patients demonstrated significantly (p<0.05) greater baseline disease severity with respect to mean (SD) joint count [TJC: 8.9 (6.2) vs. 7.4 (6.6)], SJC: 7.4 (5.0) vs. 5.9 (4.6)], morning stiffness [83.5 (90.2) vs. 61.8 (77.4) min/day], PGA: 56.1 (24.1) vs. 54.1 (24.7) mm, pain [58.5 (24.3) vs. 50.1 (24.0) mm], DLQI score [6.1 (6.9) vs. 6.3 (5.3)] and HAQ-DI [1.1 (0.6) vs. 0.8 (0.6)]. The rate of baseline mMDA was slightly lower for ADA patients (4.3% vs. 7.4%; p=0.178). Baseline prevalence of enthesis was comparable (ADA: 28.4% vs. csDMARD: 23.4%; p=0.276), while dactylitis was significantly more prevalent for csDMARD patients (26.2% vs. 36.3%; p=0.031).

Overall effect of treatment group, over 24 months, significantly (p<0.05) favored the ADA vs. csDMARD-treated patients for TJC [estimate (95%CI): -2.4 (-3.4, -1.4)], SJC [1.8 (-2.5, -1.2)], PGA [-3.7 (-9.3, 1.9)], DLQI [-1.5 (-2.5, 0.5)], and HAQ-DI [-0.1 (-0.2, 0.0)] (Figure 1). There was no significant difference for morning stiffness and pain.

At month 24, statistically comparable (p>0.05) baseline-adjusted values (the least square means; LSM) were observed for ADA- vs. csDMARD-treated patients for TJC [LSM (95%CI): 1.8 (12.2, 4.3) vs. 3.0 (2.1, 3.8)], SJC [12.0 (0.8, 1.7) vs. 2.1 (15.2, 7.7)], morning stiffness [32.4 (19.1, 45.6) vs. 29.9 (11.1, 48.6) min/day], PGA [31.6 (28.1, 35.2) vs. 36.9 (31.8, 41.9) mm], pain [35.3 (31.5, 39.0) vs. 38.4 (33.1, 43.7) mm], DLQI [2.9 (2.2, 3.6) vs. 2.9 (2.0, 3.8)], and HAQ-DI [0.7 (0.8, 0.8) vs. 0.9 (0.8, 1.0)].

Achievement of mMDA at month 24 was reported by 34.1% and 34.9% of ADA- and csDMARD-treated patients, respectively (p=0.892). Rates of dactylitis (10.6% vs. 10.0%) and enthesitis (9.6% vs. 14.4%) were comparable in the ADA vs. csDMARD groups respectively.

Conclusion: The results of this real-world Canadian study indicate a physician selection bias for treatment with ADA for PsA patients with more severe disease burden, indicated by greater baseline disease activity and PROs. ADA-treated patients experienced a greater treatment effect over 24 months compared to csDMARD-treated patients. However, despite the greater treatment effect of ADA, residual disease burden in the two groups was comparable at 24 months.

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AB0556 COMPARING EFFICACY OF GUSELKUMAB VERSUS USTEKINUMAB IN PATIENTS WITH PSORIASIS ARTHRITIS: AN ADJUSTED COMPARISON USING INDIVIDUAL PATIENT DATA FROM DISCOVER 1&2 AND PSUMMIT TRIALS

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Background: Guselkumab is an anti-interleukin (IL)-23 monoclonal antibody recently approved for a treatment of Psoriasis arthritis (PsA). In two large Phase III trials of patients with PsA (DISCOVER -1 & -2) guselkumab had been shown to be superior versus placebo. In this indication no direct comparison is available between guselkumab and ustekinumab, a monoclonal antibody targeting IL-12 and IL-23. Indirect comparisons based on relative treatment effects versus a common comparator (placebo) only allow for analyses up to week 24 due to cross-over to active arms in available PsA trials.

Objectives: To compare indirectly joint and skin efficacy of guselkumab versus ustekinumab up to week 52, using pooled patient-level trial data from DISCOVER 1&2 and PSUMMIT 1&2, adjusting for cross-trial population differences.

Methods: Patient level data, including baseline characteristics and outcome data on American College of Rheumatology (ACR) response, Psoriasis Area Severity Index (PASI) response from the guselkumab arms of DISCOVER -1 & -2 were pooled with the data from the ustekinumab trials PSUMMIT -1&2. Analyses were performed for bio-naïve and bio-experienced populations separately. Differences in patient characteristics across trial populations were adjusted for using multivariate logistic regression, including: gender, age, body mass index, previous TNF use, disease duration, PASI level, number of swollen and tender joints. This method of indirect comparisons allows for analysis of comparative efficacy beyond controlled induction period and odds ratios’ resulting from this model were translated into predicted response rates for ustekinumab, assuming same patient population, as enrolled in the guselkumab trial arms.

Results: Majority of baseline characteristics for patients on guselkumab (100mg q8w, 100mg q4w) were comparable to patients on ustekinumab 45/90mg, in both bio-naive and bio-experienced group of patients. The probability of reaching a ACR 20 in both the bio-naive & bio-experienced population was significantly higher for guselkumab vs ustekinumab at weeks 52 for both dosing regimens of guselkumab (bio-naive ACR 20: q8w OR= 1.88 [1.28;2.76], q4w (OR= 1.92 [1.29;2.86]; bio experienced ACR20 q8w OR=2.72[1.71;6.31], q4w OR=4.77 [1.95;1653]). Similarly guselkumab was superior over ustekinumab on PASI 90 outcome at week 52 in both bio-naive & bio-experienced patients with BSA ≥3 % at baseline (bio-naive: q8w: OR= 2.59 [1.68;3.99]), q4w OR= 3.19 [2.03;5.00], and bio-experienced q8w OR= 3.96 [1.39;11.27], q4w OR=13.10[4.18;41.04]. Figure 1 represents an unadjusted pooled DISCOVER 1&2 trial results and estimated proportions of ustekinumab treated patient group achieving ACR 20 in bio-naive patient group up to week 52 using the method described above.

Conclusion: An adjusted comparison using patient level data from pivotal Phase III studies demonstrates both dosages of guselkumab to be significantly more effective versus ustekinumab in both skin and joint outcomes in both bio-naive & bio experienced patients up to week 52.

AB0557 ACHIEVING TREATMENT TARGETS IN PSORIATIC ARTHRITIS WITH APREMILAST IN CANADIAN PRACTICE: REAL WORLD RESULTS FROM APPRAISE

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Figure 1 ACR 20 response for guselkumab vs ustekinumab in bio-naive patients

Figure 1 ACR 20 response for guselkumab vs ustekinumab in bio-naive patients
Background: Real-world evidence on achieving treatment targets with apremilast (APR) in patients (pts) with PsA is limited. In the phase 3 PALACE trials, pts reached remission (REM)/low disease activity (LDA) targets at 52 wks most frequently when early APR treatment was initiated and pts were in moderate disease activity, as measured by Clinical Disease Activity Index for PsA (cDAPSA) score. In APPRAISE, we assessed APR effectiveness/tolerability in pts with PsA in routine clinical practice in Canada.

Objectives: This interim efficacy analysis focused on the available data on APR effectiveness measured as rate of achieving cDAPSA REM or LDA at 12 mos and Pt Acceptable Symptom Status (PASS) results.

Methods: The prospective, multicenter, observational APPRAISE study assessed APR effectiveness/tolerability in adults with active PsA in routine clinical care enrolled from July 2018-March 2020. Pts were followed from treatment initiation to 12 mos, with visits suggested every 4 mos. The primary effectiveness endpoint was the rate of achieving at least LDA (cDAPSA <14) at 12 mos. Pt-reported outcome measures were assessed. Data reported are as observed in pts continuing APR treatment.

Results: In total, 101 pts were enrolled in APPRAISE. Mean age was 52 yrs; 56% were women. Mean (SD) PsA duration at baseline (BL) was 6 (8) yrs. Oligoarticular disease (≤4 joint involvement) was most common (41%), followed by polyarticular (35%). Most pts (92%) received prior conventional DMARDs and 17% received prior biologic therapy; concomitant MTX was reported in 41% at BL. By 12 mos, 41/101 enrolled pts discontinued, 35 reached 12 mos follow-up (4 mos: n=92; 8 mos: n=61), and 25 have yet to reach 12 mos. The majority (92%) of discontinuations due to lack/loss of effectiveness or AEs occurred within 4-8 mos. AEs were primarily GI related early in treatment. The proportion of pts with continued APR achieving cDAPSA REM/LDA treatment targets increased significantly over time (Figure 1). Significant reductions were seen over 12 mos in swollen/tender joint counts and plaque psoriasis, with reduced mean (SD) body surface area of −4% (9%) (Table 1). Prevalence of dactylitis/enthesitis at BL, 4, 8, and 12 mos was 17%/33%, 9%/24%, 5%/19%, and 0%/21%, respectively. Pain assessment (VAS) significantly improved over time. The proportion of pts achieving PASS with continued APR increased significantly over 12 mos (BL: 27%; 12 mos: 65%) (Figure 1). COVID restrictions impacted in-office assessment visits, necessitating reliance on virtual visits.

Conclusion: Pts with PsA receiving APR were assessed at regular intervals in routine clinical care in Canada. This interim analysis revealed a greater number of pts receiving APR (66%) who completed the 12-mo follow-up achieved REM or LDA, as measured by cDAPSA over 12 mos. A majority of pts (85%) reported satisfaction with their disease state, as measured by PASS. No new safety signals were observed.

Table 1. Change in Clinical Parameters and Pt-Reported Outcomes From BL To 4, 8, and 12 Mos

<table>
<thead>
<tr>
<th>Outcome Measure*, Mean (SD)</th>
<th>BL (n = 101)</th>
<th>4 Mos (n = 92)</th>
<th>8 Mos (n = 61)</th>
<th>12 Mos (n = 35)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease/Clinical Parameters</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tender joint count (0-68)</td>
<td>7.5 (6.7)</td>
<td>−2.5 (6.3)*</td>
<td>−3.9 (5.2)*</td>
<td>−2.2 (6.4)</td>
</tr>
<tr>
<td>Swollen joint count (0-66)</td>
<td>5.4 (5.4)</td>
<td>−3.0 (4.5)*</td>
<td>−3.1 (4.3)</td>
<td>−3.1 (4.4)*</td>
</tr>
<tr>
<td>PhGA</td>
<td>42.9 (18.8)</td>
<td>−19.0 (24.6)*</td>
<td>−24.2 (24.2)*</td>
<td>−21.2 (26.3)*</td>
</tr>
<tr>
<td>Body surface area, %</td>
<td>3.1 (6.1)</td>
<td>−2.2 (6.6)*</td>
<td>−2.7 (7.5)*</td>
<td>−4.2 (9.1)*</td>
</tr>
<tr>
<td>cDAPSA</td>
<td>22.2 (13.3)</td>
<td>−7.9 (12.1)*</td>
<td>−10.1 (13.5)*</td>
<td>−6.9 (12.0)*</td>
</tr>
<tr>
<td>Pt-Reported Outcomes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PGA, mm</td>
<td>50.0 (24.6)</td>
<td>−10.2 (27.5)*</td>
<td>−9.1 (21.9)*</td>
<td>−3.6 (39.7)</td>
</tr>
<tr>
<td>Pain, mm</td>
<td>48.3 (25.3)</td>
<td>−9.8 (26.2)*</td>
<td>−12.2 (28.7)*</td>
<td>−7.3 (26.0)</td>
</tr>
<tr>
<td>HAQ-DI</td>
<td>0.9 (0.7)</td>
<td>−0.13 (0.5)*</td>
<td>−0.15 (0.6)</td>
<td>−0.1 (0.7)</td>
</tr>
</tbody>
</table>

*Denotes significant change from BL (P<0.05) from paired-sample t-tests; note that mean change from BL may be greater than the mean BL value when improvements of large magni- tude, for pts with relatively elevated BL values, are observed in samples with lower n’s.

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Background: COMPLETE-PsA was an observational study of biologic-naïve Canadian adults with active psoriatic arthritis (PsA) treated with adalimumab or non-biologic disease-modifying anti-rheumatic drugs (nbDMARD) after switch from initial therapy.

Objectives: The aim of this analysis was to assess the 24-month clinical effec- tiveness and safety of adalimumab vs. nbDMARD in the treatment of PsA in a real-life setting.

Methods: Eligible patients were biologic naïve adults, with active PsA who required change in their treatment regimen due to inadequate response or intolerance, per the judgment of the treating physician. Patients were enrolled between July/2011 and December/2017 and followed for up to 24 months. Patients were treated as per routine care. The primary endpoint, change in DAS28 to month 24, was assessed with baseline-adjusted multivariable mod- els and the least square mean (LSM) estimates were generated; Physician’s Global Assessment of disease activity (PGA, 100mm VAS) was assessed using similar methodology. Probability of achieving the following therapeutic response thresholds was ascertainment and odds ratios (ORs) were gener- ated: 50%/70% improvement in the American College of Rheumatology cri- teria (ACR50/ACR70), DAS28-3.2 (low disease activity or remission; LDA/ remission), DAS28≤2.6 (remission), modified minimal disease, modified DAS28 of 5/7 of: TJC and SJC ≤1 each, BSA ≤3%, pain ≤15 (VAS, mm), Patient Global Assessment [PGA] ≤20, HAQ-DI ≤0.5, and no enthesis, and psoriasis (PsO) BSA ≤3%.

Results: A total of 277 adalimumab and 148 nbDMARD- treated patients were included as part of the intent-to-treat population. Baseline methotrex- ate was reported by 61.7% and 81.1% of adalimumab and nbDMARD-treated patients, respectively. PsO BSA at baseline was predominantly <3% for both adalimumab (60.2%) and nbDMARD (64.6%) patients. Adalimumab-treated patients reported significantly (p<0.05) higher mean (SD) disease activity for both DAS-28 (4.8 (1.2) vs. 4.3 (1.1)) and PGA (59.4 (19.5) vs. 51.0 (21.8) mm) at baseline.

For the primary endpoint, baseline-adjusted month 24 DAS28 levels were signific- antly lower for adalimumab vs. nbDMARD patients [LSM (95%CI)]: 2.4 (2.2-2.6) vs. 3.0 (2.7-3.3); p<0.037. In addition, rapid and sustained reductions in DAS28 were observed for adalimumab-treatment patients, with overall treatment effect significant (p<0.001) in favor of adalimumab [estimate (95%CI)]: -1.1 (-1.4,-.7); similar results were observed for PGA [-12.9 (-17.1,-8.0)]. Adalimumab-treated patients were included as part of the intent-to-treat population. Baseline methotrexate was reported by 61.7% and 81.1% of adalimumab and nbDMARD-treated patients, respectively. PsO BSA at baseline was predominantly <3% for both adalimumab (60.2%) and nbDMARD (64.6%) patients. Adalimumab-treated patients reported significantly (p<0.05) higher mean (SD) disease activity for both DAS-28 (4.8 (1.2) vs. 4.3 (1.1)) and PGA (59.4 (19.5) vs. 51.0 (21.8) mm) at baseline.