Table 1. The association between radiographic spinal progression (mSASSS change score) and NSAID intake in patients with axSpA in multivariable longitudinal GEE

<table>
<thead>
<tr>
<th>NSAID intake score, per 10 points</th>
<th>COX2i vs NS inhibitors</th>
<th>COX2i vs NS inhibitors</th>
<th>COX2i vs NS inhibitors</th>
<th>COX2i vs NS inhibitors</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSAID type</td>
<td>NS inhibitors vs NS NSAID 0.30 (0.07, 0.66)</td>
<td>0.25 (0.07, 0.57)</td>
<td>0.26 (0.40, 0.92)</td>
<td>0.20 (0.06, 0.33)</td>
</tr>
<tr>
<td>Non-selective NSAID intake score, per 10 points</td>
<td>0.06 (-0.12, 0.00)</td>
<td>-0.04 (-0.09, 0.01)</td>
<td>-0.07 (-0.17, 0.03)</td>
<td>-0.06 (-0.13, 0.00)</td>
</tr>
<tr>
<td>Analysis stratified according to NSAID type</td>
<td>0.06 (-0.13, 0.02)</td>
<td>-0.03 (-0.07, 0.02)</td>
<td>-0.09 (-0.18, 0.01)</td>
<td>-0.06 (-0.13, 0.00)</td>
</tr>
</tbody>
</table>

Conclusion: Higher NSAID intake is associated with lower radiographic spinal progression, particularly in r-axSpA patients. COX2i might possess a stronger inhibitory effect on radiographic progression as compared to NS-NSAIDs.

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OP0022 DISEASE ACTIVITY-GUIDED TAPERING OF BIOLOGICS IN PATIENTS WITH INFLAMMATORY ARTHRITIS: A RANDOMISED, OPEN-LABEL, EQUVALENTIAL TRAIAL

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A RANDOMIZED, DOUBLE-BLIND TRIAL COMPARING SECUKINUMAB 300 MG AND 150 MG AT WEEK 52 IN PATIENTS WITH ANKYLOSING SPONDYLITIS WHO DID NOT ACHIEVE INACTIVE DISEASE DURING AN INITIAL 16 WEEKS OF OPEN-LABEL TREATMENT WITH SECUKINUMAB 150 MG

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Background: Ankylosing spondylitis (AS) is a chronic, systemic inflammatory condition characterized by inflammatory back pain and is associated with extra-musculoskeletal manifestations and systemic comorbidities. Secukinumab (SEC) doses of 150 mg and 300 mg are approved to treat AS, although no dose escalation studies are available in patients who have inadequate response to SEC 150 mg.

Objectives: The ASLEAP study (NCT03350815) estimated the difference in clinical response to SEC 300 mg vs 150 mg at Week (Wk) 52 in patients with AS who failed to achieve Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease status on SEC 150 mg at Wk 16.

Methods: In this randomized, double-blind, parallel-group, multicenter, phase 4 study, 322 patients with AS were assigned to receive open-label SEC 150 mg administered per the label for 16 Wks (period 1). At Wk 16, patients who did not achieve inactive disease (ASDAS < 1.3) at Wks 12 and 16 were randomized 1:1 in a double-blind manner to SEC 150 mg or escalated to SEC 300 mg q4w to Wk 52 (period 2). The primary efficacy variable was achievement of ASDAS < 1.3 and the primary analysis time point was Wk 52. Secondary efficacy variables were achievement of ASDAS clinically important improvement ≥ 1.1, 50% improvement as measured by achievement of ASDAS < 1.3, ASDAS clinically important improvement ≥ 1.1, BASDAI50, ASAS20, ASAS40, and ASAS partial remission, and change from baseline in BASDAI, ASAS Health Index (ASAS-HI), and the Functional Assessment of Chronic Illness Therapy – Fatigue Scale (FACIT-F). Safety was evaluated by incidence of treatment-emergent adverse events (TEAEs) through Wk 52. No statistical hypothesis tests for superiority or equivalence were planned in the protocol and none were performed.

Results: Of 279 patients receiving SEC 150 mg who completed the 16-wk open-label period 1, 22 (79%) achieved ASDAS < 1.3 at Wks 12 or 16 and continued receiving SEC 150 mg; 207 patients did not attain ASDAS < 1.3 at Wk 12 and Wk 16 and initiated period 2. Demographics and baseline disease characteristics were balanced between patients randomized to SEC 150 mg and SEC 300 mg, including the proportion of patients who were TNFi naive (SEC 150 mg: 73 [72.3%]; SEC 300 mg: 73 [69.5%]) (Table 1). Approximately 60% of patients in either SEC group were HLA-B27 positive. After having an inadequate response to SEC 150 mg through Wk 16, patients receiving either dose of SEC experienced similar improvements at Wk 52 in disease activity as measured by achievement of ASDAS < 1.3, ASDAS clinically important improvement ≥ 1.1, BASDAI50, ASAS20, ASAS40, and ASAS partial remission; and mean changes in BASDAI, quality of life as measured by ASAS HI, and fatigue as measured by FACIT-F (Figure 1). The incidence of TEAEs through Wk 52 was similar between patients receiving SEC 300 mg (63.4%) and 150 mg (68.6%).