Objectives Olvi-Vec (olivimulogene nanivacirepvec, aka GL-VAC) is an oncolytic vaccinia virus-based immunotherapy. This Phase 3 study aims to test the hypothesis that the combination of Olvi-Vec followed by further platinum-doublet chemotherapy is particularly effective against tumors by virus-mediated immune activation and re-sensitization of tumor cells to chemotherapy in heavily pre-treated patients with platinum-resistant/refractory ovarian cancer (PRROC) as shown in the Phase 2 VIRO-15 study (table 1). Primary objective is progression-free survival (PFS) by updated data in PRROC patients.

Abstract TP026/#1435 Table 1 Previous phase 2 VIRO-15 study updated data in PRROC patients

<table>
<thead>
<tr>
<th>Overall Response Rate (ORR)</th>
<th>Progression-Free Survival (PFS)</th>
<th>Overall Survival (OS)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ORR by RECIST 1.1</strong></td>
<td><strong>PFS</strong></td>
<td><strong>OS</strong></td>
</tr>
<tr>
<td>All patients (n=27) (69%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>platinum-resistant (n=14)</td>
<td>59% (7/12)</td>
<td>15 weeks (9/27)</td>
</tr>
<tr>
<td>platinum-refractory (n=13)</td>
<td>54% (7/13)</td>
<td>15 weeks (8/13)</td>
</tr>
</tbody>
</table>

RECIST 1.1 in intent-to-treat population (ITT; all randomly assigned patients). Secondary objectives are: i) objective response rate (ORR) and duration of response (DOR) by RECIST 1.1, PFS by RECIST 1.1 (in modified ITT population), PFS by iRECIST, overall survival (OS), and safety; ii) to determine ORR by the Gynecological Cancer Intergroup (GCIG) CA-125 criteria, and Clinical Benefit Rate (CBR=(CR + PR + SD ≥15 weeks)/total number of patients evaluated by RECIST 1.1 or iRECIST). RECIST & iRECIST response will be assessed by blinded central imaging review (BCIR). Additional analyses of efficacy endpoints in modified population are included.

Methods Phase 3 OnPrime Study design is summarized in figure 1. The study is enrolling and will have 30 sites in the USA [NCT05281471].

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.
Results The primary endpoint of this trial is the 12-month progression-free survival (PFS) rate. The secondary endpoints are overall survival, PFS, time to first subsequent treatment, time to second progression (PFS2), time to the second subsequent treatment, and safety. All patients should provide tumor slides obtained during cytoreductive surgery, for a prospective examination of somatic homologous recombination deficiency (HRD) and homologous recombination repair gene alterations. Pre- and post-niraparib (at the time of disease progression if available) blood samples will be collected for circulating cell-free DNA analyses. Molecular biomarkers that may indicate clinical response/resistance to niraparib will be identified.

Conclusions In total, 102 patients will be recruited from five sites. An interim analysis is planned after recruitment of 68 participants. Accrual is expected to be completed in 2024, followed by presentation of results in 2025.

TP028/#658  RATIONALE AND STUDY DESIGN OF THE KOV-HIPEC-02 TRIAL: A RANDOMIZED, MULTICENTER, OPEN-LABEL PHASE III TRIAL OF HYPERHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER

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Objectives Hyperthermic intraperitoneal chemotherapy (HIPEC) during cytoreductive surgery has emerged to achieve a higher concentration of chemotherapeutic agents and treat micro-metastases on peritoneal surfaces by overcoming chemotherapy resistance with hyperthermia. At advanced staged ovarian cancer treated with neoadjuvant chemotherapy, HIPEC with cisplatin 75–100 mg/m² following interval cytoreductive surgery increases progression-free survival and overall survival (OV-HIPEC-01 and KOV-HIPEC-01). In chemotherapy-naïve ovarian cancer patients, survival benefit is not identified with HIPEC (KOV-HIPEC-01). In ovarian cancer, HIPEC is thought to overcome chemotherapy resistance.

Methods This trial (KOV-HIPEC-02) is a multicenter, open-label, 1:1 randomized, phase III trial that will enroll 140 patients in platinum-resistant recurrent epithelial ovarian cancer. Institutional review board approval was obtained. The experimental arm will receive cytoreductive surgery and HIPEC followed by standard chemotherapy, and the control arm will receive standard chemotherapy without HIPEC until disease progression. If patients are assigned to the HIPEC group, the HIPEC procedure is carried out using the open or closed technique by infusing 41.5–42.0°C doxorubicin 35 mg/m² and mitomycin 15 mg/m² for 90 minutes. The primary objective of the trial is to evaluate progression-free survival (PFS) between the HIPEC group and the control group. Secondary objectives are overall survival (OS), cancer-specific survival, safety, and the quality of life according to whether HIPEC was performed during surgery in patients with platinum-resistant recurrent ovarian cancer. The first patient was enrolled in April 2020.

Results There are no available results at the time of submission.

Conclusions There are no available results at the time of submission.