Rucaparib vs Chemotherapy in Patients With Advanced, Relapsed Ovarian Cancer and a Deleterious BRCA Mutation: Efficacy and Safety From ARIEL4, a Randomized Phase 3 Study

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Presenting Author Disclosures

- Advisory boards: Clovis Oncology, Roche, and Tesaro
Introduction

- The PARP inhibitor rucaparib is approved as monotherapy treatment for patients with BRCA-mutated, relapsed OC who have received ≥2 prior lines of platinum-based chemotherapy\(^1,2\)
  - Approval was based on data from 2 phase 1/2 studies\(^3,4\)

- ARIEL4 (NCT02855944) is a phase 3 confirmatory study evaluating the efficacy and safety of rucaparib vs standard-of-care chemotherapy in patients with BRCA-mutated, relapsed OC
  - Designed in consultation with US FDA and EMA

BRCA, BRCA1 or BRCA2; OC, ovarian cancer; EMA, European Medicines Agency; FDA, Food and Drug Administration; OC, ovarian cancer; PARP, poly(ADP-ribose) polymerase; US, United States.

ARIEL4 Study Population

Patients with:
- Relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer
- ≥2 prior chemotherapy regimens, including ≥1 platinum-based regimen\(^a\)
- Deleterious germline or somatic BRCA mutation
- No prior PARP inhibitor or single-agent paclitaxel treatment

Platinum status
- Resistant
- Partially sensitive
- Fully sensitive

Treatment
- Rucaparib 600 mg BID
- Weekly paclitaxel
- Platinum-based chemotherapy\(^b\)

\(^a\)With treatment-free interval ≥6 months following first chemotherapy received. \(^b\)At investigator’s discretion.

BID, twice daily; BRCA, BRCA1 or BRCA2; PARP, poly(ADP-ribose) polymerase; PFI, progression-free interval.
**ARIEL4 Study Schema**

**Treatment**
28-day cycles

- **Rucaparib**
  600 mg BID
  (n=233)

- **Standard-of-care chemotherapy**
  (n=116)
  - If platinum-resistant or partially platinum-sensitive: paclitaxel
  - If fully platinum-sensitive: single-agent platinum or doublet chemotherapy

**Follow-up**
28 days after last treatment dose, then long-term follow-up every 8 weeks

**Optional crossover**
(n=74/116; 64%)
Patients in the chemotherapy group could crossover to rucaparib upon PD

**Randomization stratification factor:** Platinum status (platinum-resistant, partially platinum-sensitive, fully platinum sensitive)

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**Notes:**

- At investigator’s discretion.
- Per RECIST.
- Platinum resistant: PFI $\geq$6–$<12$ months, partially platinum sensitive: PFI $\geq$12 months.
- BID, twice daily; BRCA, BRCA1 or BRCA2; PARP, poly(ADP-ribose) polymerase; PD, progressive disease; PFI, progression-free interval; RECIST, Response Evaluation Criteria In Solid Tumors, version 1.1.
Analysis Populations

ITT population
All randomized patients
- 349 randomized
  - 233 assigned rucaparib
  - 116 assigned chemotherapy
  - Excluded from efficacy population:
    • 13 BRCA reversion

Efficacy population
Patients with deleterious BRCA mutations, excluding those with BRCA reversion mutations
- 233 assigned rucaparib
  - 220 from rucaparib group
    - 44 treatment ongoing
- 116 assigned chemotherapy
  - 105 from chemotherapy group
    - 5 treatment ongoing

Excluded from efficacy population:
• 1 non-BRCA
• 10 BRCA reversion

BRCA reversion mutations restoring BRCA protein function have been associated with resistance to platinum and to PARP inhibitors.1
BRCA, BRCA1 or BRCA2; ITT, intent to treat; PARP, poly(ADP-ribose) polymerase.
Statistical Analysis Plan for Efficacy Endpoints

**Efficacy Population**
(Patients with deleterious BRCA mutations, excluding those with BRCA reversion mutations)

- **Primary Endpoint**
  - Investigator-assessed PFS

- **Secondary Endpoints**
  - ORR
  - DOR
  - ORR by RECIST and/or GCIG CA-125 response
  - PRO based on EORTC QLQ-C30 Global Health status

**ITT Population**
(All randomized patients)

- **Primary Endpoint**
  - Investigator-assessed PFS

- **Secondary Endpoints**
  - ORR
  - DOR
  - ORR by RECIST and/or GCIG CA-125 response
  - PRO based on EORTC QLQ-C30 Global Health status

- Overall survival is a standalone efficacy endpoint outside of the step-down analysis

**Definitions**

- BRCA, *BRCA1* or *BRCA2*: CA-125, cancer antigen 125; DOR, duration of response; EORTC QLQ, European Organization for Research and Treatment of Cancer quality of life questionnaire; GCIG, Gynecological Cancer Intergroup; ITT, intent to treat; ORR, objective response rate; PFS, progression-free survival; PRO, patient-reported outcomes; RECIST, Response Evaluation Criteria In Solid Tumors, version 1.1.
Baseline Patient Characteristics: ITT Population

<table>
<thead>
<tr>
<th></th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median age, years (range)</td>
<td>58.0 (38–81)</td>
<td>58.5 (38–85)</td>
<td>58.0 (38–85)</td>
</tr>
<tr>
<td>Geographic region, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central/Eastern Europe</td>
<td>135 (57.9)</td>
<td>67 (57.8)</td>
<td>202 (57.9)</td>
</tr>
<tr>
<td>Northern/Southern Europe</td>
<td>59 (25.3)</td>
<td>35 (30.2)</td>
<td>94 (26.9)</td>
</tr>
<tr>
<td>Northern/South America</td>
<td>39 (16.7)</td>
<td>14 (12.1)</td>
<td>53 (15.2)</td>
</tr>
<tr>
<td>Median time since cancer diagnosis, months (range)</td>
<td>43 (13–185)</td>
<td>44 (14–140)</td>
<td>43 (13–185)</td>
</tr>
<tr>
<td>Diagnosis, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epithelial ovarian cancer</td>
<td>220 (94.4)</td>
<td>111 (95.7)</td>
<td>331 (94.8)</td>
</tr>
<tr>
<td>Fallopian tube cancer</td>
<td>7 (3.0)</td>
<td>3 (2.6)</td>
<td>10 (2.9)</td>
</tr>
<tr>
<td>Primary peritoneal cancer</td>
<td>6 (2.6)</td>
<td>2 (1.7)</td>
<td>8 (2.3)</td>
</tr>
<tr>
<td>Histology, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serous</td>
<td>208 (89.3)</td>
<td>105 (90.5)</td>
<td>313 (89.7)</td>
</tr>
<tr>
<td>Endometrioid</td>
<td>18 (7.7)</td>
<td>6 (5.2)</td>
<td>24 (6.9)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (3.0)</td>
<td>5 (4.3)</td>
<td>12 (3.4)</td>
</tr>
<tr>
<td>ECOG PS, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>125 (53.6)</td>
<td>72 (62.1)</td>
<td>197 (56.4)</td>
</tr>
<tr>
<td>1</td>
<td>108 (46.4)</td>
<td>44 (37.9)</td>
<td>152 (43.6)</td>
</tr>
<tr>
<td>BRCA germline status, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Germline</td>
<td>198 (85.0)</td>
<td>95 (81.9)</td>
<td>293 (84.0)</td>
</tr>
<tr>
<td>Somatic</td>
<td>35 (15.0)</td>
<td>19 (16.4)</td>
<td>54 (15.5)</td>
</tr>
<tr>
<td>Not available</td>
<td>0</td>
<td>2 (1.7)</td>
<td>2 (0.6)</td>
</tr>
</tbody>
</table>

BRCA, BRCA1 or BRCA2; ECOG PS, Eastern Cooperative Oncology Group performance status; ITT, intent to treat.
## Prior Anti-Cancer Treatment, Platinum Status, and Disease Burden: ITT Population


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*Randomization stratification factor; platinum resistant: PFI ≥1–<6 months, partially platinum sensitive: PFI ≥6–<12 months, fully platinum sensitive: PFI ≥12 months.

ITT, intent to treat; PFI, progression-free interval.

<table>
<thead>
<tr>
<th>Prior chemotherapy regimens, n (%)</th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>134 (57.5)</td>
<td>68 (58.6)</td>
<td>202 (57.9)</td>
</tr>
<tr>
<td>3–5</td>
<td>88 (37.8)</td>
<td>44 (37.9)</td>
<td>132 (37.8)</td>
</tr>
<tr>
<td>≥6</td>
<td>11 (4.7)</td>
<td>4 (3.4)</td>
<td>15 (4.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior platinum-based regimens, n (%)</th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>12 (5.2)</td>
<td>6 (5.2)</td>
<td>18 (5.2)</td>
</tr>
<tr>
<td>2</td>
<td>156 (67.0)</td>
<td>74 (63.8)</td>
<td>230 (65.9)</td>
</tr>
<tr>
<td>≥3</td>
<td>65 (27.9)</td>
<td>36 (31.0)</td>
<td>101 (28.9)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prior nonplatinum regimens immediately before randomization, n (%)</th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>179 (76.8)</td>
<td>92 (79.3)</td>
<td>271 (77.7)</td>
</tr>
<tr>
<td>≥1</td>
<td>54 (23.2)</td>
<td>24 (20.7)</td>
<td>78 (22.3)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Median PFI after last dose of prior platinum regimen, months (range)</th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5.6 (1.1–67.4)</td>
<td>5.8 (1.0–90.1)</td>
<td>5.7 (1.0–90.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Platinum status, n (%)</th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platinum resistant</td>
<td>120 (51.5)</td>
<td>59 (50.9)</td>
<td>179 (51.3)</td>
</tr>
<tr>
<td>Partially platinum sensitive</td>
<td>65 (27.9)</td>
<td>31 (26.7)</td>
<td>96 (27.5)</td>
</tr>
<tr>
<td>Fully platinum sensitive</td>
<td>48 (20.6)</td>
<td>26 (22.4)</td>
<td>74 (21.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measurable disease at baseline, n (%)</th>
<th>Rucaparib (n=233)</th>
<th>Chemotherapy (n=116)</th>
<th>Overall (N=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>224 (96.1)</td>
<td>106 (91.4)</td>
<td>330 (94.6)</td>
</tr>
</tbody>
</table>
Primary Endpoint – Investigator-assessed PFS: Efficacy Population

At risk (events)
- Rucaparib (n=220)
  - 220 (0)
  - 121 (75)
  - 53 (134)
  - 23 (158)
  - 11 (165)
  - 3 (168)
  - 1 (168)
  - 0 (168)
- Chemotherapy (n=105)
  - 105 (0)
  - 42 (50)
  - 9 (78)
  - 4 (82)
  - 1 (84)
  - 0 (85)
  - 0 (85)

HR and associated P value calculated using a stratified Cox proportional hazards model.
HR, hazard ratio; PFS, progression-free survival.
Primary Endpoint – Investigator-assessed PFS: ITT Population

HR and associated $P$ value calculated using a stratified Cox proportional hazards model.
HR, hazard ratio; ITT, intent to treat; PFS, progression-free survival.
Investigator-assessed PFS: BRCA Reversion Mutation Subgroup

HR, 2.77
95% CI, 0.99–7.76

Median, mo
Rucaparib (n=13) 2.9 1.8–4.2
Chemotherapy (n=10) 5.5 1.9–6.6

HR, 2.77
95% CI, 0.99–7.76

HR calculated using a stratified Cox proportional hazards model. \( P \) value was significant for treatment by BRCA reversion mutation (yes vs no) interaction test (\( P = 0.0097 \)).
BRCA, \( BRCA1 \) or \( BRCA2 \); HR, hazard ratio; PFS, progression-free survival.
**Secondary Endpoints – Response: Efficacy Population**

<table>
<thead>
<tr>
<th></th>
<th>Rucaparib</th>
<th>Chemotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RECIST ORR, n/N (%) [95% CI]^a</strong></td>
<td>85/211 (40.3) [33.6–47.2]</td>
<td>31/96 (32.3) [23.1–42.6]</td>
</tr>
<tr>
<td></td>
<td>P=0.13^b</td>
<td></td>
</tr>
<tr>
<td>Complete response</td>
<td>10 (4.7)</td>
<td>2 (2.1)</td>
</tr>
<tr>
<td>Partial response</td>
<td>75 (35.5)</td>
<td>29 (30.2)</td>
</tr>
<tr>
<td>Stable disease</td>
<td>77 (36.5)</td>
<td>38 (39.6)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>25 (11.8)</td>
<td>15 (15.6)</td>
</tr>
<tr>
<td>Not evaluable</td>
<td>24 (11.4)</td>
<td>12 (12.5)</td>
</tr>
<tr>
<td><strong>RECIST and/or CA-125 response, n/N (%) [95% CI]^c</strong></td>
<td>110/217 (50.7) [43.8–57.5]</td>
<td>44/101 (43.6) [33.7–53.8]</td>
</tr>
</tbody>
</table>

- Data were similar for the ITT population:
  - RECIST ORR: rucaparib, 37.9% (95% CI, 31.6–44.7) vs chemotherapy, 30.2% (95% CI, 21.7–39.9)
  - Median DOR: rucaparib, 9.4 months vs chemotherapy, 7.2 months (HR^d, 0.56 [95% CI, 0.34–0.93])


^a Patients with measurable disease at baseline. ^b Per Stratified Cochran-Mantel-Haenszel test. ^c Patients with measurable disease at baseline and/or evaluable by CA-125. ^d Per Cox proportional hazards model. CA-125, cancer antigen 125; DOR, duration of response; HR, hazard ratio; ITT, intent to treat; ORR, objective response rate; RECIST, Response Evaluation Criteria In Solid Tumors, version 1.1.
Secondary Endpoint – Change From Baseline in EORTC QLQ-C30 Global Health Status

<table>
<thead>
<tr>
<th>Efficacy Population</th>
<th>ITT Population</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rucaparib (n=197)</strong></td>
<td><strong>Rucaparib (n=207)</strong></td>
</tr>
<tr>
<td><strong>Chemotherapy (n=91)</strong></td>
<td><strong>Chemotherapy (n=101)</strong></td>
</tr>
<tr>
<td><strong>LS Mean (SE)(^a)</strong></td>
<td><strong>LS Mean (SE)(^a)</strong></td>
</tr>
<tr>
<td>0.5 (0.55)</td>
<td>0.6 (0.54)</td>
</tr>
<tr>
<td>0.3 (0.86)</td>
<td>0.4 (0.82)</td>
</tr>
<tr>
<td><strong>LS mean difference (SE)(^b)</strong></td>
<td><strong>LS mean difference (SE)(^b)</strong></td>
</tr>
<tr>
<td>0.2 (1.00); 95% CI, -1.8 to 2.2</td>
<td>0.3 (0.96); 95% CI, -1.6 to 2.2</td>
</tr>
</tbody>
</table>


Data were analyzed using a repeated measures ANCOVA model, with the baseline value as a covariate, and treatment and randomization stratification as factors.

\(^a\)LS mean change from baseline during first 6 cycles. \(^b\)Rucaparib vs chemotherapy.

ANCOVA, analysis of covariance; D, day; EORTC QLQ, European Organization for Research and Treatment of Cancer quality of life questionnaire; ITT, intent to treat; LS, least square; SE, standard error.
Most Common TEAEs (≥20% in Either Group)

- Median treatment duration: rucaparib, 7.3 months (range <1–41); chemotherapy, 3.6 months (range <1–25)
- Nineteen (8.2%) patients in the rucaparib group and 14 (12.4%) in the chemotherapy group discontinued due to TEAEb
- MDS/AML was reported by 4 patients in the rucaparib group (1 during treatment, 3 during long-term follow-up) and no patients in the chemotherapy group


aFour patients (rucaparib, 1; chemotherapy, 3) discontinued before receiving study treatment and are excluded from the safety population. bExcluding disease progression. ALT, alanine aminotransferase; AML, acute myeloid leukemia; AST, aspartate aminotransferase; MDS, myelodysplastic syndrome; TEAE, treatment-emergent adverse event.
Conclusions

• Patients with BRCA-mutated advanced, relapsed OC who received rucaparib had a significant improvement in PFS vs standard-of-care chemotherapy.

• The rucaparib safety profile was consistent with that reported in prior studies.

• This is the first prospective report from a randomized study demonstrating that the presence of a BRCA reversion mutation predicts for primary resistance to rucaparib.

• Overall survival will be presented once death events are mature (at visit cutoff, 51% of death events had occurred).

BRCA, BRCA1 or BRCA2; OC, ovarian cancer; PFS, progression-free survival.
Acknowledgments

ARIEL4 co-coordinating investigators: Rebecca Kristeleit, Guy’s and St Thomas’ NHS Foundation Trust, London, UK
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…and all ARIEL4 study patients and their families and caregivers

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