Abstracts

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 (LVI) (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, LVI 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)

1Filip Fruhaufl, 1Daniela Fischerova, 1Roman Kocián, 2Nicolo Bizzari, 1Reyes Oliver Peréz, 1David Cibula, 1General University Hospital and First Faculty of Medicine, Charles University, Gynecologic Oncology Centre, Department of Obstetrics and Gynecology, Prague, Czech Republic; 2Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Ginecologia Oncologica, Rome, Italy; 3University Hospital October 12, Center of Gynecologic Oncology and Endoscopy, Department of Gynecology and Obstetrics, Madrid, Spain

10.1136/ijgc-2023-IGCS.465

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 (LN) 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)

1Chul Hun Choi, 2Byoung Gie Kim*, 3Jeong-Won Lee, 4Yoo Young Lee, 5Duck Cho, 6Byoung-Kwan Park, 7Sang Yong Song, 8Dae-Yeon Kim, 9Kyoung Kim, 10Seung Seung Ki, 11Jung-Yun Lee, 12Myong Cheol Lim, 13Wu, Hyun Kim, 14Chang Yull Kang, 15Samsung Medical Center, Sungkyunkwan University School of Medicine, Department of Obstetrics and Gynecology, Seoul, Korea, Republic of; 16Sungkyunkwan University School of Medicine, Samsung Medical Center, Seoul, Korea, Republic of; 17Samsung Medical Center, Obstetrics and Gynecology, Seoul, Korea, Republic of; 18Asan Medical Center, Department of Obstetrics and Gynecology, Seoul, Korea, Republic of; 19Seoul National University Bundang Hospital, Department of Obstetrics and Gynecology, Seongnam-Si, Korea, Republic of; 20Seoul National University Hospital, Obstetrics and Gynecology, Seoul, Korea, Republic of; 21Yonsei University Health System, Obstetrics and Gynecology, Seoul, Korea, Republic of; 22Center for Gynecologic Cancer, National Cancer Center, Department of Obstetrics and Gynecology, Gayang, Korea, Republic of; 23Cellid, Pharmacology, Seoul, Korea, Republic of

10.1136/ijgc-2023-IGCS.466

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 Enrollment 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.