Mosunetuzumab is efficacious and well tolerated in patients aged <65 years and ≥65 years with relapsed/refractory follicular lymphoma and ≥2 prior therapies: subgroup analysis of a pivotal Phase II study

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Cytokine release syndrome (CRS) was graded using ASTCT criteria. In the ongoing, pivotal, Phase II study (NCT02500407), mosunetuzumab was administered intravenously (IV) mosunetuzumab in 21 cycles (C) in patients aged <65 years in C1 and C2, and was optional from C3 onwards. CRS events were numerically less frequent in patients aged ≥65 years in comparison with those aged <65 years (3 vs 14 events; p = 0.035). Patients aged <65 years had a median duration of CRS events of 4.9 days (range: 0–17) vs 5.1 days (range: 0–17) in patients aged ≥65 years. CRS was comparable across age groups (Table 3).

The pharmacokinetic disposition of mosunetuzumab was comparable across the age groups.

High response rates with associated durability were achieved in both age subgroups.

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The pharmacokinetic disposition of mosunetuzumab was comparable across the age groups.

Age was considered as a continuous variable in a population pharmacokinetic (PK) model and was not found to be significantly associated with mosunetuzumab PK parameters (p = 0.05).

Table 3. Response rates and DoR.

<table>
<thead>
<tr>
<th>Efficacy endpoint</th>
<th>≤65 years (N=30)</th>
<th>≥65 years (N=30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR rate, % (50 C)</td>
<td>55 (4 14-16-7)</td>
<td>70 (5 13-19-5)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>ORR, % (50 C)</td>
<td>77 (6 13-29-2)</td>
<td>80 (7 13-29-1)</td>
<td>0.18</td>
</tr>
<tr>
<td>DoR</td>
<td>22 (7 14-4)</td>
<td>28 (8 14-4)</td>
<td>0.23</td>
</tr>
<tr>
<td>18-month event-free rate, % (50 C)</td>
<td>66 (6 13-29-2)</td>
<td>75 (5 13-29-1)</td>
<td>0.35</td>
</tr>
<tr>
<td>DoCR</td>
<td>NE (N=9)</td>
<td>NE (N=7)</td>
<td>NE</td>
</tr>
<tr>
<td>18-month event-free rate, % (50 C)</td>
<td>66 (6 13-29-2)</td>
<td>75 (5 13-29-1)</td>
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</tr>
</tbody>
</table>

*Conclusions

Mosunetuzumab is efficacious with low rates of severe CRS events and no drug-related fatal AEs in older and younger patients with R/R FL who have received ≥2 prior therapies.

Ratios of neutropenia and SAEs of infection were similar between groups (Table 6).

Fourty-three neutropenia events were reported in patients aged ≥65 years, of which 37% were severe, 20 events were reported in patients aged <65 years, all events were resolved.

Table 6. AEs of special interest.

<table>
<thead>
<tr>
<th>AEs of special interest</th>
<th>≤65 years (N=30)</th>
<th>≥65 years (N=30)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutropenia</td>
<td>30 (100)</td>
<td>20 (100)</td>
<td>0.65</td>
</tr>
<tr>
<td>Granulocytopenia</td>
<td>15 (50)</td>
<td>15 (50)</td>
<td>1.00</td>
</tr>
<tr>
<td>Infection</td>
<td>15 (50)</td>
<td>15 (50)</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Conclusions

Mosunetuzumab is efficacious with low rates of severe CRS events and no drug-related fatal AEs in older and younger patients with R/R FL who have received ≥2 prior therapies.

The safety profile of mosunetuzumab is generally similar between older and younger patients, but numerically lower rates of CRS events and AEs were observed in older patients.

The authors are grateful to the patients, their families, and the investigators for their participation in the study; the nurses, research coordinators, and study staff for their support; and the members of the steering committee for their leadership and guidance.

References


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