Characterization of response to nivolumab plus ipilimumab (N+I) or sunitinib (S) in patients (Pts) with previously untreated advanced renal cell carcinoma (arcc): Checkmate 214

**Table: 875P**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N+I int/poor-risk pts</th>
<th>S int/poor-risk pts</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total n = 425</td>
<td>CR n = 40</td>
</tr>
<tr>
<td>BOR (95% CI), %</td>
<td>42 (37–47)</td>
<td>9</td>
</tr>
<tr>
<td>Median (range) time to response, months</td>
<td>2.8 (0.9–11.3)</td>
<td>2.8 (0.9–11.0)</td>
</tr>
<tr>
<td>Median (95% CI) duration of response, months</td>
<td>(NR (21.8–NE))</td>
<td>NR</td>
</tr>
<tr>
<td>Pts with ongoing response in responders, n/N (%)</td>
<td>128/177 (72)</td>
<td>34/40 (85)</td>
</tr>
<tr>
<td>12-month PFS rate (95% CI), %</td>
<td>50 (44–55)</td>
<td>97 (83–100)</td>
</tr>
<tr>
<td>18-month OS rate (95% CI), %</td>
<td>78 (74–81)</td>
<td>100 (100–100)</td>
</tr>
</tbody>
</table>

BOR, best overall response; NE, not estimable; NR, not reached; PR, partial response
Methods: In CheckMate 214, pts with previously untreated aRCC were randomly assigned 1:1 to N 3 mg/kg + I 1 mg/kg Q2W for 4 doses then N 3 mg/kg Q2W or S 50 mg QD for 4 weeks on, 2 weeks off. Efficacy, safety, and quality of life (QoL) were explored in int/poor-risk pts with complete response (CR) or partial response to N+I or S.

Results: At 25.2 months median follow-up, confirmed ORR per independent radiology review committee in int/poor-risk pts was 42% for N+I vs 27% for S (P < 0.001; Table) with 36% vs 18% of pts achieving best tumor reduction ≥50% with N+I vs S. Of N+I vs S responders, 72% vs 63% have ongoing response, 47% and 34% remain on treatment, and 53% and 66% discontinued, most often for disease progression (N+I, 22%; S, 40%) or toxicity (N+I, 23%; S, 13%). N+I responders received a median of 21.0 months of treatment (vs 18.8 months for N+I nonresponders). Response lasting >18 months was seen in 13% of N+I and 4% of S pts. Grade 3–4 treatment-related adverse events (TRAEs) occurred in 52% of N+I and 68% of S responders. Mean change from baseline at 24 weeks in Functional Assessment of Cancer Therapy–Kidney Symptom Index 19 score was 3.0 in N+I responders (better) vs −0.7 in S responders (worse). Updated 3-year data on responders, including use of subsequent therapies, will be presented.

Conclusions: ORR and OS were significantly improved with N+I compared with S in pts with int/poor-risk aRCC in CheckMate 214. Responses to N+I were more likely to be CRs and were more durable than responses to S. High-grade TRAEs were less frequent and QoL was better in N+I responders compared with S responders.

Clinical trial identification: NCT023231749.

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The IMDC classification scheme for OS has been validated in 2L mRCC.

In the current study, we explored the role of IMDC predictors and the addition of new prognostic factors in mRCC using a previously collected dataset from the French national program of mRCC (CIRCITMA).

In addition to the IMDC predictors, the 2 new prognostic factors were tested in the 1L subgroup. The high-poor risk group (n = 121, 105 deaths, HR 8.3 [95% CI 5.5-9.7]; 16.1 [95% CI 8.0-27.7] months of treatment (vs 16.8 [95% CI 8.5-21.7] and 12.9-21.7] months, respectively). Time from first to second line and tumor burden confirmed their significant effect on OS with HR 1.68 [95% CI 1.23-2.31] and 1.43 [95% CI 1.03-1.99]. The new classification, derived by counting the number of IMDC and new predictors in each patient, allowed a better performance compared to previous models.

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