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Tremelimumab (T) + durvalumab (D) combined with metronomic oral vinorelbine (MOV): Results of the recurrent cervical cancer (RCC) cohort of the MOVIE study

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Background
The standard of care of RCC includes chemotherapy + bevacizumab with a limited PFS around 7 months. In this setting, single-agent anti-PD1 may be effective in a minor subset of patients (pts). We hypothesized that combining an anti-PD-L1 (D) with anti-CTLA4 (T) and MOV would improve antitumor activity.

Methods
MOVIE is multi-cohort phase I/II study combining T+D with MOV for RCC. T was administered 75 mg Q4W IV, for up to 4 cycles and D was administered 1500 mg Q4W IV, for up to 26 cycles. MOV dosing was 40 mg thrice weekly, until disease progression. Primary endpoint of phase II part was the clinical benefit rate (CBR= CR, PR or SD ≥ 24 weeks) according to RECIST 1.1. Continuous monitoring of efficacy was performed using a Bayesian approach.

Results
31 patients (pts) were included with a median age of 56y (range, 30-75). PS was 0 (11 pts, 35%) or 1 (20 pts, 65%). Prior treatment included cisplatin or carboplatin, radiotherapy and bevacizumab in 100%, 81%, and 38% of pts respectively. As of April 2021, 11 pts were still on treatment, 16 stopped for disease progression and 4 for toxicity. With a median follow-up of 12.9 months (1.7–23.4), 16/30 patients showed a CBR; the objective response rate (ORR) was 41.4% (12/29) with 5 CR, 7 PR and 4 SD ≥ 24 wks. Bayesian estimations of the mean CBR according to the prior distributions defined are reported in the table. Sixteen pts (51.6%) had grade (G) ≥ 3 treatment-related adverse events (TRAE), including 11 pts with immune-related TRAE (35.5%) and 16 pts (51.6%) with chemotherapy-related TRAE. No toxic death was recorded.

<table>
<thead>
<tr>
<th>Prior non-informative beta (1,1)</th>
<th>Informative Prior Beta (1.8,4.2)</th>
<th>Less informative optimism Beta (0.75,1.75)</th>
</tr>
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<tbody>
<tr>
<td>Mean [95% CI]</td>
<td>53.1% [36.0%; 69.8%]</td>
<td>49.4% [33.5%; 65.5%]</td>
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Conclusions
T+D+MOV study met its primary efficacy endpoint, while the combination has a significant but manageable toxicity profile. Further evaluation of the combination of chemotherapy with immunotherapy is warranted in this difficult to treat population.

Clinical trial identification
NCT03518606.

Legal entity responsible for the study
Unicancer.

Funding
Institut National du Cancer (INCA), AstraZeneca, Pierre Fabre.
Disclosure

All authors have declared no conflicts of interest.

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