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Secondary Efficacy Endpoints: Results from a Phase 3 Study Comparing ABP 501 with Adalimumab in Subjects with Moderate to Severe Rheumatoid Arthritis

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SESSION INFORMATION
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Session Title: Rheumatoid Arthritis - Small Molecules, Biologics and Gene Therapy
Poster III
Session Type: ACR Poster Session C
Session Time: 9:00AM-11:00AM

Background/Purpose:
ABP 501 is being developed as a biosimilar candidate to adalimumab (Humira®), a fully human recombinant monoclonal antibody. Evidence from analytical and pharmacokinetic comparisons indicates that ABP 501 is highly similar to adalimumab. Primary efficacy endpoints and safety results from a phase 3 study comparing ABP 501 with adalimumab in subjects with rheumatoid arthritis (RA) are reported separately. Here we report the secondary efficacy endpoints of the study. The objective was to evaluate and compare American College of Rheumatology 20% response criteria (ACR20), ACR50, and ACR70, as well as the change from baseline in Disease Activity Score in 28 joints using C-reactive protein (DAS28-CRP) over weeks 2–24 for ABP 501 and adalimumab based on results from a phase 3 study.

Methods:
This was a randomized, double-blind, active-controlled study in adult subjects with moderate to severe RA who had an inadequate response to methotrexate. Subjects were randomized in a 1:1 ratio (ABP 501: n=264; adalimumab: n=262) to receive either ABP 501 or adalimumab 40 mg subcutaneously every 2 weeks. The primary endpoint was risk ratio (RR) of ACR20 assessed at week 24 with a safety follow-up to week 26 (end of study). Here we report descriptive results of the secondary efficacy endpoints that included risk difference (RD) of ACR20, RR of ACR50 and ACR70, and difference in change from baseline of DAS28-CRP over the entire study.

Results:
Baseline characteristics were well balanced between groups. The table shows the response rate for ACR20, ACR50, and ACR70 throughout the study. At week 24, the RD of ACR20, ACR50 and ACR70 for ABP 501 vs adalimumab was 2.60% (2-sided 90% CI, –3.728% to 8.936%), –2.84% (90% CI, –10.220 to 4.547) and 3.15% (90% CI, –3.177 to 9.470), respectively. The RR of ACR50 and ACR70 was 0.95 (90% CI, 0.819–1.097) and 1.13 (90% CI, 0.872–1.464), respectively, at week 24. The differences in mean change from baseline in DAS28-CRP between ABP 501 and adalimumab were –0.08 (90% CI, –0.24 to 0.08) at week 8, –0.09 (90% CI, –0.26 to 0.07) at week 12, –0.09 (90% CI, –0.25 to 0.08) at week 18, and –0.01 (90% CI, –0.18 to 0.17) at week 24. The overall safety and immunogenicity profile of ABP 501 was comparable to that of adalimumab and is reported separately.

Table. Response Rate (%) of ACR20, ACR50, and ACR70 by Visit and Treatment

<table>
<thead>
<tr>
<th>Week</th>
<th>ACR 20</th>
<th></th>
<th>ACR 50</th>
<th></th>
<th>ACR 70</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>ABP 501</td>
<td>adalimumab</td>
<td>ABP 501</td>
<td>adalimumab</td>
<td>ABP 501</td>
<td>adalimumab</td>
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<tr>
<td>2</td>
<td>35.4</td>
<td>24.5</td>
<td>11.0</td>
<td>6.2</td>
<td>0.8</td>
<td>1.9</td>
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<tr>
<td>4</td>
<td>51.5</td>
<td>45.0</td>
<td>19.5</td>
<td>17.8</td>
<td>5.1</td>
<td>3.9</td>
</tr>
<tr>
<td>8</td>
<td>63.5</td>
<td>62.5</td>
<td>31.1</td>
<td>28.5</td>
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<td>10.2</td>
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<tr>
<td>12</td>
<td>74.6</td>
<td>65.5</td>
<td>41.3</td>
<td>43.5</td>
<td>15.3</td>
<td>13.3</td>
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<tr>
<td>18</td>
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<td>75.9</td>
<td>50.0</td>
<td>47.2</td>
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</tr>
<tr>
<td>24</td>
<td>74.6</td>
<td>72.4</td>
<td>49.2</td>
<td>52.0</td>
<td>26.0</td>
<td>22.9</td>
</tr>
</tbody>
</table>

Conclusion:

Along with the primary endpoint, these data support the results that efficacy of ABP 501 was similar to adalimumab.

Disclosure: A. K. Matsumoto, Abbvie, Amgen, Pfizer, Takeda, 2; K. Pavelka, None; W. Rizzo, None; R. Gupta, None; W. Shergy, None; P. Heycaj, None; N. Zhang, Amgen, 3; P. P. Kaur, Amgen, 3.

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