The MOONSTONE study is investigating new treatment options for ovarian cancer.

### Methods

**The MOONSTONE study (NCT03955471) is:**

**Phase II**

- **Study design:** Open-label, single-arm study.
- **Screening:** Day 28 to 1.
- **Treatment period:** Day 1 to disease progression or unacceptable toxicity (up to 3 years).

**Trial objective**

The objective of this study is to evaluate the safety and efficacy of niraparib + dostarlimab in patients with advanced, relapsed, high-grade, BRCA wild-type platinum-resistant ovarian cancer who have progressed and have received prior bevacizumab.

**Background**

**Ovarian cancer**

Ovarian cancer has one of the highest mortality rates of all gynaecologic cancers. While initial response to chemotherapy and first-line platinum-based chemotherapy might be favourable, up to 70% of patients relapse and the majority of tumours become resistant.

The anti-VEGF monoclonal antibody, bevacizumab, is approved for treatment of recurrent platinum-resistant ovarian cancer in combination with single-agent chemotherapy. However, there is still a strong clinical need for new treatment options.

### Study population

**Key inclusion criteria**

- Female, 18 years of age or older
- Non-germplasm ovarian cancer
- Karnofsky Performance Status ≥70 and ≤100
- Measurable or non-measurable disease
- This includes efficacy in patients with BRCA wild-type tumours who, in advanced ovarian cancer, have worse survival outcomes than those with BRCA mutations.

**Key exclusion criteria**

- Prior treatment with PARP or anti–PD-1 or anti–PD-L1 agent
- Known or suspected deleterious germline BRCA mutation, including BRCA mutations within the tumour
- Disease progression within 3 months (as radiologically confirmed per RECIST v.1.1) of the last platinum therapy

**Study objectives and endpoints**

- **Primary endpoint**
  - Efficacy in confirmed patients with BRCA wild-type tumours

- **Secondary endpoints**
  - Duration of disease control in patients with ferritin elevation of 50% or CR

- **Key secondary endpoints**
  - ORR assessed by investigator
  - OS
  - DCR
  - ORR assessed by an independent review committee
  - Safety and tolerability of combination treatment

**Exploratory endpoints**

- Efficacy in confirmed patients with BRCA wild-type tumours

**Study status**

- Currently recruiting

**Study completion:** September 2023

More information can be found on the MOONSTONE study page at [GSK website](http://www.gsk.com).