The DART Study: Part 1 results of dose escalation and expansion cohorts of dalantercept plus axitinib in advanced renal cell carcinoma


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Objective Response Rate Analysis RECORd v1.3

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<thead>
<tr>
<th>Treatment</th>
<th>Overall</th>
<th>Partial</th>
<th>Overall</th>
<th>Percentage</th>
<th>Percentage</th>
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<tr>
<td>Bevacizumab</td>
<td>2 (33.3)</td>
<td>0 (0)</td>
<td>2 (33.3)</td>
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<td>Nivolumab</td>
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<td>2 (33.3)</td>
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<tr>
<td>Bevacizumab + Nivolumab</td>
<td>2 (33.3)</td>
<td>0 (0)</td>
<td>2 (33.3)</td>
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Conclusions and Discussion

- In this investigator-sponsored, advanced RCC population, the combination of dalantercept and axitinib is well tolerated with a generally non-overlapping safety profile.
- Based upon the efficacy data at the 1.2 mg/kg dose level and preliminary activity, dalantercept 1.2 mg/kg was selected as the RDQ in Part 2 of this study.
- The single-arm, uncontrolled nature of dalantercept monotherapy and the phase II trial conducted with clinically meaningful activity (partial responses 35%) and prolonged disease control (72%) in patients with 1 or 2 prior lines of therapy.
- The preliminary median PFS of 8.3 months in all dose levels combined is encouraging.
- The randomized Part 2 of the DART study is actively enrolling patients who have received one VEGFR TKI and may have received prior mTOR inhibitor and/or any number of prior immune therapies.
- DART study details are at https://clinicaltrials.gov/ct2/show/NCT01773386.

References