Optimization of Assessment of Disease Progression Between Blinded Central Independent Review and Investigator Assessment in the PRIMA/ENGOT-ov26/GOG-3012 Trial

Abstract no. #531

Results

Pre-intervention discordance
- In an initial patient subset (n=80), the average discordance between BICR and INV of PD and non-PD was 30%.
- Of the 31 patients that Inv deemed PD but BICR did not, the most common source of discordance was performance status and fluid collections arising from new non-loci lesions (Table 1).

Table 1. Pre-intervention discordance rate between INV and BICR®

<table>
<thead>
<tr>
<th>Location of discordant foci</th>
<th>Non-targeted progression</th>
<th>Targeted progression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin sections</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td>patient #1</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td>patient #2</td>
<td>5%</td>
<td>10%</td>
</tr>
</tbody>
</table>

Post-intervention discordance
- In a different subset of patients (n=55), the average discordance between BICR and INV of PD and non-PD was 15%.
- Of the 8 patients that Inv deemed PD but BICR did not, the most common source of discordance was presence of interval change and reduced size of stable non-loci lesions (Table 1).

Table 2. Post-intervention discordance rate between INV and BICR®

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Methods

- Discordance between BCR and INV progression was assessed using the randomized, double-blind, placebo-controlled Phase 3 PRIMA/ENGOT-ov26/GOG-3012 trial in patients with newly diagnosed stage IIB-IV OC, who were assigned to receive either niraparib or placebo.
- The primary endpoint was PFS as per Response Evaluation Criteria in Solid Tumours (RECIST 1.1 by BICR).
- HRD status was determined using Myriad MyRiskCD®assy.

Results

- In a different subset of patients (n=55), the average discordance between BICR and INV of PD and non-PD was 15%.
- Of the 8 patients that Inv deemed PD but BICR did not, the most common source of discordance was presence of interval change and reduced size of stable non-loci lesions (Table 1).

Conclusions

- PRIMA/ENGOT-ov26/GOG-3012 highlights the need to optimize BICR and INV concordance using early, specified, OC-specific training to maximize trial validity.

Disclosures

- None.

References

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