Adalimumab Improves Health-Related Quality of Life (HRQoL) in Patients with Moderate to Severe Hidradenitis Suppurativa (HS): Results from the First 12 Weeks of PIONEER II

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**BACKGROUND**

- Hidradenitis Suppurativa (HS)/Acne Inversa, is an inflammatory skin disease characterized by recurrent, painful abscesses and nodules that may lead to physical debilitation and depression.¹,²
- Currently there are no approved pharmaceutical treatments for HS.
- Recent data indicate that tumor necrosis factor-alpha (TNFα) blockage is of benefit to patients with HS.³,⁴
- Using the Dermatology Life Quality Index (DLQI) among other assessments, a large impact of HS on a patient’s quality of life has been documented.⁵–⁷
- The current study, PIONEER II, is a randomized, placebo (PBO)-controlled trial of adalimumab (ADA) treatment in patients with moderate to severe HS.

**OBJECTIVE**

- The objective of this study was to assess the effect of ADA treatment compared with PBO on health-related quality of life (HRQoL) in patients with moderate to severe HS.
METHODS

Study Design

- Patients were randomly assigned (in a 1:1 ratio) to receive ADA 40 mg every week or PBO. ADA was administered as a subcutaneous injection, 160 mg at Week 0, 80 mg at Week 2, and 40 mg weekly starting from Week 4 (Figure 1).
- The results described in this poster encompass Period A of PIONEER II.

Figure 1. Study Design

* Starting at Week 4 following 160 mg at Week 0, 80 mg at Week 2. This analysis encompasses Period A. Abbreviation: ADA, adalimumab.
METHODS (CONTINUED)

Patients

• Eligibility for study participation included the following: adult men and women who were anti-TNFα-naïve, diagnosed with HS for ≥1 year prior to baseline, and had an inadequate response to a trial of oral antibiotics for the treatment of HS. Patients had a total abscess and inflammatory nodule (AN) count of ≥3. HS lesions were to be present in ≥2 body areas, one of which was Hurley Stage II or III.8

• Exclusion from study participation included prior treatment with anti-TNFα; other active skin disease that could interfere with assessment of HS; and draining fistula count of >20 at baseline.

• Concomitant use of oral antibiotic therapy (doxycycline or minocycline) for the treatment of HS is allowed provided the dosing regimen has been stable for at least 28 days prior to Baseline and the regimen must remain stable throughout study participation.

HRQoL Measures

• DLQI
  – The DLQI was used to assess the symptoms and the impact of skin problems on quality of life
  – The DLQI can be used to evaluate six areas: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Subjects will be asked to respond to the 10 items of the DLQI based on a recall period of ‘the last week’.9
  – Higher DLQI score is associated with greater impairment in dermatology-specific quality of life.

• EQ-5D
  – Standardized generic measure of health status comprised of the following five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.10
  – Index score ranges from 0–1, where a score of 0 indicates the patient has health-related problems that interfere with daily activities and a score of 1 indicates the patient has no problems performing daily activities.
  – Visual analog scale (VAS) ranges from 0–100 where 0 represents the worst imaginable health state and 100 the best imaginable health state.
  – Lower index and VAS scores indicate a greater impact on HRQoL.

Data Analyses

• All HRQoL comparisons between adalimumab and placebo were assessed separately using analysis of covariance controlling for Hurley Stage, baseline score, and use of antibiotics.

• The proportion of subjects achieving a minimally clinically important difference in DLQI (5 point change) was also examined
RESULTS

Study Population

- 326 patients were randomly assigned to ADA weekly or PBO in Period A (ITT_A population), (Figure 1).

- Of the 326 patients in the ITT_A Population, the majority were female (67.8%) and white (83.7%). The mean age of patients was 35.5 years. Patients had HS for an average of 11.5 years, and had a mean AN count of 11.3 (Table 1).

- There were no significant differences between PBO and ADA weekly in the HRQoL measures at baseline.

  – At baseline, the disease burden of HS had a large impact on the HRQoL scores in both DLQI (14.5 [7.49]), EQ-5D (0.5 [0.35]) and VAS (58.7 [23.25]).

Table 1. Patient Demographics and Baseline Characteristics (ITT_A Population)

<table>
<thead>
<tr>
<th></th>
<th>Total N=326</th>
<th>PBO (N=163)</th>
<th>ADA Weekly (N=163)</th>
<th>P-Value PBO vs ADA Weeklya</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>221 (67.8)</td>
<td>113 (69.3)</td>
<td>108 (66.3)</td>
<td>0.636</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>105 (32.2)</td>
<td>50 (30.7)</td>
<td>55 (33.7)</td>
<td></td>
</tr>
<tr>
<td>Whiteb, n (%)</td>
<td>273 (83.7)</td>
<td>130 (79.8)</td>
<td>143 (87.7)</td>
<td>0.071</td>
</tr>
<tr>
<td>Black, n (%)</td>
<td>29 (8.9)</td>
<td>20 (12.3)</td>
<td>9 (5.5)</td>
<td></td>
</tr>
<tr>
<td>Age, years; mean [SD]</td>
<td>35.5 [11.13]</td>
<td>36.1 [12.18]</td>
<td>34.9 [9.96]</td>
<td>0.299</td>
</tr>
<tr>
<td>Hurley Stage IIa, n (%)</td>
<td>175 (53.7)</td>
<td>89 (54.6)</td>
<td>86 (52.8)</td>
<td>0.739</td>
</tr>
<tr>
<td>Hurley Stage IIIa, n (%)</td>
<td>151 (46.3)</td>
<td>74 (45.4)</td>
<td>77 (47.2)</td>
<td></td>
</tr>
<tr>
<td>Disease duration, years; mean [SD]</td>
<td>11.5 [9.03]</td>
<td>11.8 [9.41]</td>
<td>11.3 [8.66]</td>
<td>0.564</td>
</tr>
<tr>
<td>AN count; mean [SD]</td>
<td>11.3 [9.68]</td>
<td>11.9 [11.02]</td>
<td>10.7 [8.10]</td>
<td>0.255</td>
</tr>
<tr>
<td>Modified Sartorius Score; mean [SD]</td>
<td>115.0 [84.32]</td>
<td>122.6 [88.00]</td>
<td>107.5 [80.03]</td>
<td>0.106</td>
</tr>
<tr>
<td>Current smokersc, n (%)</td>
<td>214 (65.8)</td>
<td>109 (67.3)</td>
<td>105 (64.4)</td>
<td>0.64</td>
</tr>
<tr>
<td>EQ-5D; mean [SD]</td>
<td>n=320 0.5 [0.35]</td>
<td>n=160 0.5 [0.36]</td>
<td>n=160 0.6 [0.330]</td>
<td>0.102</td>
</tr>
<tr>
<td>EQ-5D VAS; mean [SD]</td>
<td>n=315 58.7 [23.25]</td>
<td>n=158 58.3 [23.07]</td>
<td>n=157 59.2 [23.50]</td>
<td>0.728</td>
</tr>
</tbody>
</table>

Abbreviations: PBO, placebo; ADA, adalimumab; AN, abscess and inflammatory nodule; NRS, numeric rating scale for pain; DLQI, Dermatology Life Quality Index; VAS, Visual Analogue Scale

a: P-value for differences between treatment groups was based on chi-square test or Fisher’s exact test for categorical variables and one way anova test for continuous variables.

b: Non-white races were combined for analysis of race.

b: Ex-users of nicotine and non-users of nicotine were combined for analysis of nicotine.
RESULTS (CONTINUED)

DLQI

- By Week 12, patients in the ADA group had a significantly \((P < .001)\) greater improvement in DLQI score compared with those in the PBO group (Figure 2).
- Clinically meaningful improvements in the DLQI were observed as early as Week 4.

Figure 2a: Reduction in DLQI From Baseline to Week 12*

Figure 2b: Proportion of Subjects with a MCID in DLQI Score From Baseline to Week 12

*Week 12 imputation method used was LOCF. \(P\)-values were calculated from ANCOVA with stratum (baseline Hurley stage and antibiotics use), baseline value and treatment in the model.
†\(P < .001\).
SD, standard deviation.
RESULTS (CONTINUED)

**EQ-5D**

- By week 12, patients in the ADA group reported greater improvement in overall health status, as shown by significantly ($P < .001$) greater increases in EQ-5D index and VAS scores, compared with patients in the PBO group (Figure 3).

*Figure 3: Change in EQ-5D from Baseline to Week 12*

*Week 12 imputation method used was Last Observation Carried Forward (LOCF). P-values were calculated from ANCOVA with stratum (baseline hurley stage and antibiotics use), baseline value and treatment in the model.

†$P < .001$.

SD, standard deviation
CONCLUSION

• Overall, ADA-treated patients had significantly greater improvements in quality of life compared with PBO-treated patients, including:
  – Clinically and statistically significant improvements in skin-related quality of life as measured by the DLQI, and
  – Overall health status as measured by both EQ-5D and the EQ-5D VAS

REFERENCES


DEDICATION

The authors would like to dedicate this poster to Parvez Mulani.

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