was 26.3 (15.4) for UST and 23.5 (12.3) for TNFi; at 1-year follow-up, 43.5% of UST- and 43.6% of TNFi-treated patients reached cDAPSA LDA/remission. MDA was reached in 24.2% of UST- and 28.0% of TNFi-treated patients, and VLDA was in 12.5% of UST- and 10.2% of TNFi-treated patients. After PS adjustment (stoppers/switchers as non-responders), odds ratios (95% CI) at 1 year did not differ significantly between UST and TNFi groups for reaching cDAPSA LDA/remission (1.08 [0.54; 2.15]), MDA (0.96 [0.45; 2.05]) or VLDA (0.98 [0.35; 2.76]). In total, 23 (20.4%) patients reported ≥1 treatment emergent adverse event with UST and 30 (22.2%) with TNFi; 6 (5.3%) and 10 (7.4%) patients, respectively, discontinued treatment because of an adverse event.

Conclusion: In theItalian PsA cohort, UST had better overall persistence compared with TNFi, as well as in specific subgroups: females, patients on monotherapy without methotrexate, with BMI <25 or >30 kg/m², and patients receiving UST as 2nd-line treatment. At 1 year, both treatments showed similar effectiveness, as measured by cDAPSA responses and MDA/VLDA achievement.

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Table 1. Safety and efficacy outcomes up to 3 years

<table>
<thead>
<tr>
<th>Safety (SS)</th>
<th>Any TEAE</th>
<th>Serious TEAEs</th>
<th>Key TEAEs of special major concern</th>
<th>Malignancies</th>
<th>Injection site reactions</th>
<th>Surgical mortality</th>
<th>Liver function abnormalities</th>
<th>Study discontinuation due to TEAEs</th>
<th>Efficacy (FAS)</th>
<th>MDA, Wk 152</th>
<th>OLE NRI, %</th>
<th>MDA, Wk 152</th>
<th>OLE NRI, %</th>
<th>MDA, Wk 152</th>
<th>OLE NRI, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>BKK (n=126)</td>
<td>114 (90.5) [106.1]</td>
<td>17 (13.5) [12.2]</td>
<td>5 (4.0) [1.7]</td>
<td>1 (0.8) [0.3]</td>
<td>0</td>
<td>0</td>
<td>12 (9.5) [3.5]</td>
<td>4 (3.1) [1.8]</td>
<td>16 (7.8) [2.8]</td>
<td></td>
<td></td>
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<tr>
<td>BKZ (n=78)</td>
<td>106 (83.6) [94.6]</td>
<td>7 (9.5) [6.4]</td>
<td>3 (3.8) [1.4]</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>13 (10.3) [4.1]</td>
<td>1.1 (14) [5.3]</td>
<td>24 (14.7) [4.6]</td>
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</table>

No anaphylactic reactions or major adverse cardiac events were reported. aIncludes pts within the indicated analysis set specifically assigned to all arms who were subsequently re-randomized to 160mg, or [b] 320mg, after double-blind period. [c] Microscopic colitis; [d] Malignant melanoma in situ; [e] Pts with BL. BSA <33%; NRI: n=79, 58, 137 respectively; [f] Pts with BL <0; NRI: n=34, 25, 59 respectively; [g] Pts with BL MAE>0, NRI: n=45, 42, 107 respectively. LDLI: Leeds Dactylitis Index; MASES: Maastricht AS Enthesitis Score; OC: observed cases.
Conclusion: The safety profile of BKZ in pts with PsA reflects previous observations\textsuperscript{2} for up to 3 years. High threshold disease control was achieved by >50% of BKZ-treated pts up to 3 years, reflected in long-term improvements in joint and skin outcomes.

REFERENCES:

Figure. ACR50 responders up to 3 years

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Table 1. Overview of baseline characteristics in PsA patients depending on gender

Objectives: The aim of this interim analysis is to describe selected baseline (BL) demographics, to evaluate secukinumab treatment outcomes on disease activity, depressive mood and retention rate depending on the gender of PsA patients.

Methods: AQUILA is an ongoing, multi-center study including more than 3000 patients with active PsA or ankylosing spondylitis. Patients were observed from BL to week (w) 52. Real-world data was assessed prospectively and analyzed as observed. Data was collected on impact of disease (Psoriatic Arthritis Impact of Disease - 12 items, PsAID-12 score), skin disease activity (Psoriasis Area and Severity Index, PASI), joint counts and severity of depressive mood (Beck’s Depression Inventory version II, BDI-II), in addition to patient’s global assessment (PGA). Moreover, retention rates (time from study inclusion until premature secukinumab treatment discontinuation) were assessed through Kaplan-Meier plots. This interim analysis focuses on the subgroups of male and female PsA patients.

Results: At BL, 1278 PsA patients were included: 41.5% (n=531) male and 58.5% (n=747) female. Demographic data (Table 1) of male and female PsA patients differed most obviously regarding proportion of overweight patients, smokers, pretreatment with nonsteroidal anti-inflammatory drugs (NSAIDs) and biologicals/biosimilars (b-bsDMARDs).

Mean PsAID-12 values over time were higher in women; nevertheless, PsAID-12 improved comparably for both genders from BL to week 52 (♀: 4.8 at BL to 2.9 at w52, ∆: 5.3 at BL to 3.5 at w52, Figure 1A). This was similar to the course of improvements for mean PGA across genders (♂: 4.9 at BL to 3.0 at w52, ∆: 5.6 at BL to 1.5 at w52). In terms of PASI scores, both BL mean values and improvements over time were similar across genders (♀: 6.8 at BL to 1.9 at w52, ∆: 7.0 at BL to 1.0 at w52). Mean joint counts (tender/swollen) also improved similarly (∆: 6.8, 3.7 at BL to 3.1/0.9 at w52, ∆: 7.3/3.7 at BL to 2.8/0.9 at w52). Over time, male patients showed overall reduced BDI-II values; nevertheless, BDI-II reductions were comparable across the genders (∆: 10.2 at BL to 8.1 at w52, ∆: 13.0 at BL to 10.6 at w52). Secukinumab treatment retention rate for men was (not significantly) higher than for women (Figure 1B).

Conclusion: In a real-world setting, secukinumab improved disease activity and depressive mood of PsA patients in both men and women. Women showed overall all higher burden of disease. Altogether, this interim analysis shows that secukinumab is an effective treatment up to 52 weeks with high treatment retention rate depending on gender.

REFERENCES:

Impact of disease and treatment retention in PsA patients stratified by gender

Demographics* Male (N=531) Female (N=747)

Age, years 51.9 (11.6) 53.1 (11.2)
BMI, kg/m² 26.1 (5.2) 25.9 (5.4)
BMI >25 to ≤30 56.5% 56.5%
BMI >30 43.5% 43.5%
PsAID-12 4.8 (2.2) 4.8 (2.2)
PASI 4.9 (2.6) 4.9 (2.6)
Tender joint counts 6.8 (7.9) 6.8 (7.9)
Swollen joint counts 3.7 (5.3) 3.7 (5.3)
BSI 11.5 (3.0) 11.5 (3.0)
Medication prior to secukinumab:
NSAID 51.0% 51.0%
csDMARD 46.6% 46.6%
b-bDMARD 27.4% 27.4%

Table 1. Overview of baseline characteristics in PsA patients depending on gender

Note: P-values are of exploratory nature

Figure 1. Impact of disease and treatment retention in PsA patients stratified by gender

A) PsAID-12 (mean) B) Retention rate

Note: P-values are of exploratory nature

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