Introduction

Rheumatoid Arthritis (RA) is an autoimmune disorder characterized by progressive inflammation and joint damage.

Treatment of active disease includes the appropriate use of disease-modifying anti-rheumatic drugs (DMARDs), usually started concurrently with corticosteroids (CS).

Significant improvement in RA outcomes is associated with monotherapy, but low CS is often needed, and increasing CS doses are associated with increased risk of drug-related side effects.

The objective of this study was to evaluate the outcomes of patients treated with a new DMARD, Furst (ACT_CSS_POS_RA), in a randomized clinical trial with a double-blind, placebo-controlled, parallel group design.

Methods

With RA defined as Disease Activity Score with 28 Joint Count score (DAS28) > 4.2, patients were randomized to receive Furst or placebo. Safety data was collected during the study.

Statistical analyses were conducted by combining mean change from baseline using one-sample t-tests.

Results (cont’d)

Figure 3. Improvement in PROs (HAQ-DI, FACIT-F, and Patient’s Global Assessment of Pain) from the 12-Week Open-label RCI Treatment Period (mITT Population)

Figure 4. Improvement in PROs (WPA Questionnaire) from the 12-Week Open-label RCI Treatment Period (mITT Population)

Results (cont’d)

Table 1. Baseline Demographics and PROs (mITT Population)

Table: Baseline Demographics and PROs (mITT Population)

Results

- 30% of patients achieved the modified intermediate-low disease activity level (mITT); 80% were stable and 96% were DAS28-CRP < 3.2.
- Disease activity and PROs improved significantly in Furst-treated patients compared to placebo.

<table>
<thead>
<tr>
<th>Week</th>
<th>HAQ-DI</th>
<th>FACIT-F</th>
<th>Patient’s Global Assessment of Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 2</td>
<td>p=0.01</td>
<td>p=0.01</td>
<td>p=0.01</td>
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<tr>
<td>Week 4</td>
<td>p=0.01</td>
<td>p=0.01</td>
<td>p=0.01</td>
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<td>Week 6</td>
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<td>p=0.01</td>
<td>p=0.01</td>
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<tr>
<td>Week 8</td>
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<td>p=0.01</td>
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<tr>
<td>Week 12</td>
<td>p=0.01</td>
<td>p=0.01</td>
<td>p=0.01</td>
</tr>
</tbody>
</table>

Conclusions

- Furst (ACT_CSS_POS_RA) significantly improved disease activity and PROs compared to placebo in patients with active RA.
- Patients treated with Furst had significantly improved PROs compared to placebo, indicating improved quality of life.

References


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Disclosures

None.