Niraparib Efficacy and Safety in Patients with BRCA-Mutated (BRCAm) Ovarian Cancer: Results from Three Phase 3 Niraparib Trials

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Background
- Niraparib is an oral poly(ADP-ribose) polymerase (PARP) inhibitor approved for the maintenance treatment of patients with advanced ovarian, fallopian tube, or primary peritoneal cancer after first-line chemotherapy and in the recurrent setting
- BRCA mutations occur in approximately 20%–25% of patients with epithelial ovarian cancer and are associated with improved outcomes in comparison with patients with BRCA wild-type ovarian cancer
- Niraparib has shown efficacy in tumors with and without BRCA mutations, and the efficacy and safety of niraparib in patients with BRCA mutated (BRCAm) was assessed in the PRIMA, NOVA, and NORA trials

Objectives
- To summarize the efficacy and safety of niraparib in patients with BRCAm ovarian cancer across three phase 3 trials:
  - PRIMA/ENGOT-OV26/GO21-30212 (PRIMA; NCT02655016)
  - ENGOT-OV16/NOVA (NCT01847274)
  - NORA (NCT03701516)

Methods
- PRIMA was a randomized, double-blind, placebo-controlled, phase 3 trial of niraparib maintenance therapy in patients newly diagnosed, advanced ovarian cancer that responded to first-line platinum-based chemotherapy
- NOVA and NORA were randomized, double-blind, placebo-controlled phase 3 trials of niraparib maintenance therapy in patients with platinum-sensitive, recurrent ovarian cancer
- Subgroup analysis by BRCA status was prospectively in all three trials

Conclusions
- Patients with BRCAm ovarian cancer derived a significant PFS benefit from niraparib maintenance treatment across all three trials in first-line and recurrent settings after response to platinum-based chemotherapy
- No new safety signals were identified

Results (cont’d)

Efficacy
- In PRIMA, NOVA, and NORA, patients with BRCAm ovarian cancer derived a significant progression-free survival (PFS) benefit from niraparib maintenance treatment across all subgroups examined (Figure 2)

Figure 2. Progression-Free Survival in Patients with BRCAm Ovarian Cancer

Table 1. BRCAm Patient Characteristics and Baseline Demographics

<table>
<thead>
<tr>
<th></th>
<th>BRCAm (1L maintenance)</th>
<th>BRCAm (2L maintenance)</th>
<th>NORA (2L maintenance)</th>
<th>Total (all lines of maintenance)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>56.5 (22–82)</td>
<td>57 (22–82)</td>
<td>57 (36–63)</td>
<td>56 (22–82)</td>
</tr>
<tr>
<td>ECOG Performance</td>
<td>0 (0–3)</td>
<td>0 (0–3)</td>
<td>0 (0–3)</td>
<td>0 (0–3)</td>
</tr>
<tr>
<td>Recurrence</td>
<td>2 (0–10)</td>
<td>2 (0–10)</td>
<td>2 (0–10)</td>
<td>2 (0–10)</td>
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<tr>
<td>Multiparous</td>
<td>90% (84%–96%)</td>
<td>90% (84%–96%)</td>
<td>90% (84%–96%)</td>
<td>90% (84%–96%)</td>
</tr>
<tr>
<td>Prior platinum</td>
<td>90% (84%–96%)</td>
<td>90% (84%–96%)</td>
<td>90% (84%–96%)</td>
<td>90% (84%–96%)</td>
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<tr>
<td>Prior bevacizumab</td>
<td>32% (18%–49%)</td>
<td>32% (18%–49%)</td>
<td>32% (18%–49%)</td>
<td>32% (18%–49%)</td>
</tr>
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</table>

Acknowledgments
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Conflict of Interest
Dr. González-Martín reports personal fees outside the submitted work from GlaxoSmithKline, Pfizer, Seattle Genetics, Novartis, and Nippon Kayaku Co., Ltd. Professors Glick, Dr. Toly, Dr. Grob, and Dr. Alexander, Neovii Inc., and, respectively, NIH, (Shangahi, China). Dr. Barron is a new employee at the company. He contributed to the development of the poster and met Gliadel company criteria.

Non-Medical TeAEs of any grade occurring in ≥20% of patients in the niraparib arm

Hematological TeAEs of any grade occurring in ≥20% of patients in the niraparib arm

Neutropenia (grade 3–4) in ≥20% of patients in the niraparib arm

No patients had neutropenic fever

CRTHAK (grade 3–4) in ≥20% of patients in the niraparib arm

No patients had CRTHAK

No patients had non-hematological TeAEs of any grade occurring in ≥20% of patients in the niraparib arm

References
6. Sara L et al.