IGCS20_1308

12 ONCOLYTIC VACCINIA (OLVI-VEC) PRIMED IMMUNOCHEMOTHERAPY IN PLATINUM-RESISTANT/ REFRACTORY OVARIAN CANCER

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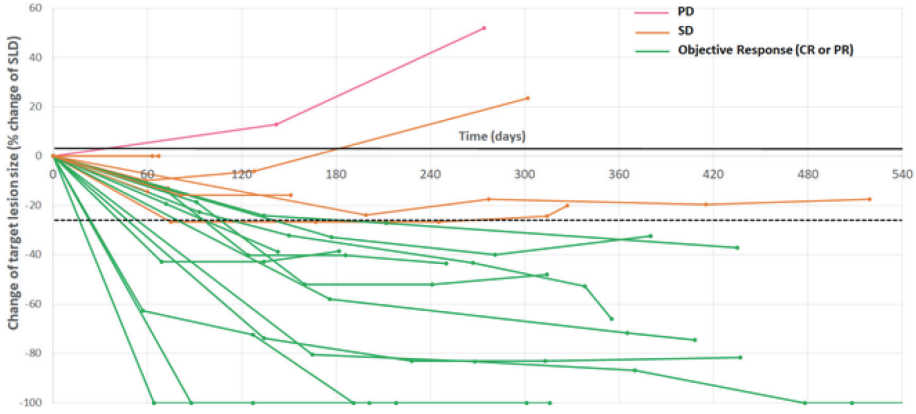
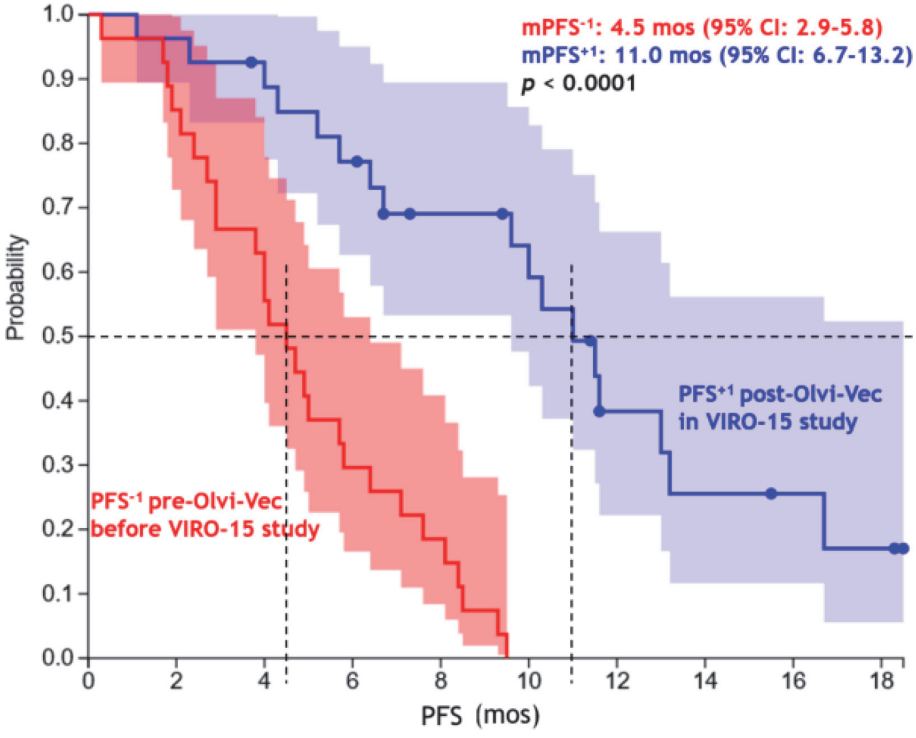
Introduction Intraperitoneal oncolytic vaccinia virus (Olvi-Vec) was administered to heavily pretreated patients with platinum-resistant/refractory ovarian cancer (PRROC) followed by intravenous carboplatin-doublet (CD) ± bevacizumab (Bev) in a Phase-2 trial (NCT02759588). Primary objectives: RECIST overall response rate (ORR) & progression-free survival (PFS).

Methods Patients with PRROC who progressed after most recent therapies received 2 days of Olvi-Vec followed by CD ±Bev, then maintenance with single-agent therapies ± Bev. Pre-&post-virotherapy tumor biopsies were obtained for translational analyses.

Results 27 patients enrolled: median 4 prior regimens, 82% prior Bev, 52% platinum-refractory and 48% platinum-resistant. Mean cycles of CD±Bev were 6(±3). Median follow-up was 26.5 months. RECIST ORR was 54% (95%CI:33–74%): 2(8%) complete response, 11(46%) partial response; 8(33%) stable disease. Median duration of response was 7.6 months (95%CI:3.7–9.6). Clinical benefit rate was 88%. Median PFS was 11.0 months (95%CI:6.7–13.0), and PFS-6-month was 77%. CA-125 ORR was 85% (95%CI:65–96%). There were no Grade 4 adverse events with virotherapy. Performance status was preserved/improved in 24 (89%) patients while on CD±Bev. Post-virotherapy intra-tumoral infiltration of CD8+



Abstract 12 Figure 1



Abstract 12 Figure 2

Abstract 12 Table 1 Baseline characteristics

Characteristic	Patients (n = 27)
Age, median (range)	62 (35-78)
Histology	
High grade serous	25 (92.6%)
Intermediate grade serous	1 (3.7%)
Mixed	1 (3.7%)
ECOG performance status	
0	17 (63%)
1	10 (37%)
Prior number of lines, median (range)	4 (2-9)
Prior platinum lines, median (range)	2 (1-5)
Platinum status at enrollment	
Platinum-resistant	13 (48%)
Platinum-refractory	14 (52%)
Prior antiangiogenic therapy with bevacizumab	
Yes	22 (81%)
No	5 (19%)
Prior PARP inhibitor therapy	
Yes	20 (74%)
No	7 (26%)
Baseline genomic profiles	
Tumor PD-L1 expression	
Positive	1 (3.7%)
Negative	25 (92.6%)
Unknown	1 (3.7%)
BRCA1/2 mutations	
Positive	8 (30%)
Negative	19 (70%)
Microsatellite instability status	
Stable	19 (70%)
Unknown	8 (30%)
Tumor mutational load	
Low	13 (48%)
Intermediate	4 (15%)
Unknown	10 (37%)
Response & PFS from last prior line before enrollment into VIRO-15 trial	
ORR by RECIST	4/27 (15%)
ORR by CA-125	5/24 (21%)
PFS (mos), median (95% CI)	4.5 (2.9 – 5.8)
PFS-6-month	30%

T-cells and upregulation of STAT1 expression (p=0.008) were demonstrated.

Conclusions Despite PRROC, prior bevacizumab, and progression on last therapy, the majority of patients achieved RECIST response with median PFS exceeding their prior line of therapy. Virus-induced changes in the tumor microenvironment may explain the apparent clinical reversal of platinum resistance.

IGCS20_1440

13 EFFICACY ON INDIVIDUALIZED STARTING DOSE (ISD) AND FIXED STARTING DOSE (FSD) OF NIRAPARIB PER INVESTIGATOR-ASSESSMENT (IA) IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER (OC)

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Introduction Niraparib is a poly(ADP-ribose) polymerase inhibitor approved for maintenance treatment of patients with newly diagnosed or recurrent OC that responded to platinum-based chemotherapy and treatment in heavily-pretreated recurrent OC. Here we report efficacy in patients receiving the FSD and ISD in the PRIMA/ENGOT-OV26/GOG-3012 trial (NCT02655016).

Methods This double-blind, placebo-controlled, phase 3 study randomized 733 patients to receive niraparib or placebo for 36 months or until disease progression/toxicity. A protocol amendment introduced ISD: 200 mg in patients with body weight <77 kg or platelets <150,000/μL, or 300 mg in all others. The primary endpoint was PFS by blinded independent central review (BICR). IA PFS was a sensitivity analysis. At the primary analysis data cut, follow-up was 11.2 months and 17.1 months in the ISD and FSD subgroups, respectively. An ad hoc analysis of IA PFS was performed using an updated data cut with additional 6 months follow-up.

Abstract 13 Table 1

Median PFS	IA PFS in the overall population and the ISD and FSD subgroups, HR (95% CI)	
	Original data cut 17 May 2019	Updated data cut 17 Nov 2019
Overall, N=733	0.63 (0.51, 0.76) *P*<0.0001	0.64 (0.53, 0.77) *P*<0.0001
FSD, n=487	0.60 (0.47, 0.77)	0.62 (0.49, 0.78)
ISD, n=246	0.68 (0.48, 0.96)	0.68 (0.49, 0.94)

FSD, fixed starting dose; HR, hazard ratio; IA, investigator assessment; ISD, individualized starting dose; PFS, progression-free survival.

Results BICR and IA PFS were highly concordant in the overall population. Efficacy of niraparib based on IA PFS in FSD vs ISD subgroups for each data cut were similar (table 1). Dose interruptions, modifications, and hematologic toxicity were lower with the ISD. Exposure–response data supported the clinical data.

Conclusions The 200- or 300-mg ISD by baseline body weight and platelet counts demonstrated comparable efficacy while improving the safety profile of niraparib. Use of this regimen for first-line maintenance of advanced OC patients is approved by the US FDA.

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Plenary V

IGCS20_1271

14 PHASE II TRIAL EVALUATING EFFICACY AND SAFETY OF STANDARD OF CARE WITH OR WITHOUT BEVACIZUMAB IN PLATINUM-RESISTANT EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER

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Introduction There are no ongoing clinical trials investigating bevacizumab efficacy beyond disease progression in platinum-