

# Niraparib Ovarian Cancer Clinical Trials Overview



Ongoing and Completed Clinical Trials Investigating PARPi (Niraparib) in Ovarian cancer

Monotherapy  
PARPi

## First-Line Maintenance Platinum Responsive

PRIMA<sup>1</sup> ★

Phase 3, randomized, double-blind: niraparib vs placebo  
Primary results reported in [NEJM](#)

PARPi + anti-  
VEGF

OVARIO<sup>2,3</sup>

Phase 2, open-label: platinum-based CT + bevacizumab followed by niraparib + bevacizumab  
Interim results reported at [SGO 2020](#)

PARPi + anti-PD-1

FIRST<sup>4</sup> ★

Phase 3, randomized, double-blind: Platinum-based chemotherapy + dostarlimab ± bevacizumab followed by niraparib + dostarlimab ± bevacizumab vs SOC platinum-based therapy followed by niraparib ± bevacizumab<sup>5</sup>  
Recruiting

PARPi + anti-PD-1  
+ anti-VEGF

## Recurrent Maintenance Platinum Responsive

NOVA<sup>5</sup> ★

Phase 3, randomized, double-blind: niraparib vs placebo  
Primary results reported in [NEJM](#)

## Recurrent Treatment Platinum Responsive

ENGOT-OV24-NGSO/AVANOVA<sup>b,6,7</sup>

Phase 1/2, open-label: niraparib vs niraparib + bevacizumab  
Primary results reported in [Cancer Chemother Pharmacol](#) & [Lancet Oncol](#)

## 4L+ Treatment

QUADRA<sup>8</sup> ★

Phase 2, open-label: niraparib in patients who have received ≥ 3 lines of CT  
Primary results reported in [Lancet Oncol](#)

## Platinum Resistant 2L+ Treatment

MOONSTONE<sup>c,9</sup> ★

Phase 2, open-label: niraparib + dostarlimab  
Recruiting

TOPACIO<sup>d,10,11</sup>

Phase 1/2, open-label: niraparib + pembrolizumab  
Primary results reported in [Annals of Oncol](#) & [Jama Oncol](#)

OPAL<sup>12</sup>

Phase 2, open-label: niraparib + dostarlimab + bevacizumab  
Active, Not Recruiting

- Enrollment complete
- Ongoing
- Non-GSK sponsored<sup>b</sup>
- ★ Registrational

Note: NORA (NCT03705156; Sponsored by Zai Lab [Shanghai] Co., Ltd.) is another non-GSK sponsored Phase 3, randomized, double-blind, placebo-controlled study conducted in China evaluating ZL-2306 (niraparib) for maintenance therapy in Chinese patients with platinum-sensitive relapsed ovarian cancer<sup>13,14</sup>

<sup>a</sup> The study has an adaptive design for modification of the control arm to allow for evolution of the SOC. Patients will receive SOC during the chemotherapy run-in period (cycle 1) before randomization to study treatment (cycle 2). concurrent bevacizumab use must be determined prior to randomization at cycle 2;

<sup>b</sup> A phase 1/2 investigator-sponsored (Nordic Society of Gynaecological Oncology-Clinical Trial Unit [NSGO-CTU]) trial; <sup>c</sup> in patients without known *BRCA* mutation who have platinum-resistant disease and who have also been previously treated with bevacizumab;

<sup>d</sup> TOPACIO was performed in collaboration with Merck Inc., to evaluate the safety and efficacy of the combination of niraparib and pembrolizumab in the treatment of patients with advanced or metastatic TNBC or recurrent PROC.

CT = chemotherapy; PARPi = poly(ADP-ribose) polymerase inhibitor; PD-1 = programmed cell death-1; PROC = platinum-resistant ovarian cancer; TNBC = triple negative breast cancer; VEGF = vascular endothelial growth factor.

Some information contained in this response may be outside the approved local label for niraparib. Use of niraparib is only for the indications covered in the approved local label. Dostarlimab (GSK4057190, TSR-042) is an investigational humanized anti-programmed cell death-1 (PD-1) antibody under development for the treatment of advanced solid tumors in an ongoing Phase 1 dose escalation and cohort expansion study (GARNET).

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