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.

Introduction The objective of this study is to compare the overall accuracy of US, PET/CT and DW/MRI in preoperative assessment of cervical cancer.

Methods All patients with histopathologically verified cervical cancer that is recurrent after or refractory to 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.

ePoster Viewing: Trials-in-Progress

AS03. Cervical cancer

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 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.