that of 48 patients with prior surgery, 36 had interval debulking and 12 upfront surgery; 94% (34/36) and 100% (12/12) had no RD, respectively. Mean niraparib dose at treatment initiation was 207.8 mg/day compared with 181.3 mg/day reported in PRIMA (Mirza, et al. J Clin Oncol;2020:38(15 suppl):6050). Niraparib was discontinued before the end of the ATU period in 8/67 patients (due to adverse events [AEs], n=4; disease progression, n=3; patient request, n=1). 86 treatment-related AEs occurred in 28/67 patients, most commonly thrombocytopenia (25% of patients [grade 3/4 in 7%]), nausea (10% [1%]), and abnormal haemoglobin (9% [0%]).

Abstract 2022-RA-1134-ESGO Table 1 Patient characteristics

	Patients exposed to niraparib (N=67)
Patient characteristics, n (%)	
Mean age, years (SD)	70.7 (9.2)
ECOG	
0	32 (48)
1	31 (46)
2	4 (6)
High-grade aOC histology	
Serous	65 (97)
Endometrioid	2 (3)
FIGO stage at diagnosis	
IIIA	4 (6)
IIIB	7 (10)
IIIC	38 (57)
IVA	8 (12)
IVB	10 (15)
HRD testing	6 (9)
Yes	6 (9)
No	61 (91)
HRD status	
HRd	2 (33)
HRp	2 (33)
Missing/non-contributory HR	2 (33)
Ascites at diagnosis	
Yes	34 (51)
No	33 (49)
Prior treatment with bevacizumab	
Yes	4 (6)
No	63 (94)
Prior surgery	
Yes	48 (72)
No	19 (28)
Type of surgery	
Upfront	12 (25)
No residual disease	12/12 (100)
Interval	36 (75)
No residual disease	34/36 (94)
Residual disease	**n=48**
Yes	2 (4)
No	46 (96)

aOC, advanced ovarian cancer; ECOG, Eastern Cooperative Oncology Group; FIGO, International Federation of Gynecologic Oncology; HR, homologous recombination; HRd, HR deficient; HRD, HR deficiency; HRp, HR proficient; SD, standard deviation.

Conclusion In the first real-life data from patients without maintenance treatment options, no additional safety concerns were observed with niraparib at a comparable median dose versus PRIMA in an older population. The enrolment of 67 patients in 8 months highlights the need for access to treatments for patients with newly-diagnosed aOC in France.

2022-RA-1137-ESGO USE OF AN ALLOGENEIC, CELL-BASED VACCINE DCP-001 IN HIGH GRADE SEROUS OVARIAN CANCERPATIENTS AFTER PRIMARY TREATMENT; A PHASE I CLINICAL TRIAL

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Introduction/Background DCP-001 is a cell-based relapse vaccine developed to prevent disease recurrence following primary treatment. Trials in patients with acute myeloid leukemia have shown DCP-001 to be well-tolerated and interim results of an ongoing phase II study (ADVANCE II) revealed durable clinical responses. Interestingly, the tumor-associated antigens expressed by DCP-001 are shared across tumor types, most notably ovarian cancer (OC). Here, we present data on the anti-tumor efficacy of DCP-001 in humanized OC mice models and initial safety and tolerability data of the phase I clinical trial evaluating DCP-001 immunization in high-grade serous OC patients.

Methodology Prior to initiation of a clinical trial, the efficacy of DCP-001 against OC cells was tested in a mouse model. Humanized mice were engrafted with SKOV3 cells and vaccinated when tumors reached an average volume of 75–100 mm^3. Impact of DCP-001 vaccination was assessed on tumor growth. In the phase I trial, patients receive 6 immunizations with DCP-001; 4 bi-weekly vaccinations containing $25x10^6$ cells followed by 2 monthly boosters containing $10x10^6$ cells. Safety and tolerability is monitored up to 28 days after the last vaccination.

Results In a pre-clinical humanized OC mouse model, DCP-001 vaccination led to significant reduction of tumor growth rate resulting in partial and complete tumor regressions. In patients, DCP-001 vaccination was well-tolerated and DCP-001 related adverse events were only mild to moderate and mostly related to local injection site reactions. Patients reported fatigue, diarrhea, headache, nausea, temperature elevation and generalized joint and muscle pain. No severe adverse events were observed.

Conclusion Pre-clinical data in humanized OC mice demonstrated that DCP-001 reduces tumor growth and provided a rational for clinical therapeutic exploitation in OC patients. Initial data from the phase I trial demonstrates that DCP-001 is safe and well-tolerated and justifies continued exploration of this novel immunotherapy concept in OC patients.