Efficacy and Safety of Povorcinib for Extensive Vitiligo: Results From a Double-Blinded, Placebo-Controlled, Dose-Ranging Phase 2b Study

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Presenting Author Disclosures

• Investigator for Aclaris Therapeutics, Immune Tolerance Network, Incyte, and Pfizer
• Consultant for AbbVie, Arcutis, Avita Medical, Chromaderm, Immune Tolerance Network, Incyte, Pfizer, TWi, Viela Bio, and Villaris
• Holds stock options for Tara Medical and Zerigo Health
Vitiligo is a chronic autoimmune disease that targets melanocytes, resulting in patches of skin depigmentation\(^1\)

Disease pathogenesis is largely regulated by interferon-γ activation of the JAK signaling pathway\(^2\)

Povorcinib is an oral, small-molecule, selective JAK1 inhibitor with potential activity in the treatment of nonsegmental vitiligo

Objective: To evaluate the efficacy and safety of povorcinib in patients with extensive nonsegmental vitiligo in a phase 2b trial (NCT04818346)

JAK, Janus kinase.
Study Design (NCT04818346)

Patient population:
- Adults 18–75 years old
- Nonsegmental vitiligo
- Vitiligo-affected BSA*:
  - Total body ≥8%
  - Face ≥0.5%
- VASI score:
  - T-VASI ≥8
  - F-VASI ≥0.5

Efficacy assessments:
- % change from baseline in T-VASI†
- % patients achieving T-VASI50, F-VASI50, and F-VASI75

Safety assessments:
Incidence of TEAEs

BSA, body surface area; F-VASI, facial VASI; F-VASI50/75, ≥50%/≥75% reduction from baseline in F-VASI; qd, once daily; TEAE, treatment-emergent adverse event; T-VASI, total VASI; T-VASI50, ≥50% reduction from baseline in T-VASI; VASI, Vitiligo Area Scoring Index.

* Total and facial BSA were locally assessed. † Week 24 assessment was the primary endpoint.
## Patient Demographics and Clinical Characteristics at Baseline

### Table: Patient Demographics and Clinical Characteristics at Baseline

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Placebo (n=43)</th>
<th>15 mg (n=43)</th>
<th>45 mg (n=43)</th>
<th>75 mg (n=42)</th>
<th>Total (N=171)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, median (range), y</strong></td>
<td>51.0 (24–72)</td>
<td>45.0 (23–67)</td>
<td>51.0 (25–72)</td>
<td>52.5 (24–74)</td>
<td>50.0 (23–74)</td>
</tr>
<tr>
<td><strong>Female, n (%)</strong></td>
<td>24 (55.8)</td>
<td>29 (67.4)</td>
<td>21 (48.8)</td>
<td>19 (45.2)</td>
<td>93 (54.4)</td>
</tr>
<tr>
<td><strong>Race, n (%)</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>White</td>
<td>34 (79.1)</td>
<td>32 (74.4)</td>
<td>38 (88.4)</td>
<td>28 (66.7)</td>
<td>132 (77.2)</td>
</tr>
<tr>
<td>Asian</td>
<td>2 (4.7)</td>
<td>4 (9.3)</td>
<td>0 (16.7)</td>
<td>7 (16.7)</td>
<td>13 (7.6)</td>
</tr>
<tr>
<td>Black</td>
<td>2 (4.7)</td>
<td>3 (6.9)</td>
<td>1 (2.3)</td>
<td>3 (7.1)</td>
<td>9 (5.3)</td>
</tr>
<tr>
<td>Hispanic, n (%)</td>
<td>8 (18.6)</td>
<td>6 (14.0)</td>
<td>11 (25.6)</td>
<td>7 (16.7)</td>
<td>32 (18.7)</td>
</tr>
<tr>
<td><strong>Fitzpatrick skin type, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>I–III</td>
<td>28 (65.1)</td>
<td>26 (60.5)</td>
<td>35 (81.4)</td>
<td>25 (59.5)</td>
<td>114 (66.7)</td>
</tr>
<tr>
<td>IV–VI</td>
<td>15 (34.9)</td>
<td>17 (39.5)</td>
<td>8 (18.6)</td>
<td>17 (40.5)</td>
<td>57 (33.3)</td>
</tr>
<tr>
<td><strong>Baseline F-VASI, mean (SD)</strong></td>
<td>1.5 (0.8)</td>
<td>1.3 (0.8)</td>
<td>1.3 (0.8)</td>
<td>1.1 (0.7)</td>
<td>1.3 (0.8)</td>
</tr>
<tr>
<td><strong>Baseline T-VASI, mean (SD)</strong></td>
<td>28.3 (21.5)</td>
<td>27.1 (20.1)</td>
<td>23.6 (19.8)</td>
<td>22.7 (14.2)</td>
<td>25.5 (19.1)</td>
</tr>
<tr>
<td><strong>Duration of disease, mean (SD), y</strong></td>
<td>19.5 (14.0)</td>
<td>17.6 (13.0)</td>
<td>19.9 (15.5)</td>
<td>20.5 (13.7)</td>
<td>19.4 (14.0)</td>
</tr>
<tr>
<td><strong>Family history of vitiligo, n (%)</strong></td>
<td>15 (34.9)</td>
<td>9 (20.9)</td>
<td>11 (25.6)</td>
<td>14 (33.3)</td>
<td>49 (28.7)</td>
</tr>
<tr>
<td><strong>Thyroid disorders, n (%)</strong></td>
<td>11 (25.6)</td>
<td>12 (27.9)</td>
<td>12 (27.9)</td>
<td>12 (28.6)</td>
<td>47 (27.5)</td>
</tr>
<tr>
<td><em><em>Previous therapy,</em> n (%)</em>*</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Topical corticosteroid</td>
<td>18 (41.9)</td>
<td>24 (55.8)</td>
<td>21 (48.8)</td>
<td>25 (59.5)</td>
<td>88 (51.5)</td>
</tr>
<tr>
<td>Topical calcineurin inhibitor</td>
<td>14 (32.6)</td>
<td>13 (30.2)</td>
<td>17 (39.5)</td>
<td>20 (47.6)</td>
<td>64 (37.4)</td>
</tr>
<tr>
<td>Any phototherapy</td>
<td>20 (46.5)</td>
<td>17 (39.5)</td>
<td>13 (30.2)</td>
<td>27 (64.3)</td>
<td>77 (45.0)</td>
</tr>
</tbody>
</table>

* Patients could have used multiple previous lines of therapy.