Conclusion: The 0-4 SQ grade was not equivalent to that of the 0-3 SQ grade used PD scoring and it increased the variance in the majority of SQ grades. This study shows that the PD pixel algorithm has a stronger linear correlation when compared to the SQ grading, suggesting a more accurate method at interpreting treatment response, as the intervals between grades are more equal. Therefore, built in algorithms to detect PD signal in US machines are the future for drug monitoring in inflammatory arthritis.

REFERENCES:


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Late breaking abstract session

LB0003

EFFICACY AND SAFETY OF FILGOTINIB FOR PATIENTS WITH RHEUMATOID ARTHRITIS NAIVE TO METOTREXATE THERAPY: FINCH3 PRIMARY OUTCOME RESULTS

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Background: Filgotinib (FIL), an orally administered, potent, selective inhibitor of Janus kinase 1 (JAK1), has shown good efficacy and was well tolerated for treatment of rheumatoid arthritis (RA).

Objectives: To compare efficacy and safety of FIL with and without methotrexate (MTX) in patients with RA who were naïve to MTX therapy.

Methods: This phase 3, double-blind, active-controlled study randomized patients with moderately to severely active RA (2:1:1:2) to FIL 200mg daily + MTX weekly (up to 20mg), FIL 100mg + MTX, FIL 200mg (+placebo [PBO]), or MTX (+PBO) for up to 52 weeks; results through week 24 are presented. Primary efficacy endpoint was proportion of patients achieving ACR20 response at week 24; additional assessments included ACR50 and ACR70 responses; DAS28-CRP score ≤3.2 and <2.6, and changes in van der Heijde mTSS, HAQ-DI, SF-36 PCS, and FACIT-Fatigue. Safety endpoints included types and rates of adverse events (AEs). Logistic regression adjusting for stratification factors with nonresponder imputation was used for treatment comparisons for ACR response and other binary endpoints. Mixed-effect model adjusting for baseline value, stratification factors, treatment, visit, and treatment by visit interaction as fixed effects with observed cases was used for continuous endpoints.

Results: Of 1,252 randomized patients, 1,249 received study drug (416 FIL 200mg+MTX; 207 FIL 100mg+MTX; 210 FIL 200mg monotherapy; 416 MTX monotherapy) and were analyzed; 1,130 completed week 24. Most (76.9%) were female; mean time since RA diagnosis was 2.2 years (median 0.4 years); mean (standard deviation [SD]) DAS28-CRP was 5.7 (1.0); and 35.9% were using oral steroids at baseline. At week 24, significantly more patients in the FIL 200mg +MTX (81.0%; P<0.001) and FIL 100mg+MTX (80.2%; P<0.05) arms achieved an ACR20 response compared to MTX monotherapy (71.4%)(Table 1). Compared to MTX monotherapy, more patients receiving FIL with or without MTX achieved ACR25, ACR50, ACR70, and ACR90 responses.

Table 1. Efficacy Outcomes at Week 24

<table>
<thead>
<tr>
<th>FIL 200 mg + MTX</th>
<th>FIL 100 mg + MTX</th>
<th>FIL 200 mg monotherapy</th>
<th>MTX monotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR20, %</td>
<td>81.0</td>
<td>80.2</td>
<td>78.1</td>
</tr>
<tr>
<td>ACR50, %</td>
<td>65.5</td>
<td>57.0</td>
<td>51.8</td>
</tr>
<tr>
<td>ACR70, %</td>
<td>43.2</td>
<td>40.1</td>
<td>40.7</td>
</tr>
<tr>
<td>DAS28-32 %</td>
<td>56.9</td>
<td>62.0</td>
<td>62.9</td>
</tr>
<tr>
<td>DAS28 CRP &lt;2.6, %</td>
<td>54.1</td>
<td>62.5</td>
<td>62.4</td>
</tr>
<tr>
<td>mTSS, mean change from BL</td>
<td>0.20</td>
<td>0.22</td>
<td>–0.04</td>
</tr>
<tr>
<td>HAQ-DI, mean change from BL</td>
<td>–0.94**</td>
<td>–0.90</td>
<td>–0.09</td>
</tr>
<tr>
<td>SF-36 PCS, mean change from BL</td>
<td>12.3**</td>
<td>11.1*</td>
<td>10.4</td>
</tr>
<tr>
<td>FACIT-Fatigue, mean change from BL</td>
<td>10.6</td>
<td>11.4</td>
<td>10.2</td>
</tr>
</tbody>
</table>

*All patients who were randomized and received at least 1 dose of study drug; data were included in efficacy analyses.
+P<0.05 vs MTX monotherapy; **P<0.01 vs MTX monotherapy; ***P<0.001 vs MTX monotherapy; *Comparison not adjusted for multiplicity.

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ACR50 and ACR70 responses, DSAS2-CRP >2.6 and ≤3.2, and reported improvements in SF-36 PCS (Table 1). The onset of activity was rapid, with significantly more patients achieving ACR50 and DSAS2-CRP >2.6 with Fil than MTX at week 2. The Fil safety profile was consistent with prior studies through week 24 (Table 2).

Conclusion: The JAK1 inhibitor Fil in combination with MTX led to significant improvements in RA signs and symptoms, physical function, and patient-reported outcomes compared to MTX alone and was well tolerated in patients with early active RA naïve to MTX. Clinically meaningful response to Fil occurred as early as 2 weeks after treatment initiation.

Background: There have been few head-to-head clinical trials comparing different biologic disease-modifying anti-rheumatic drugs (bDMARDs) in patients (pts) with psoriatic arthritis (PsA).

Objectives: To report 24-week (wk) results of a study directly comparing efficacy and safety of ixekizumab (IXE), an IL-17A inhibitor, and adalimumab (ADA), a TNF inhibitor, in bDMARD-naive pts with PsA.

Methods: The study (NCT03151551; SPIRIT-H2H) included pts with active PsA and inadequate responders to csDMARD therapy. Patients were randomised (1:1) to IXE or ADA for 52 wks (on-label dosing based on presence/absence of moderate to severe psoriasis). The primary objective was superiority of IXE vs ADA measured by the proportion of pts achieving both ACR50 and PASI100 responses at wk 24. Key secondary objectives were ACR50 response at wk 24 (≥35% improvement in 6 tender joint counts, 6 swollen joint counts, patient global assessment of disease activity, and patient global assessment of pain) and PASI100 response at wk 24 (≥90% improvement in PASI and psoriasis-related quality of life). Continuous variables were analysed using mixed models for ITT population. Categorical variables were evaluated using logistic regression analyses with NRI in the treatment model.

Results: 566 pts were randomised (283 to IXE and 283 to ADA). All primary and key secondary efficacy endpoints at wk 24 were better with IXE vs ADA for skin and composite T2T outcomes, enthesitis resolution (Figure 1), and skin-related quality of life (Table 2). No unexpected safety signals were observed.

Conclusion: In bDMARD naive pts with active PsA and skin disease, IXE showed superior efficacy to ADA based on simultaneous achievement of ACR50 and PASI100 responses at wk 24. Better improvements with IXE vs ADA were also attained in individual PsA domains and composite T2T outcomes.