantar (ppp) and fingernail psoriasis (np) by baseline severity was evaluated.

Methods: Patients with moderate-to-severe ppp (pp-Physician Global Assessment [pp-PGA] score ≥3) or np (PGA-Fingernails [PGA-F] ≥3) were included. Efficacy outcomes were reported through Week 24 (pooled PSO-1/PSO-2, before PSO-2 rerandomization) and Week 52 (PSO-1, continuous deucravacitinib), stratified by baseline PASI score 12- < 15 (low) or ≥ 15 (high) and baseline BSA involvement 10% - ≤15% (low) or > 15% (high).

Results: Patients with ppp and/or np from the PSO-1/PSO-2 pooled population ($n = 57$ and 112, respectively) and from PSO-1 ($n = 18$ and 39) were analysed. Week 24 ppp outcomes were similar across low and high PASI subgroups (pp-PGA 0/1, 62.5% and 55.1%; improvement from baseline pp-PASI [mean, 12.7, 16.4], −9.9 and −10.6, respectively) and BSA subgroups, with similar trends for np (PGA-F 0/1, 25.0% and 41.9%). At Week 52, outcomes in ppp were comparable in baseline PASI subgroups (pp-PGA 0/1, 66.7% and 53.3%; improvement from baseline pp-PASI [mean 10.1, 12.5], −9.7 and −10.2) and in BSA subgroups; outcomes for np showed similar trends (PGA-F 0/1, 50.0% and 51.6%).

Conclusions: Deucravacitinib was effective in palmoplantar and fingernail psoriasis regardless of baseline disease severity of plaque psoriasis.

Deucravacitinib in patients with plaque psoriasis who screened positive for psoriatic arthritis in POETYK PSO-1 and PSO-2: Effect on joint pain and peripheral joint disease versus placebo and apremilast

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Aims: Deucravacitinib is approved for treatment of moderate-to-severe plaque psoriasis. In the phase 3 POETYK PSO-1/PSO-2 trials, significantly more patients receiving deucravacitinib achieved PASI 75 and sPGA 0/1 at Week-16 versus placebo or apremilast. In this analysis, efficacy on peripheral joint disease, joint pain, and HRQoL at Weeks-16 and 24 was evaluated.

Methods: POETYK PSO-1/PSO-2 randomized patients 1:2:1 to placebo, deucravacitinib or apremilast.

The self-administered Psoriatic Arthritis Screening and Evaluation (PASE) questionnaire was completed by patients with self-reported peripheral joint complaints at baseline. Peripheral joint pain and joint disease were measured using a visual analogue scale (VAS). All patients completed the 36-item Short Form (SF-36) physical component summary (PCS).

Results: This analysis included 185 PASE-positive patients (score of ≥47). Improvement, assessed by mean adjusted change from baseline (CFB), was greater in patients treated with deucravacitinib versus placebo at Week-16 for joint pain, joint disease and SF-36 PCS (Table 1). Adjusted mean CFBs were greater in patients treated with deucravacitinib at Week-24 versus apremilast for joint pain and joint disease and similar for SF-36 PCS (Table).

Conclusions: PASE-positive patients treated with deucravacitinib reported greater improvements in joint disease and joint pain versus apremilast and placebo and SF-36 PCS scores versus placebo. The effect amongst deucravacitinib patients improved through the 24-weeks.

Table 1: Adjusted mean CFB at Week-16 and 24.

TABLE 1 Adjusted mean CFB at week-16 and 24.

				Versus placebo		Versus apremilast	
	Deucravacitinib	**Placebo**	**Apremilast**	**95% CI**	***p*-Value**	**95% CI**	***p*-Value**
Joint pain VAS							
N=	73	31	51				
Week 16	−15.2	−3.2	−8.5	−22.5 to −1.4	0.026		
Week 24	−22.8		−8.6			−23.1 to −5.3	0.002
Joint disease VAS							
N=	71	33	48				
Week 16	−17.4	−3.8	−13.4	−23.8 to −3.4	0.009		
Week 24	−19.6		−8.8			−19.8 to −1.9	0.018
SF-36 PCS							
N=	85	40	55				
Week 16	4.4	0.9	3.8	0.6 to 6.4	0.017		
Week 24	5.8		3.7			−0.4 to 4.8	

Efficacy and safety of tildrakizumab for the treatment of moderate-to-severe plaque psoriasis of the scalp: Week 52 results from a phase 3b, randomized, double-blind, placebo-controlled trial

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Aims: Tildrakizumab, an anti-interleukin-23 p19 antibody approved for the treatment of adults with moderate-to-severe plaque psoriasis, was investigated for treatment of scalp psoriasis in a Phase 3b, randomized, double-blind, placebo-controlled study (NCT03897088). The primary endpoint, Investigator's Global Assessment (IGA) mod 2011 (scalp) response ('clear [0]' or 'almost clear [1]' with ≥2-point reduction from baseline) at Week (W)16, was met. The aim of this abstract is to report results through W52.

Methods: Patients originally randomized to tildrakizumab 100 mg continued dosing at W16 and every 12 weeks thereafter; patients originally randomized to placebo switched to tildrakizumab 100 mg at W16, W20, W32 and W44. Efficacy endpoints included IGA mod 2011 (scalp) and ≥90% improvement from baseline in Psoriasis Scalp Severity Index (PSSI 90) responses. Missing data were imputed as nonresponse. Safety was assessed in all treated patients.

Results: Of 231 patients randomized to tildrakizumab/placebo ($n=117/114$), 171 ($n=89/82$) were included in the primary efficacy population. From W16 to W52, IGA mod 2011 (scalp) and PSSI 90 response rates increased from 49.4% to 62.9% and 60.7% to 65.2%, respectively, in patients randomized to tildrakizumab and from 7.3% to 56.1% and 4.9% to 57.3%, respectively, in patients originally randomized to placebo. Amongst W16 IGA mod 2011 (scalp) and PSSI 90 responders to tildrakizumab, 36/44 (81.8%) and 44/54 (81.5%), respectively, sustained response at W52. No new safety signals were observed through W52; most treatment-emergent adverse events were of mild-to-moderate severity, with no severe events or deaths.

Conclusions: Efficacy and safety of tildrakizumab in patients with moderate-to-severe scalp psoriasis were maintained through W52.

A systematic review of the efficacy of TYK2 inhibitors in patients with dermatological disease

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Aim: This study seeks to systematically review existing data on the efficacy of TYK2 inhibitors in comparison to placebo or standard treatments for improving skin signs and enhancing the quality of life in dermatological diseases.

Methods: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), the US National Institutes of Health Ongoing Trials Register, the ISRCTN registry, the World Health Organization International Clinical Trials Registry Platform, the Australian New Zealand Clinical Trails registry, and EU Clinical Trails Registry were systematically searched from inception to Sept 10th 2023 for clinical studies assessing the efficacy and safety of TYK2 inhibitors in dermatological disease. Studies assessing TYK2 effectiveness by reporting clinical response and/or patient reported outcomes were included. Two reviewers independently assessed risk of bias and extracted study data. A narrative synthesis was performed.

Results: The initial search identified 572 references, with 490 records remaining after deduplication. Of these, 17 records representing 13 clinical trials, one matching adjusted indirect comparison, and one case study were included for analysis. Results indicate that Deucravacitinib is superior to placebo, Apremilast and Adalimumab in treating adult patients with moderate-to-severe plaque psoriasis and superior to placebo in the treatment of adults with SLE. Comparative investigations on brepocitinib and ropsacitinib were more limited. Oral brepocitinib demonstrated superiority over placebo in managing plaque psoriasis, alopecia areata and hidradenitis suppurativa (HS). Topical Brepocitinib exhibited superiority over placebo in treating atopic dermatitis, but not plaque psoriasis. Ropsacitinib demonstrated superiority over placebo in the

management of plaque psoriasis. Importantly, all three medications maintained an acceptable safety profile.
Conclusions: This review outlines the current understanding of the efficacy and safety of three TYK2 inhibitors in dermatological conditions.

Infection risk with JAK inhibitors in dermatoses: A meta-analysis informing the Australasian medical dermatology collaboration consensus recommendations

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Background: Evolving evidence suggests Janus kinase inhibitors (JAKi) may predispose to infection, particularly tuberculosis and human herpes viruses. The aim of this review was to evaluate comparative infection risk in patients on a systemic JAKi for a dermatologic indication.
Methodology: A systematic review of the literature was carried out to June 2023, using databases EMBASE, Medline, SCOPUS and Cochrane Library of Registered Trials. Placebo-controlled randomized trials that compared systemic JAKi with placebo for a dermatologic indication and reported the incidence of infection in patients were eligible for inclusion. Primary outcome measures were the incidence of serious and opportunistic infections, upper respiratory tract infections, herpes simplex, varicella zoster, tuberculosis, neutropaenia and lymphopaenia. Meta-analyses of incidence ratios of infections was carried out to determine odds ratio between JAKi and placebo.
Results: From 7632 abstracts, 40 studies were identified as meeting inclusion criteria. Meta-analysis found no significant increased risk of serious (OR 0.92, 95% CI 0.60–1.40, $p=0.70$) or opportunistic infections (OR 0.65, 95% CI 0.32–1.31, $p=0.23$). Incidence of varicella zoster was significantly higher in the JAKi cohort (OR 1.72, 95% CI 1.08–2.72, $p=0.022$). Meta-analysis demonstrated no significantly increased risk of herpes simplex infections (OR 1.43, 95% CI 0.93–2.23, $p=0.102$), but a significantly higher risk in those with atopic dermatitis compared to alopecia areata (OR 1.73, 95% CI 1.13–2.69, $p=0.013$). JAKi were not associated with higher rates of neutropaenia (OR 1.49, 95% CI 0.86–2.56, $p=0.155$) or lymphopenia compared to placebo (OR 0.68, 95% CI 0.60–1.11, $p=0.099$).
Conclusions and Relevance: The results of this report largely support the safety of these agents from an infection perspective, however, do signal that vigilance should be practiced in patients at risk for recurrent or serious herpes virus infections.

Real-world evidence for ustekinumab treatment of severe psoriasis: drug survival and efficacy results from the Australasian psoriasis registry

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Aim: Ustekinumab (Stelara), a monoclonal antibody targeting interleukin-12 (IL-12) and IL-23, was listed on the Australian Pharmaceutical Benefits Scheme (PBS) in 2010 for the treatment of severe chronic plaque psoriasis. Whilst evidence from the pivotal ACCEPT, PHOENIX I & II trials support its use, the effectiveness of ustekinumab in the Australian real-world setting is not well-known. This analysis examines patient characteristics, efficacy and drug survival of ustekinumab from the Australasian Psoriasis Registry (APR).
Methods: Data were collected from patients in the APR with plaque psoriasis prescribed ustekinumab. Patient demographics and Psoriasis Area and Severity Index (PASI) at specific time points from 02/10/2009 until 07/07/2020 were analysed. Cox proportional hazards regression and Kaplan–Meier estimates were used to examine the relationship between patient characteristics and drug survival/time to PASI 75, PASI 90, PASI 100, PASI ≤3, ≤2 and ≤1.
Results: 464 complete patient records from nine clinics were identified. Overall drug survival was 93%, 84%, 74%, 69%, 56% and 34% at 9, 15, 27 months and 3, 5 and 10 years, respectively. Female sex, greater weight or having PASI>1

at any time during the study was associated with shorter drug survival.

Absolute PASI ≤3 and PASI 75 was achieved by 83% and 95% of patients, respectively. Bio-naïve patients were less likely to achieve PASI 75 compared to bio-experienced patients [adjusted hazard ratio (aHR) 0.48 (95% CI, 0.39–0.58); $p < 0.001$]. Patients of male sex, having psoriatic arthritis, or having higher baseline PASI were less likely to achieve PASI 100, PASI ≤1 and PASI ≤2.

Conclusion: Real-world data from the APR suggest that there may be a difference in drug survival and response to ustekinumab in patients based on sex, baseline PASI, the presence of psoriatic arthritis and whether patients are bio-experienced or bio-naïve.

Deucravacitinib in plaque psoriasis: 3-year safety and efficacy results from the phase 3 POETYK PSO-1 AND PSO-2 TRIALS

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Aims: Deucravacitinib, approved for the treatment of adults with moderate-to-severe plaque psoriasis, was superior to placebo and apremilast in the 52-week, phase 3 POETYK PSO-1 and PSO-2 trials. Upon completion, patients could enrol in the long-term extension (LTE) trial. Deucravacitinib maintained efficacy through 2 years with no new safety signals. Here, we report safety and efficacy up to 3 years.

Methods: PSO-1/PSO-2 randomized patients 1:2:1 to placebo, deucravacitinib or apremilast. At Week 52, patients received open-label deucravacitinib. Safety was evaluated in patients who received ≥1 dose. Exposure-adjusted incidence rate (EAIR) per 100 person-years (PY) was calculated. Efficacy outcomes included Psoriasis Area and Severity Index (PASI) 75/PASI 90 and static Physician's Global Assessment score 0/1. Efficacy was reported using modified non-responder imputation (mNRI) in patients who received continuous deucravacitinib from Day 1 of the parent trial. As-observed data and results by treatment failure rule imputation were also analysed.

Results: A total of 1519 patients received ≥1 dose of deucravacitinib, with 513 patients receiving continuous deucravacitinib. Cumulative exposure from randomization was 3294.3 PY. EAIRs/100PY were similar, or decreased, from the 2-year to 3-year cumulative period, respectively, for AEs (154.4, 144.8), serious AEs (6.1, 5.5), discontinuation due to AEs (2.8, 2.4), herpes zoster (0.7, 0.6), malignancies (0.9, 0.9), major adverse cardiovascular events (0.4, 0.3), venous thromboembolism (0.1, 0.1) and deaths (0.4, 0.3). Clinical response rates were maintained at Week 148 by mNRI (PASI 75, 73.2% [95% CI, 68.7–77.8]; PASI 90, 48.1% [95% CI, 43.2–53.1]; sPGA 0/1, 54.1% [95% CI, 49.1–59.1]), with similar results regardless of data imputation methodology.

Conclusions: Deucravacitinib demonstrated a consistent safety profile with no increases in AE/serious AE rates and no new/long-term safety signals. Efficacy was sustained in patients treated continuously with deucravacitinib. These findings support deucravacitinib having a consistent safety profile and durable efficacy for up to 3 years.

The use of dupilumab as an alternate approach in bullous pemphigoid

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Research indicates innate immune cells may play a role in the morbidity of bullous pemphigoid (BP). Dupilumab is an interleukin-4 and interleukin-13 inhibitor, with PBS approval in Australia for use in atopic dermatitis. Emerging evidence suggests therapeutic potential in BP. This case series aimed to examine the utility of dupilumab in BP patients with complex comorbidities precluding high-dose oral corticosteroid therapy.

Two patients with histologically and serologically confirmed BP received approval for 2-weekly dosing of subcutaneous dupilumab 300 mg. Patient A (82 years, male) had a history of uncontrolled diabetes and complicated peripheral vascular disease. He suffered from BP secondary

to linagliptin use, thus far unresponsive to doxycycline, nicotinamide and topical and oral steroid therapy. High-dose prednisolone therapy also increased his risk of vascular ulceration and re-infection, complicating treatment. Patient B (72 years, female) had a history of Hepatitis C cirrhosis and schizophrenia requiring full-time care. She continued to suffer BP flares despite topical steroid therapy and doxycycline administration. Further, prednisolone use worsened her paranoid delusions, and IVIG infusions in hospital and infusion centres had proved difficult logistically due to behavioural issues.

Following dupilumab therapy, Patient A attained skin clearance and cessation of blister recurrence, but continuing peripheral vascular ulcerations with infections. More optimal glycaemic control was achieved due to steroid-free therapy. Patient B attained blister resolution, bypassing the need for transfers for IVIG infusions, permitting uninterrupted community-based care. No side effects were reported.

In conclusion, a favourable clinical response in BP to dupilumab was demonstrated in socially and clinically complex patients. Logistical and clinical benefits including reduced hospital visits, transfers and hospital admissions for infusions; and a steroid-free approach, respectively, were made evident. Dupilumab therapy thus offers promise as a community-based approach in BP patients unable to access or tolerate first and second-line therapies.

Dupilumab for resistant chronic actinic dermatitis: A case series and review of the literature

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Chronic actinic dermatitis (CAD) is a rare, eczematous photosensitive disorder of unclear aetiology. Conventional treatments include photoprotection and topical corticosteroids (TCS). Oral corticosteroids and steroid-sparing systemic agents are sometimes used in severe or recalcitrant cases. Dupilumab is an interleukin-4 inhibitor, approved for use in atopic dermatitis (AD). We present two cases of recalcitrant CAD successfully treated with dupilumab at a dose of 600 mg at week 0, followed by 300 mg every 2 weeks.

An 85-year-old man with longstanding CAD not responding to photoprotection, systemic agents and TCS presented for management. He had prominent erythema and scaling involving the neck and hands. Previous treatments including prednisolone, methotrexate, mycophenolate and phototherapy were ineffective. Azathioprine was not tolerated and cyclosporine was effective, but ceased after 2 years of therapy. Dupilumab was commenced and a significant improvement was noted within weeks, with complete resolution of CAD after 3 months. This was sustained at his most recent follow-up 16 months later.

A 75-year-old man presented with a severe flare of longstanding AD with superimposed CAD. Previous treatments including methotrexate, phototherapy and TCS were all ineffective. Dupilumab was commenced and at 5 months, the AD had resolved, while the sun exposed areas had improved significantly. At 10 months, pruritus had resolved and there was minimal CAD. There was a sustained improvement at the latest follow-up 12 months later.

There has been increasing evidence supporting dupilumab use in diseases other than atopic dermatitis. However, its use in CAD has only been reported in case reports and small case series to date. We found a total of 28 patients at sites outside Australia treated with dupilumab for CAD. Most patients (26/28) showed a reduction in disease severity. Our report indicates that dupilumab is useful in the management of resistant CAD.

A real-world Australian experience of the epidemiology, diagnosis and management of hidradenitis suppurativa in a tertiary referral centre

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Aim: This study aims to characterize the real-world experience in diagnosis and systemic therapy of hidradenitis suppurative (HS) in a tertiary hospital with a dedicated HS clinic.

Methods: A retrospective cohort study was conducted on patients treated in the Dermatology HS Clinic at a single adult tertiary referral service. Data was extracted from the BioGrid database and the institutional electronic medical records.

Results: Between June 2019 and February 2023, 253 patients with HS were identified. There was a female preponderance of 2:1. The most common comorbidities reported were depression (7.5%), polycystic ovarian syndrome (7.1%), obesity (5.1%) and Type 2 diabetes mellitus (4.7%). The Dermatology Life Quality Index at initial appointment was 10.3 and at final review was 10.2. The average total abscess and inflammatory nodule (AN) count at initial appointment was 7.0, and this decreased to 4.7

at the final appointment. Common treatments included topical resorcinol 15% (62.8%), oral doxycycline (44.6%), clindamycin (26.1%), rifampicin (18.6%) metronidazole (17.0%) and amoxicillin-clavulanate (15.8%).

Adalimumab was prescribed to 25.7% patients, of which 12.3% required an increased dose of 80 mg weekly due to poor disease control. Treatment with adalimumab was discontinued in 32.3% of patients; 76% were switched to alternative biologic therapy. The average duration of adalimumab therapy in these patients was 96.0 weeks. Other biologic treatments included tildrakizumab (6.7%), infliximab (3.6%), secukinumab (2.4%), ustekinumab (1.6%) and risankizumab (0.4%).

23.3% patients received intra-lesional steroid injections, 23.3% patients underwent a deroofing procedure, and 16.3% patients underwent an incision and drainage of abscess.

Conclusion: Real-world studies are essential in HS to understand the nuances and complex nature of management. This is the first Australian cohort analysis that demonstrates that even with objective improvement in active disease, quality of life remains significantly impacted. This highlights the need for early multidisciplinary intervention and further development of advanced therapies.

Atopic dermatitis and risk of psoriasis: A systematic review and meta-analysis of cohort studies

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Aims: Emerging evidence has reported the association between atopic diseases, including atopic dermatitis, and the risk of developing psoriasis. However, the inconsistency remains amongst studies. To the best of our knowledge, this is the first systematic review and meta-analysis to determine the risk of incident psoriasis in patients with atopic dermatitis and the risk of incident psoriasis in patients with atopic diseases.

Methods: A systematic search of MEDLINE, Scopus, EMBASE, Cochrane Library and medRxiv was performed through September 2023 to identify eligible cohort studies examining the risk of incident psoriasis in populations with atopic dermatitis and cohort studies determining the risk of incident psoriasis in populations with atopic diseases, versus controls without the diseases. Two reviewers independently extracted study characteristics and outcomes. If consensus is required, a third reviewer will be consulted. Quality assessments were performed according to the Newcastle-Ottawa Scale (NOS). The PRISMA and Meta-analysis of Observational Studies in Epidemiology (MOOSE) reporting guidelines were followed. The reported adjusted hazard ratio (aHR) from the model adjusted for potential confounders were selected to ensure the minimized effect of confounders and were pooled using the random-effects meta-analysis.

Results: Of 9946 identified studies, a total of 4 cohort studies, including 18,603,229 participants, were eligible for inclusion and were pooled in the meta-analysis. The risk of psoriasis was significantly higher in patients with atopic dermatitis, with the greatest effect size amongst atopic diseases (pooled aHR, 3.63; 95% CI, 2.79–4.70). Additionally, patients with allergic rhinitis (pooled aHR, 1.27; 95% CI, 1.17–1.38) and asthma (pooled aHR, 1.27; 95% CI, 1.23–1.31) were associated with an increased risk of psoriasis compared with the control without atopic diseases. Overall, all atopic diseases were at an increased risk of incident psoriasis (pooled aHR, 1.13; 95% CI, 1.06–1.21).

Conclusions: In conclusion, patients with underlying atopic diseases, especially atopic dermatitis, are significantly associated with an increased.