Niraparib Therapy in Patients With Newly Diagnosed Advanced Ovarian Cancer (PRIMA/ENGOT-OV26/GOG-3012)

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Niraparib is Effective in Recurrent OC (BRCA\textsuperscript{mut} and BRCA\textsuperscript{wt})

- Advanced ovarian cancer is a leading cause of cancer deaths in women with up to 85% recurrence after completion of standard first-line platinum-based chemotherapy\textsuperscript{1}

- Despite current options for maintenance treatment, there is still a high unmet need for many patients
  - \textbf{Olaparib}: limited to patients with \textit{BRCA} mutations; \approx20\% of OC patients\textsuperscript{2}
  - \textbf{Bevacizumab}: limited use due to safety concerns and limited data in the growing number of patients receiving NACT
  - \textbf{Active surveillance}: many patients undergo watchful waiting following chemotherapy

- Niraparib was the first oral PARP inhibitor approved as maintenance for all patients with recurrent OC (BRCA\textsuperscript{mut} and BRCA\textsuperscript{wt})
  - NOVA study demonstrated efficacy of niraparib maintenance after platinum CT in all biomarker populations: gBRCA\textsuperscript{mut}: hazard ratio 0.27 (95\% CI 0.17–0.41, P<0.0001); homologous recombination deficient: hazard ratio 0.38 (95\% CI 0.24–0.59, P<0.0001) and non-gBRCA\textsuperscript{mut}: hazard ratio 0.45 (95\% CI 0.34–0.61, P<0.0001)\textsuperscript{3}
  - QUADRA study showed niraparib treatment benefit in patients with at least 3 prior therapies: BRCA\textsuperscript{mut} 39\% ORR, homologous recombination deficient 26\% ORR, duration of response 9.4 months\textsuperscript{4}

\textsuperscript{1} GLOBOCAN, 2018; \textsuperscript{2} Moore, NEJM 2018; \textsuperscript{3} Mirza, NEJM 2016; \textsuperscript{4} Moore, Lancet Oncol 2019.

\textit{CI}, confidence interval; CT, chemotherapy; NACT, neoadjuvant chemotherapy; mut, mutant; OC, ovarian cancer; ORR, objective response rate; PARP, poly (ADP-ribose) polymerase; wt, wild-type.
Hypothtsis: PRIMA/ENGOT-OV26/GOG-3012 was designed to test the efficacy and safety of niraparib therapy after response to platinum-based chemotherapy in patients with newly diagnosed advanced ovarian cancer, including those at high risk of relapse (ClinicalTrials.gov: NCT02655016)

<table>
<thead>
<tr>
<th>Key Inclusion Criteria</th>
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</thead>
<tbody>
<tr>
<td>• High grade serous or endometroid pathology</td>
</tr>
<tr>
<td>• Stage III: PDS with visible residual disease post surgery, NACT, or inoperable</td>
</tr>
<tr>
<td>• Stage IV: PDS regardless of residual disease, NACT, or inoperable</td>
</tr>
<tr>
<td>• CR or PR following platinum first-line treatment</td>
</tr>
<tr>
<td>• Tissue for homologous recombination testing was required at screening (Myriad myChoice®)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patients with Stage III disease who have had complete cytoreduction (i.e., no visible residual disease) after PDS</td>
</tr>
</tbody>
</table>

CR, complete response; HRD, homologous recombination deficiency; NACT, neoadjuvant chemotherapy; OC, ovarian cancer; PDS, primary debulking surgery; PR, partial response.
PRIMA Trial Design

Patients with newly-diagnosed OC at high risk for recurrence after response to 1L platinum-based chemotherapy

2:1 Randomization

Niraparib

Placebo

Endpoint assessment

Primary Endpoint: Progression-free survival by BICR
Key Secondary Endpoint: Overall Survival
Secondary Endpoints: PFS2, TFST, PRO, Safety

Stratification Factors

- Neoadjuvant chemotherapy administered: Yes or no
- Best response to first platinum therapy: CR or PR
- Tissue homologous recombination test status: deficient or proficient/not-determined

Hierarchical PFS Testing

- Patients with homologous recombination deficient tumors, followed by the overall population.
- Statistical assumption: a hazard ratio benefit in PFS of
  - 0.5 in homologous recombination deficient patients
  - 0.65 in the overall population
- >90% statistical power and one-sided type I error of 0.025

• Body weight ≥77 kg and platelets ≥150,000/μL started with 300 mg QD
• Body weight <77 kg and/or platelets <150,000/μL started with 200 mg QD

1L, first-line; BICR, blinded independent central review; CR, complete response; OC, ovarian cancer; OS, overall survival; PFS2, progression-free survival 2; PR partial response; PRO, patient-reported outcomes; TFST, time to first subsequent therapy.
PRIMA Tissue Test for Homologous Recombination

Testing for Homologous Recombination Deficiency (HRd) and Proficiency (HRp)

- Next generation sequencing of DNA from tumor tissue (Myriad Genetics myChoice® Test)
- Provides a score based on algorithmic measurement of 3 tumor factors:
  - Loss of heterozygosity (LOH)
  - Telomeric allelic imbalance (TAI)
  - Large-scale state transitions (LST)
- Homologous recombination status is determined by the following:
  - HR-deficient tumors: Tissue test score ≥42 OR a BRCA mutation
  - HR-proficient tumors: Tissue test score <42
  - HR-not-determined

1https://myriadmychoice.com/portfolio/ovarian-cancer/mychoice-hrd-ovarian-cancer/#result
PRIMA Enrollment and Outcomes

733 randomized
- 5 did not receive intervention
  - 3 HRd

728 received intervention
- 370 HRd

484 received niraparib
- 245 HRd
  - 177 (37%) still receiving niraparib at data cutoff
    - 121 HRd

244 received placebo
- 125 HRd
  - 69 (28%) still receiving placebo at data cutoff
    - 42 HRd

307 discontinued*
- 58 due to AE
- 218 due to PD (45%)
- 12 patient request

124 HRd
- 27 due to AE
- 80 due to PD
- 8 patient request

177 (37%) still receiving niraparib at data cutoff

175 discontinued*
- 5 due to AE
- 162 due to PD (66%)
- 1 patient request

83 HRd
- 2 due to AE
- 76 due to PD
- 0 patient request

Median follow up of 13.8 months

*19 patients (8 HRd) and 7 patients (5 HRd) discontinued due to other reasons in the niraparib and placebo arms, respectively. AE, adverse event, HRd, homologous recombination deficient, PD, progression of disease.
### PRIMA Patient Characteristics and Baseline Demographics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Niraparib (n=487)</th>
<th>Placebo (n=246)</th>
<th>Overall (N=733)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (range), years</td>
<td>62 (32, 85)</td>
<td>62 (33,88)</td>
<td>62 (32, 88)</td>
</tr>
<tr>
<td>Weight, median, kg</td>
<td>66</td>
<td>66</td>
<td>66</td>
</tr>
<tr>
<td>Stage at initial diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>318 (65)</td>
<td>158 (64)</td>
<td>476 (65)</td>
</tr>
<tr>
<td>IV</td>
<td>169 (35)</td>
<td>88 (36)</td>
<td>257 (35)</td>
</tr>
<tr>
<td>Prior NACT, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>322 (66)</td>
<td>167 (68)</td>
<td>489 (67)</td>
</tr>
<tr>
<td>No</td>
<td>165 (34)</td>
<td>79 (32)</td>
<td>244 (33)</td>
</tr>
<tr>
<td>Best response to platinum-based CT, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CR</td>
<td>337 (69)</td>
<td>172 (70)</td>
<td>509 (69)</td>
</tr>
<tr>
<td>PR</td>
<td>150 (31)</td>
<td>74 (30)</td>
<td>224 (31)</td>
</tr>
<tr>
<td>Homologous recombination test status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HRd</td>
<td>247 (51)</td>
<td>126 (51)</td>
<td>373 (51)</td>
</tr>
<tr>
<td>BRCAmut</td>
<td>152 (31)</td>
<td>71 (29)</td>
<td>223 (30)</td>
</tr>
<tr>
<td>BRCAwt</td>
<td>95 (20)</td>
<td>55 (22)</td>
<td>150 (20)</td>
</tr>
<tr>
<td>HRp</td>
<td>169 (35)</td>
<td>80 (33)</td>
<td>249 (34)</td>
</tr>
<tr>
<td>HRnd</td>
<td>71 (15)</td>
<td>40 (16)</td>
<td>111 (15)</td>
</tr>
</tbody>
</table>

- 35% of patients were Stage IV
- 99.6% with Stage III had residual disease post PDS
- 67% received NACT
- 31% achieved a PR to 1L CT
- 51% had HRd tumors
- 30% had BRCAmut tumors
- 34% had HRp tumors

1L, first-line; CR, complete response; CT, chemotherapy; HRd, homologous recombination deficient; HRp, homologous recombination proficient; HRnd, homologous recombination not determined; mut, mutation; NACT, neoadjuvant chemotherapy; PR, partial response; wt, wild-type.
PRIMA Primary Endpoint, PFS Benefit in the HR-deficient Population
PRIMA Primary Endpoint, PFS Benefit in the HR-deficient Population

Hazard ratio: 0.43 (95% CI, 0.31–0.59)  
$p<0.001$

Niraparib Placebo

**57% reduction in risk of relapse or death with niraparib**

<table>
<thead>
<tr>
<th></th>
<th>Niraparib (n=247)</th>
<th>Placebo (n=126)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median PFS</td>
<td>21.9 (19.3–NE)</td>
<td>10.4 (8.1–12.1)</td>
</tr>
<tr>
<td>Patients without PD or death (%)</td>
<td>86%</td>
<td>68%</td>
</tr>
<tr>
<td>6 months</td>
<td>72%</td>
<td>42%</td>
</tr>
<tr>
<td>12 months</td>
<td>59%</td>
<td>35%</td>
</tr>
</tbody>
</table>

CI, confidence interval; NE, not estimable; PD, progressive disease; PFS, progression-free survival.

Sensitivity analysis of PFS by the investigator was similar to and supported the BICR analysis.
PRIMA Primary Endpoint, PFS Benefit in the Overall Population

Hazard ratio: 0.62 (95% CI, 0.50–0.76)  
*p<0.001

38% reduction in risk of relapse or death with niraparib

<table>
<thead>
<tr>
<th></th>
<th>Niraparib (n=487)</th>
<th>Placebo (n=246)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median PFS</td>
<td>13.8 (11.5–14.9)</td>
<td>8.2 (7.3–8.5)</td>
</tr>
<tr>
<td>Patients without PD or death (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 months</td>
<td>73%</td>
<td>60%</td>
</tr>
<tr>
<td>12 months</td>
<td>53%</td>
<td>35%</td>
</tr>
<tr>
<td>18 months</td>
<td>42%</td>
<td>28%</td>
</tr>
</tbody>
</table>

CI, confidence interval; NE, not estimable; PD, progressive disease; PFS, progression-free survival.

Discordance in PFS event between investigator assessment vs BICR ≈12%.
### PRIMA Exploratory Analysis, PFS Benefit in Pre-specified Groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>HR for PFS (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall</strong></td>
<td>0.62 (0.50–0.76)</td>
</tr>
<tr>
<td><strong>Age group</strong></td>
<td></td>
</tr>
<tr>
<td>&lt;65 years</td>
<td>0.61 (0.47–0.81)</td>
</tr>
<tr>
<td>≥65 years</td>
<td>0.53 (0.38–0.74)</td>
</tr>
<tr>
<td><strong>Stage of disease at initial diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>0.54 (0.42–0.70)</td>
</tr>
<tr>
<td>IV</td>
<td>0.79 (0.55–1.12)</td>
</tr>
<tr>
<td><strong>Neoadjuvant chemotherapy</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>0.59 (0.46–0.76)</td>
</tr>
<tr>
<td>No</td>
<td>0.66 (0.46–0.94)</td>
</tr>
<tr>
<td><strong>Best response to platinum therapy</strong></td>
<td></td>
</tr>
<tr>
<td>CR</td>
<td>0.60 (0.46–0.77)</td>
</tr>
<tr>
<td>PR</td>
<td>0.60 (0.43–0.85)</td>
</tr>
<tr>
<td><strong>Homologus recombination status</strong></td>
<td></td>
</tr>
<tr>
<td>HRd–BRCAmut</td>
<td>0.40 (0.27–0.62)</td>
</tr>
<tr>
<td>HRd–BRCAwt</td>
<td>0.50 (0.31–0.83)</td>
</tr>
<tr>
<td>HRp</td>
<td>0.68 (0.49–0.94)</td>
</tr>
<tr>
<td>HRand</td>
<td>0.85 (0.51–1.43)</td>
</tr>
</tbody>
</table>

CI, confidence interval; CR, complete response; HRd, homologous recombination deficient; HRp, homologous recombination proficient; HRand, homologous recombination not determined; mut, mutation; PFS, progression-free survival; PR, partial response; wt, wild-type.
PRIMA PFS Benefit in Biomarker Subgroups

Homologous Recombination Deficient (HRd)

- Niraparib provided similar clinical benefit in the HRd subgroups (BRCAmut and BRCAwt)
PRIMA PFS Benefit in Biomarker Subgroups

Homologous Recombination Deficient (HRd)

- Niraparib provided similar clinical benefit in the HRd subgroups (BRCAmut and BRCAwt)
- Niraparib provide clinically significant benefit in the HR-proficient subgroup with a 32% risk reduction in progression or death

Expiration: 01/17/2020
PRIMA Key Secondary Endpoint, Overall Survival (11% data maturity)

- **Pre-planned** interim analysis of overall survival numerically favors niraparib over placebo
  - Overall population 84% vs 77% alive at 2 years
  - HR-deficient 91% vs 85% alive at 2 years
  - HR-proficient 81% vs 59% alive at 2 years

CI, confidence interval; HR, homologous recombination.
PRIMA Safety Overview

- TEAEs were manageable and consistent with the PARP inhibitor class
- Dose interruptions were similar to those in the previous niraparib trials
- Treatment discontinuation due to thrombocytopenia was 4.3%
- TEAEs leading to death were determined to be not treatment-related

<table>
<thead>
<tr>
<th>Adverse Event, no. (%)</th>
<th>Niraparib (n=484)</th>
<th>Placebo (n=244)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any TEAE</td>
<td>478 (98.8)</td>
<td>224 (91.8)</td>
</tr>
<tr>
<td>Grade ≥3</td>
<td>341 (70.5)</td>
<td>46 (18.9)</td>
</tr>
<tr>
<td>Led to treatment discontinuation</td>
<td>58 (12.0)</td>
<td>6 (2.5)</td>
</tr>
<tr>
<td>Led to dose reduction</td>
<td>343 (70.9)</td>
<td>20 (8.2)</td>
</tr>
<tr>
<td>Led to dose interruption</td>
<td>385 (79.5)</td>
<td>44 (18.0)</td>
</tr>
<tr>
<td>TEAEs leading to death</td>
<td>2 (0.4)</td>
<td>1 (0.4)</td>
</tr>
</tbody>
</table>

PARP, poly(ADP-ribose) polymerase; TEAE, treatment-emergent adverse event.
No new safety signals were identified for niraparib.

- Most common TEAE was reversible myelosuppression.
- One patient was diagnosed with MDS after 9 months of niraparib treatment.

TEAEs ≥20% incidence in niraparib arm. Note: Hematologic TEAEs are not combined with laboratory results. MDS, myelodysplastic syndrome; TEAE, treatment-emergent adverse event.
PRIMA Safety and Patient-Reported Outcomes

- No new safety signals were identified for niraparib
- Most common TEAE was reversible myelosuppression
- One patient was diagnosed with MDS after 9 months of niraparib treatment

TEAEs ≥20% incidence in niraparib arm. Note: Hematologic TEAEs are not combined with laboratory results.

FOSI, FACIT ovarian cancer symptom index; MDS, myelodysplastic syndrome; TEAE, treatment-emergent adverse event.
PRIMA Conclusions

• Available therapies and active surveillance do not address the high unmet need for many patients with newly diagnosed advanced ovarian cancer after platinum-based chemotherapy

• Niraparib therapy in patients with advanced ovarian cancer provided a clinically significantly improvement in PFS after response to 1L platinum-based chemotherapy in ALL patients
  - PFS overall population: hazard ratio, 0.62; p<0.001
  - PFS homologous recombination deficient: hazard ratio, 0.43; p<0.001
  - PFS homologous recombination proficient: hazard ratio, 0.68; p=0.020

• Niraparib is the first PARP-inhibitor to demonstrate benefit in patients across biomarkers subgroups after platinum-based chemotherapy in frontline, consistent with prior clinical studies of niraparib in recurrent ovarian cancer (NOVA and QUADRA)

• Patients with ovarian cancer at the highest risk of early disease progression (NACT, partial responders to 1L platinum chemotherapy) had significant benefit with niraparib therapy

• No new safety signals were observed, and quality of life was maintained on niraparib.

• Niraparib monotherapy after first-line platinum-based chemotherapy should be considered a new standard of care
We sincerely thank patients and their families for participating in this trial.

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- Denmark: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Sweden: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Italy: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Ireland: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Poland: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Czechia: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Switzerland: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG
- Hungary: D. GOG, GEICO, AGO, GINECO, ISGO, NSGO, MITO, ICORG

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Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer