

p53, and PD-L1 were analyzed to predict the survival outcomes.

**Results** Of 104 vulvar cancer patients, prognostic factors that significantly correlated with worsening PFS were coexisting vulvar lesions, such as sclerosis and extramammary Paget's disease ( $p=0.008$ ), positive lymphovascular invasion (LVSI) ( $p=0.011$ ), positive pelvic or paraaortic node metastases ( $p=0.042$ ), and positive p53 status ( $p=0.046$ ). Tumor size over 4 cm in diameter was significantly associated with worsening OS ( $p=0.001$ ). The median PFS was 26.3 months, and the median OS was 44.7 months. The patients with positive p16 and negative p53 IHC had significantly better PFS and OS,  $p=0.004$  and  $0.025$ , respectively.

**Conclusion/Implications** Coexisting vulvar lesions, LVSI status, pelvic or paraaortic node metastases, and p53 status significantly affect PFS in vulvar cancer patients. Tumor size over 4 cm is negatively associated with OS.

## ePoster Viewing: Trials-in-Progress

### AS03. Cervical cancer

TP002/#1431

#### MULTICENTRIC INTERNATIONAL IMAGING STUDY TO COMPARE THE DIAGNOSTIC ACCURACY OF ULTRASOUND, DW/MRI AND PET/CT IN PREOPERATIVE ASSESSMENT OF LYMPH NODE STATUS IN CERVICAL CANCER (CANNES)

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**Introduction** The objective of this study is to compare the overall accuracy of US, PET/CT and DW/MRI in preoperative assessment of lymph nodes (LNs) in cervical cancer. Primary end-point is the overall accuracy of imaging in detection of pelvic LN macrometastases and to prove non-inferiority of US to other methods. Main secondary end-points include overall accuracy in detection of pelvic macro- and/or micrometastases (pN1) and paraaortic LN involvement.

**Methods** All patients with histopathologically verified cervical cancer and eligible for surgery (minimally systematic PLND, PLN sampling/debulking or SLN biopsy) will be enrolled. Key exclusion criteria include FIGO stage IVA and IVB. Each patient will undergo three imaging methods performed by dedicated operators following standardized protocols within 6 weeks before surgery. Imaging will be conducted independently and blinded but surgeons will have all reports available as navigation. The surgical procedures will be done in line with institutional guidelines but all radiologically positive LNs must be removed. The final histopathological examination will be a primary reference standard and diagnostic performance of imaging will be assessed per patient and per site. If LNs are

preoperatively classified as certainly or probably infiltrated but histopathological examination including ultrastaging is negative, imaging will be repeated after surgery. If radiologically positive LNs persist, it will be considered a secondary reference standard.

**Current Trial Status** The aimed number of patients is 91. There are 3 contributing centers (Prague, Rome, Madrid). The first patient was enrolled in January/2021 and the last one is expected in December/2023. The final analysis with outcomes is planned in 2024.

TP003/#1557

#### AN OPEN LABEL, SINGLE ARM, MULTICENTER TRIAL OF DURVALUMAB AND BVAC-C, IN PATIENTS WITH HPV 16 OR 18 POSITIVE CERVICAL CANCER (DURBAC)

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**Introduction** BVAC-C, a novel B cell- and monocyte-based immunotherapeutic vaccine transfected with recombinant HPV E6/E7, exhibited favorable tolerability in the phase I study of recurrent cervical carcinoma. This ongoing clinical trial aims to assess the potential synergistic effect of BVAC-C and durvalumab (MEDI4736) in enhancing anti-tumor immune responses. The trial focuses on patients with HPV 16 or 18 positive cervical cancer that is recurrent after or refractory to first-line platinum-based chemotherapy +/- bevacizumab.

**Methods** The trial is divided into two phases. In Part A, a 3 +3 dose-escalation design investigates BVAC-C combined with 1500 mg durvalumab to establish the maximum tolerated dose (MTD) and recommended phase 2 dose. After determining the phase 2 dose, Part B proceeds with a phase 2 expansion involving up to 25 patients. The evaluation in Part B centers on both safety and clinical efficacy, as gauged by the 6-month progression-free survival (PFS) rate. Tumor response evaluation adheres to RECIST 1.1 criteria and iRECIST. Exploratory study: In addition to evaluating clinical outcomes, an exploratory study is ongoing to identify potential biomarkers, including PD-L1 expression, tumor mutational burden (TMB), and HLA typing. These assessments are conducted using tumor samples and blood specimens.

**Current Trial Status** Enrolment for Part A commenced in September 2021 across six Korean centers. Part A, encompassing 9 patients, concluded in June 2022. Currently, Part B is actively enrolling patients with 15 participants enrolled so far.