

Supplemental Online Content

Holloway RW, Mendivil AA, Kendrick JE, et al. Clinical activity of olvimulogene nanivacirepvec–primed immunochemotherapy in heavily pretreated patients with platinum-resistant or platinum-refractory ovarian cancer: the nonrandomized phase 2 VIRO-15 clinical trial. *JAMA Oncol*. Published online May 25, 2023. doi:10.1001/jamaoncol.2023.1007

eFigure. Kaplan-Meier Estimate of Overall Survival

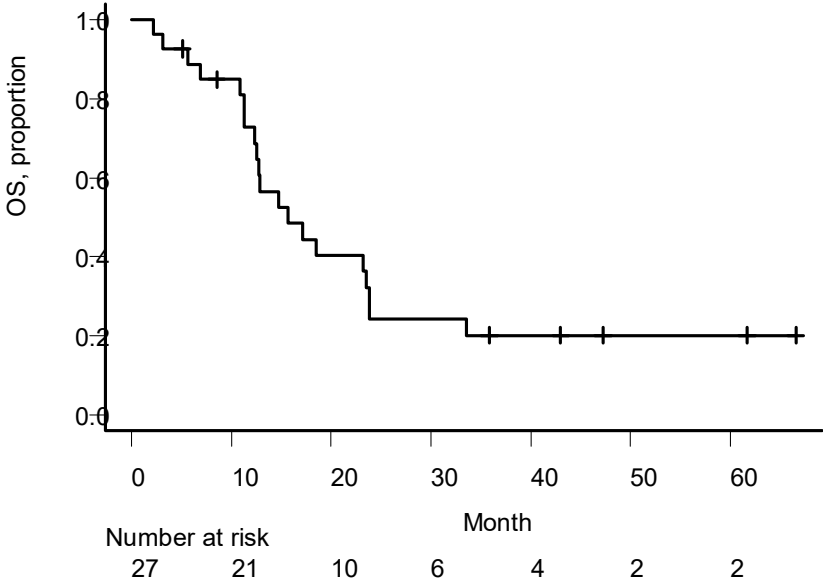
eTable 1. Patient Demographic and Clinical Characteristics

eTable 2. Adverse Events

This supplemental material has been provided by the authors to give readers additional information about their work.

Oncolytic Viral Immunotherapy in Ovarian Cancer

eFigure 1. Kaplan-Meier Estimate of Overall Survival (OS)



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eTable 1. Patient Demographic and Clinical Characteristics

Baseline Characteristics	Patients (n = 27)
Age, median (range), year	62 (35-78)
Histology	
High-grade serous	25 (92%)
Intermediate-grade serous	1 (4%)
Mixed	1 (4%)
Clinical stage	
III	1 (4%)
IIIA	1 (4%)
IIIB	4 (15%)
IIIC	17 (62%)
IV	4 (15%)
ECOG performance status	
0	17 (63%)
1	10 (37%)
BMI^a, median (range), kg/m²	23.3 (18.6-47.6)
PNI^{a,b}, median (range)	43.8 (32.0-56.8)
Prior number of lines, median (range)	4 (2-9)
Prior platinum lines, median (range)	2 (1-5)
Time from the last dose of the most recent platinum regimen to initiation of platinum-based therapy in this study, median (range), [95% CI], mo	9.9 (2.4-45.1), [9.2-17.0]
Platinum status at enrollment	
Platinum-resistant	14 (52%)
Platinum-refractory	13 (48%)
Prior therapy with bevacizumab	
Yes	22 (81%)
No	5 (19%)
Prior PARP inhibitor therapy	
Yes	20 (74%)
No	7 (26%)
Prior radiation therapy	
Yes	5 (19%)
No	22 (81%)
Baseline genetic profiles	
Tumor PD-L1 expression	
Positive	1 (4%)
Negative	25 (92%)
Unknown	1 (4%)
Germline or somatic BRCA1/2 mutations	
Germline	4 (15%)
Somatic	4 (15%)
Negative	19 (70%)
Microsatellite instability (MSI) status	
Stable	19 (70%)
Unknown	8 (30%)
Tumor mutational load	
Low	13 (48%)

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Intermediate	4 (15%)
Unknown	10 (37%)

Abbreviations: BMI, body mass index; BRCA, BReast CAncer gene; CA, cancer antigen; CI, confidence interval; CT, computed tomography; ECOG, Eastern Cooperative Oncology Group; months (mo); ORR, objective response rate; PARP, poly-adenosine diphosphate-ribose polymerase; PFS, progression-free survival; PNI, prognostic nutritional index; PD-L1, programmed death ligand-1.

^aBMI and PNI were recorded to provide insight on nutritional and immune status.

^bPNI was calculated using the formula: $PNI = 10 \times \text{serum albumin value (g/dL)} + 0.005 \times \text{absolute lymphocyte count (per mm}^3\text{)}$.

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eTable 2.

A. Treatment-Related Adverse Events (TRAEs) Related to Olvi-Vec

Incidence of TRAEs Occurring in ≥ 2 patients, n (%)				
TRAEs ¹	Any Grade	Grade 1-2	Grade 3	Grade 4
Any TRAEs	26 (96.3)	26 (96.3)	4 (14.8)	0 (0)
Pyrexia	17 (63.0)	16 (59.3)	1 (3.7)	0 (0)
Abdominal Pain	14 (51.9)	12 (44.4)	2 (7.4) ²	0 (0)
Nausea	13 (48.1)	13 (48.1)	0 (0)	0 (0)
Abdominal Distension	11 (40.7)	11 (40.7)	0 (0)	0 (0)
Rigors	10 (37.0)	10 (37.0)	0 (0)	0 (0)
Fatigue	10 (37.0)	9 (33.3)	1 (3.7) ²	0 (0)
Muscular Weakness	7 (25.9)	7 (25.9)	0 (0)	0 (0)
Vomiting	7 (25.9)	7 (25.9)	0 (0)	0 (0)
Generalized Pain	6 (22.2)	6 (22.2)	0 (0)	0 (0)
Anorexia	4 (14.8)	3 (11.1)	1 (3.7) ²	0 (0)
Headache	4 (14.8)	4 (14.8)	0 (0)	0 (0)
Dehydration	3 (11.1)	3 (11.1)	0 (0)	0 (0)

¹ All adverse events (AEs) were classified using the MedDRA v19, and were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events v4.03. TRAEs were defined as AEs determined to have a degree of attribution to Olvi-Vec, with an onset date on or after the date of first Olvi-Vec dose until 28 days after the second Olvi-Vec dose. Patients with multiple reports of same adverse event, most severe included. No deaths related to Olvi-Vec treatment; No discontinuation due to TRAEs.

² One patient experienced a serious adverse event.

B. Adverse Events (AEs) Related to Subsequent Platinum-based Chemotherapy \pm Bevacizumab

Incidence of AEs Occurring in ≥ 2 Patients				
Patients, n (%): N=27	Any Grade	Grade 1-2	Grade 3	Grade 4
Any AEs	23 (85.1)	23 (85.1)	7 (25.9)	2 (7.4)
Nausea	9 (33.3)	8 (29.6)	1 (3.7)	0 (0.0)
Vomiting	8 (29.6)	8 (29.6)	0 (0.0)	0 (0.0)
Fatigue	7 (25.9)	7 (25.9)	0 (0.0)	0 (0.0)
Diarrhea	6 (22.2)	6 (22.2)	0 (0.0)	0 (0.0)
Hypertension	6 (22.2)	4 (14.8)	2 (7.4)	0 (0.0)
Platelet count decreased	6 (22.2)	3 (11.1)	1 (3.7)	2 (7.4)
Anemia	5 (18.5)	2 (7.4)	3 (11.1)	0 (0.0)
Headache	5 (18.5)	5 (18.5)	0 (0.0)	0 (0.0)
Asthenia	3 (11.1)	3 (11.1)	0 (0.0)	0 (0.0)
Constipation	3 (11.1)	3 (11.1)	0 (0.0)	0 (0.0)
Dehydration	3 (11.1)	2 (7.4)	1 (3.7)	0 (0.0)
Hypomagnesemia	3 (11.1)	3 (11.1)	0 (0.0)	0 (0.0)
Infusion related reaction	3 (11.1)	3 (11.1)	0 (0.0)	0 (0.0)
Alopecia	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)

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Arthralgia	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Decreased Appetite	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Dizziness	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Dysgeusia	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Epistaxis	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Hypokalemia	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Hyponatremia	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Neuropathy	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
Rhinorrhea	2 (7.4)	2 (7.4)	0 (0.0)	0 (0.0)
*All AEs reported with any grade based on worst grade per patient.				

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Data Sharing Statement

Holloway. Phase 2 VIRO-15 Trial of Olvi-Vec-Primed Immunotherapy in Heavily Pretreated Patients with Platinum-Resistant or -Refractory Ovarian Cancer. *JAMA Oncol.* Published xx. Doi:xxx

Data

Data available: Yes

Data types: Deidentified participant data

How to access data: robhollowaymd@gmail.com

When available: With publication

Supporting Documents

Document types: None

Additional Information

Who can access the data: Researchers whose proposed use of the data has been approved

Types of analyses: For a specified approved purpose

Mechanisms of data availability: After approval of a proposal