Quality of Life and Acne Severity in the Post-treatment Period of an Open-Label Study Evaluating Lidose-Iso Retinoid Without Food for Treatment of Recalcitrant Acne

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BACKGROUND

• Severe recalcitrant nodular acne is known to have a significant adverse effect on quality of life (QoL).
• Isotretinoin treatment for nodular acne greatly improves patients’ QoL, and requires administration alongside a high-fat meal to achieve optimal absorption.
• Noncompliance with the food intake requirements can potentially compromise the long-term efficacy of isotretinoin therapy.
• Absorption of lidose-isotretinoin is less dependent on the amount and/or type of food than conventional isotretinoin, so it does not need to be taken with food.
• In a phase 4, single-arm study of lidose-isotretinoin taken without food (NCT01492570), a total cumulative dose of 120–150 mg/kg demonstrated clinical efficacy, reducing lesion counts and Investigator’s Global Assessment (IGA) scores. This dose also improved patients’ QoL assessments during the active treatment period (ATP) from baseline to end of treatment (EOT; Week 20).

OBJECTIVE

• To evaluate long-term efficacy and patients’ QoL during the 104-week post-treatment period (PTP) of the aforementioned phase 4 trial of lidose-isotretinoin taken without food for treatment of severe acne.

METHODS

• This was a phase 4, multicenter, open-label, single-arm study conducted in the United States in patients with severe nodular acne. Patients enrolled in an initial 20-week ATP of lidose-isotretinoin followed by a 104-week PTP to monitor maintenance of efficacy and QoL results.

Figure 1. Study Design

RESULTS

• A total of 201 patients were enrolled in the study at 21 sites; 197 make up the ITT population.
• Baseline demographics and disease characteristics are presented in Tables 1 and 2, respectively.
• Of the 197 patients in the ITT population, 163 completed an EOT assessment; 119 patients completed an assessment at the final visit (124 weeks; Figure 2).
• Mean (standard deviation) [SD] total lesion counts were significantly reduced from baseline (73.9 [46.1]) to EOT (8.4 [13.2]; P<0.001); this improvement was maintained during the PTP (EOT 12.5 [18.0]; P<0.001 vs baseline).
• Female patients of childbearing potential were required to use 2 forms of effective contraception simultaneously for 1 month before study entry, during study, and for 1 month after stopping study medication or to commit to continuous abstinence from heterosexual intercourse.

Table 1. Baseline Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All Patients Enrolled [N=201]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Male (125 [62.2])</td>
</tr>
<tr>
<td>Age, y</td>
<td>19–35 [27.8]</td>
</tr>
<tr>
<td>Range</td>
<td>12–45</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td>American Indian or Alaska native (3 [1.5])</td>
</tr>
<tr>
<td></td>
<td>Asian (8 [4.0])</td>
</tr>
<tr>
<td></td>
<td>Black or African American (17 [8.5])</td>
</tr>
<tr>
<td></td>
<td>Multiple (1 [0.5])</td>
</tr>
<tr>
<td></td>
<td>Native Hawaiian or other Pacific islander (1 [0.5])</td>
</tr>
<tr>
<td></td>
<td>White (167 [83.1])</td>
</tr>
<tr>
<td>Ethnicity, n (%)</td>
<td>Hispanic or Latino (31 [15.4])</td>
</tr>
<tr>
<td></td>
<td>SD, standard deviation</td>
</tr>
</tbody>
</table>

Table 2. Baseline Characteristics (ITT Population)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>ITT Population [N=197]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of inflammatory lesions</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Number of noninflammatory lesions</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>IGA score</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td></td>
<td>33.8 (17.0)</td>
</tr>
<tr>
<td></td>
<td>40.1 (41.3)</td>
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<tr>
<td></td>
<td>4.2 (0.5)</td>
</tr>
</tbody>
</table>

Figure 2. Patient Disposition

Example}

<One patient discontinued treatment because of an AE on Day 112. The patient was withdrawn from all evaluation on Day 101, because of gastrointestinal symptoms and severe constipation, which were the reasons for discontinuation and death, respectively, of a new case from the study. Completed-case population describes data points for the intention-to-treat population within the active treatment period and post-treatment period, respectively. EOT, end of treatment; EOS, end of study; QoL, quality of life; SD, standard deviation.

Figure 3. Lesion Counts at Each Visit

Example}

<Mean (SD) counts of inflammatory and noninflammatory lesions were reduced from baseline to EOT (P<0.001) and were sustained to EOS (P<0.001 vs baseline).

Figure 4. IGA Scores at Each Visit

Example}

<Mean (SD) IGA score reduced from baseline (4.2 [0.5]) to EOT (1.1 [1.1]; P<0.001), which was sustained to EOS (1.2 [1.5]; P<0.001).

Figure 5. Acne-QoL Scores at Each Visit

Example}

<Mean (SD) Acne-QoL score from baseline to EOT (baseline 61.5 [28.4]; EOT 99.2 [19.8]; P<0.001), which was sustained for all visits in the PTP (EOT 103.2 [17.5]; EOS 101.1 [20.0]; P<0.001).

Figure 6. Acne-QoL Domain Scores at Each Visit and at EOT and EOS

Example}

<Mean (SD) Acne-QoL scores were significant on baseline, EOS, and at EOT and EOS, respectively; EOS, end of study; EOT, end of treatment; SD, standard deviation.

CONCLUSIONS

• Two-dose daily of lidose-isotretinoin administered without food decreased mean lesion counts and mean IGA scores between baseline and EOT, and this decrement was sustained to EOS, demonstrating long-term efficacy of the dosage regimen.
• Patients’ QoL improved over the 20-week ATP in all 4 domains and in total, with improvements maintained throughout the 104-week PTP.

<Improvements seen as early as Week 4 in the ATP were maintained for the remaining 120-week monitoring period.

REFERENCES


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DISCLOSURES

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