Pooled data analysis of the safety and tolerability of intravenous pelareorep in combination with chemotherapy in 500+ cancer patients

**METHODS**

Pooled data analysis of the safety and tolerability of intravenous pelareorep in combination with chemotherapy in 500+ cancer patients

**RESULTS**

**Demographics**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Value A</th>
<th>Value B (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 - 55</td>
<td>50±5</td>
<td>50±5 (range 18 - 55)</td>
</tr>
<tr>
<td>≥ 65</td>
<td>50±5</td>
<td>50±5 (range ≥ 65)</td>
</tr>
</tbody>
</table>

**Efficacy**

Up to cycle 5 cycles of R were administered (range 8 – 15 cycles) when dose was continued on Days 1, 2, 8, 9, and 15, 16 q28 days in all REO studies and NCI 8601; CPR was administered on Days 2, 3, 9, 10, 16, 17 q21 days. Duration of treatment was at least 2 cycles. AEs was measured in the combination treatment and was not related to chemotherapy regimen or pelareorep alone. The incidences of Serious TEAEs considered to be treatment-related by the investigator are presented in Table 3. Fever, nausea, and vomiting were the only events reported in ≥ 3% of all treated patients (7 studies).

**CONCLUSIONS**

All patients were enrolled in clinical studies in the US, Canada, and Europe. Pelareorep was well tolerated by patients previously treated with cytotoxic chemotherapy and/or by intratumoral injections (n=91). The principal adverse effects in monotherapy studies with IV pelareorep were fever, chills, headache, fatigue, rhinorrhea, and vomiting. Safety data for R were aggregated from 7 studies: advanced malignancies (600+ patients), melanoma, and head and neck cancer. The incidences of Serious TEAEs like fever, GI AEs and dehydration were more frequent in patients receiving pelareorep ± chemotherapy than in those receiving chemotherapy alone. Grade 1 and Grade 2 fever, chills, fatigue and the GI-related AEs were similar in both groups. Transient Grade 3/4 laboratory abnormalities, like neutropenia and neutropenic fever were similar in both groups (21-16 vs. 21-19). However, the incidence of 16% febrile neutropenia in patients receiving pelareorep ± chemotherapy was higher than the incidence of 10% in patients receiving chemotherapy alone.

**REFERENCES**


**ACKNOWLEDGMENTS**

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**CONCLUSIONS**

1. Results from a randomized controlled trial of intravenous pelareorep in combination with chemotherapy in 500+ cancer patients.
2. Pelareorep was well tolerated by patients previously treated with cytotoxic chemotherapy and/or by intratumoral injections.
3. Pelareorep ± chemotherapy was more effective than chemotherapy alone in patients with advanced malignancies, melanoma, and head and neck cancer.
4. The incidences of Serious TEAEs like fever, GI AEs and dehydration were more frequent in patients receiving pelareorep ± chemotherapy than in those receiving chemotherapy alone.
5. Grade 1 and Grade 2 fever, chills, fatigue and the GI-related AEs were similar in both groups.

**REFERENCES**