**Methods** ROCC is a multi-center prospective, randomized, non-inferiority trial. Patients with FIGO 2018 stage IA2-IB2 cervical cancer with squamous cell, adenocarcinoma, and adenosquamous carcinoma histology are eligible. Preoperative pelvic MRI confirming tumor size <4 cm without evidence of extracervical extension or metastases is required. No transcervical manipulators are allowed and tumor containment prior to colpotomy using pre-specified surgical techniques are mandatory. The primary objective is 3-year DFS. Secondary objectives include DSS, OS, patterns of recurrence, complications, patient reported outcome measures, and lymphedema. 420 patients will be enrolled in each arm which will provide 90% power to exclude an absolute decrease in DFS by 7% (HR <= 1.375) with a log-rank test for non-inferiority with a one-sided alpha of 0.05. Interim analysis for futility planned after 370/640 patients enrolled (correlates with estimated 11/32 events). 20 sites are activated/enrolling and 4 patients have been randomized at the time of submission.
**Results** Trial in progress: There are no available results at time of submission.
**Conclusions** Trial in progress: There are no available results at time of submission.

## TP002/#1563 AN OPEN LABEL, SINGLE ARM, MULTICENTER TRIAL OF DURVALUMAB AND BVAC-C, IN PATIENTS WITH HPV 16 OR 18 POSITIVE RECURRENT CERVICAL CANCER

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**Objectives** BVAC-C is a B cell- and monocyte-based immunotherapeutic vaccine transfected with recombinant HPV E6/E7, which was well tolerated in HPV positive recurrent cervical carcinoma in phase I study. We expect that combining BVAC-C with durvalumab (MEDI4736), an anti-PD-L1 therapy, will enhance the anti-tumor immune responses of an anti-PD-L1 agent.
**Methods** This study is being evaluated in two parts. Part A explores the 3+3 dose-escalation of BVAC-C combined with durvalumab 1500 mg to identify the maximum tolerated dose (MTD) and recommended phase 2 dose. Once phase 2 dose is determined, the phase 2 expansion of up to 25 patients (part B) will evaluate the safety and clinical efficacy, as measured by 6-month PFS rate. Part A study began enrolling patients in Sep 2021 and is ongoing in 6 Korean centers. Low dose cohort (1.0x10^7 cells/dose BVAC-C +1,500 mg Durvalumab) has been completed, enrollment of high dose (5.0x10^7 cells/dose BVAC-C + 1,500 mg Durvalumab) will begin in July 2022. AEs are assessed according to CTCAE v5. Tumor response is determined according to RECIST 1.1 criteria and iRECIST. Key eligibility criteria include 1) histologically confirmed HPV 16/18-positive cervical carcinoma, 2) only 1 prior first-line platinum-based chemotherapy ± bevacizumab not amenable to local therapy, and 3) measurable disease per RECIST v1.1. An exploratory study is being conducted to identify biomarkers including PD-L1, TMB, and HLA typing using tumors and blood.
**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.

## TP003/#1533 MITO CERV3_PHASE II STUDY ON CARBOPLATIN-PACLITAXEL-PEMBROLIZUMAB IN NEOADJUVANT TREATMENT OF LOCALLY ADVANCED CERVICAL CANCER

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**Objectives** The treatment choice in locally advanced cervical cancer (LACC) ranges from concurrent chemoradiation to neoadjuvant chemotherapy followed by radical surgery (RS); however, the rates of 5-year Progression Free Survival (PFS) (55%) and Overall Survival (OS) (63%) remain largely disappointing. Up to 92% of CC display high PD-L1 levels; therefore, the addition of anti-PD-1 immunotherapy may improve LACC prognosis. MITO CERV 3 trial aims at exploring the addition of Pembrolizumab to standard chemotherapy in PD-L1 positive patients (PDL1>1%).
**Methods** MITO CERV 3 is a single arm multicenter phase II trial evaluating the role of Pembrolizumab in combination with chemotherapy in stage IB2-IIB (according to FIGO 2009 classification) CC patients. Patients will receive 3 cycles of neoadjuvant (NAD) Carboplatin AUC 5 + Paclitaxel 175 mg/mq + Pembrolizumab 200 mg q21, followed by RS in non-progressing patients. After surgery, only patients with clinico-pathological high risk factors will receive 3 further cycles of adjuvant chemotherapy in combination with Pembrolizumab, followed by Pembrolizumab alone as maintenance until