Patient-Reported Outcomes With Etanercept Therapy in Patients With Plaque Psoriasis Who Lost Response to Adalimumab

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Disclosures

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Come to our presentation and learn about the results of this study, which was recently published in the Journal of Investigative Dermatology. The study aimed to evaluate the effectiveness of etanercept therapy in patients with plaque psoriasis who had lost response to adalimumab. The results showed that etanercept was effective in improving patient-reported outcomes, with a significant improvement in the mean change in PASI 10 and DLI 10 scores. Additionally, the study found that etanercept was well-tolerated, with a low incidence of adverse events. The conclusions of the study suggest that etanercept may be a promising treatment option for patients with plaque psoriasis who have lost response to adalimumab. We look forward to discussing the findings of this study with you during our presentation.
Background

- Patients with psoriasis suffer significant social, psychological, and emotional burdens\(^1,2\)
- Clinical improvement in psoriasis symptoms with effective treatment can reverse many of the effects of psoriasis on health-related quality of life\(^3,4\)
- The tumor necrosis factor inhibitors adalimumab and etanercept are indicated for the treatment of moderate to severe plaque psoriasis
- Loss of response to adalimumab may be caused by the development of anti-adalimumab antibodies, which has been reported in up to 49% of patients\(^5-9\)
- Few studies have examined the use of etanercept in patients who have lost a satisfactory response to adalimumab

In this study, we examined efficacy of etanercept therapy in patients with secondary failure of adalimumab:
- 39.7% (95% CI: 27.6%–52.8%) achieved sPGA clear/almost clear at week 12

Response to etanercept was not affected by the presence of anti-adalimumab antibodies

We now present patient-reported outcomes in patients with secondary adalimumab failure who were subsequently treated with etanercept

CI, confidence interval; sPGA, static physician global assessment
Objective

• To evaluate the effects of etanercept on patient-reported outcomes in patients with moderate to severe plaque psoriasis who experienced secondary failure after an initial adequate response to adalimumab
Methods

Study Design

• Phase 4, open-label, single-arm, estimation study
• 45-day screening period, 24-week treatment period, 30-day follow-up after last dose of etanercept
• Patients on adalimumab at screening completed a 2-week washout before receipt of first dose of etanercept
• All patients received etanercept 50 mg twice weekly administered subcutaneously for 12 weeks followed by 50 mg once weekly for an additional 12 weeks
• ClinicalTrials.gov #NCT01543204
Methods (Cont.)

**Patient Eligibility Criteria**

- Patients were adults (≥ 18 years of age) and were receiving adalimumab or had discontinued adalimumab within 6 months before screening
- Previous response to adalimumab was defined as sPGA clear/almost clear (score 0/1)
  - In the absence of an sPGA measurement, a PASI 75 response or 75% improvement in psoriasis-affected body surface area (BSA) in response to adalimumab was acceptable
- Loss of response to adalimumab was defined as: sPGA score ≥ 3 (moderate or worse) or loss of PASI 50 response or equivalent
- At baseline, patients were ≥ 18 years of age and had sPGA ≥ 3, PASI score ≥ 10, and involved BSA ≥ 10%

BSA, body surface area; PASI, Psoriasis Area and Severity Index; PASI 50/75, 50%/75% improvement in PASI score; sPGA, static physician global assessment
Methods (Cont.)

Endpoints

• Patient assessments of itch, pain, and flaking
  – Visual analog scale = 0 (none) to 10 (worst)

• Dermatology Life Quality Index (DLQI)
  – Scale = 0 (no effect) to 30 (extremely large effect)

• Treatment satisfaction
  – Options = very dissatisfied, dissatisfied, neither satisfied nor dissatisfied, satisfied, very satisfied

• Work Productivity and Activity Impairment (WPAI) Questionnaire
  – Measures % time or % impairment for presenteeism (attending work while ill because of psoriasis), absenteeism, work productivity loss, and activity impairment
  – Only employed patients were administered work-related items
Methods (Cont.)

Statistical Considerations

• Data were analyzed as observed, with no imputation for missing data
## Results

### Demographics and Clinical Characteristics at Baseline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients (N = 64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean years (SD)</td>
<td>46.0 (12.4)</td>
</tr>
<tr>
<td>Sex, n male (%)</td>
<td>40 (62.5)</td>
</tr>
<tr>
<td>Race, n white (%)</td>
<td>53 (82.5)</td>
</tr>
<tr>
<td>Duration of psoriasis, mean years (SD)</td>
<td>15.4 (10.2)</td>
</tr>
<tr>
<td>Comorbid psoriatic arthritis, n (%)</td>
<td>19 (29.7)</td>
</tr>
<tr>
<td>Anti-adalimumab antibodies, n (%)</td>
<td>43 (67.2)</td>
</tr>
<tr>
<td>sPGA score, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>0/1/2</td>
<td>64 (100)</td>
</tr>
<tr>
<td>3/4</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td></td>
</tr>
<tr>
<td>PASI, mean score (SD)</td>
<td>16.8 (6.9)</td>
</tr>
<tr>
<td>Psoriasis-affected BSA, mean % (SD)</td>
<td>20.9 (16.0)</td>
</tr>
</tbody>
</table>

BSA, body surface area; PASI, Psoriasis Area and Severity Index; SD, standard deviation; sPGA, static physician global assessment
## Results

**Patient-Reported Outcomes at Baseline**

<table>
<thead>
<tr>
<th>Patient assessment, mean score (SD)</th>
<th>All Patients (N = 64)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Itch</td>
<td>6.5 (2.5)</td>
</tr>
<tr>
<td>Pain</td>
<td>5.0 (3.1)</td>
</tr>
<tr>
<td>Flaking</td>
<td>7.0 (2.3)</td>
</tr>
<tr>
<td>DLQI, mean score (SD)</td>
<td>12.7 (6.7)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient treatment satisfaction, n/N1 (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Very dissatisfied</td>
<td>24/62 (38.7)</td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>14/62 (22.6)</td>
</tr>
<tr>
<td>Neither satisfied nor dissatisfied</td>
<td>20/62 (32.3)</td>
</tr>
<tr>
<td>Satisfied</td>
<td>2/62 (3.2)</td>
</tr>
<tr>
<td>Very satisfied</td>
<td>2/62 (3.2)</td>
</tr>
</tbody>
</table>

| WPAI, mean (SD)                         | |
| Absenteeism (% time)                    | 2.1 (6.8)                |
| Presenteeism (% time)                   | 24.8 (26.1)              |
| Work productivity loss (% time)         | 23.3 (26.9)              |
| Daily activity impairment (% impairment)| 36.0 (31.8)              |

- At baseline:
  - Patients reported moderate severity of itch, pain, and flaking
  - Effects of psoriasis on quality of life were moderate
  - Most patients were dissatisfied or very dissatisfied with treatment
  - Moderate rates of presenteeism and loss of productivity at work were reported by employed patients
  - Patients reported impairment in daily activities

DLQI, Dermatology Life Quality Index; n, number of patients with result; N1, number of patients with data available; SD, standard deviation; WPAI, Work Productivity and Activity Impairment
**Results**

**Patient Assessments of Itch, Pain, and Flaking**

- **Itch**
  - Patient assessments of itch decreased by 56.6% from baseline to week 12.
- **Pain**
  - Patient assessments of pain decreased by 59.1% from baseline to week 12.
- **Flaking**
  - Patient assessments of flaking decreased by 57.0% from baseline to week 12.
  - Improvements in patient assessments of itch, pain, and flaking were maintained through week 24.
Results

Changes in DLQI

- Mean DLQI total scores decreased by 30.3% from baseline to week 12
- Improvements in DLQI were maintained through week 24

CI, confidence interval; DLQI, Dermatology Life Quality Index
Results

Treatment Satisfaction

- At baseline, only 6.4% of patients were satisfied or very satisfied with treatment; at weeks 12 and 24, nearly 2/3 of patients were satisfied or very satisfied with etanercept treatment.
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**Results**

**Changes in WPAI**

**Absenteeism**

**Presenteeism**

**Work Productivity Loss**

**Activity Impairment**

- In working patients, presenteeism and work productivity loss improved from baseline to week 12, and improvements were maintained through week 24; absenteeism was low throughout the study.
- Across all patients, activity impairment improved from baseline to week 12 and improvements were maintained through week 24.

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*a* Only employed patients were included in the work-related outcomes

WPAI, Work Productivity and Activity Impairment; CI, confidence interval
Conclusions

- Patients with moderate to severe plaque psoriasis who had secondary failure of adalimumab reported benefits from subsequent etanercept therapy
- Improvements in itch, pain, flaking, treatment satisfaction, DLQI, work productivity (including presenteeism and work productivity loss), and activity impairment were observed with etanercept therapy