$U_{TOX} \times TOX + U_{TWIST} \times TWIST$, where U_{TWIST} and U_{TOX} represent utilities applied to time spent in TWIST and TOX health states, respectively. U_{TWIST} was considered 1.00, i.e., the best possible quality of life for patients. U_{TOX} was calculated using EQ-5D index scores from the PRIMA trial. Restricted mean QA-PFS was calculated from the area under the quality-survival product function up to the last PFS of patients randomized to niraparib. **Results:** Maximum PFS was 27.8 months with niraparib. There were improvements in mean QA-TWiST for niraparib vs. placebo in the intention-to-treat (ITT) and homologous recombination deficient (HRd) cohorts, with mean (95% confidence interval [CI]) gains of 3.5 (1.7–5.6) and 5.9 (3.5–8.6) months, respectively. Similarly, QA-PFS was significantly longer with niraparib vs. placebo, with mean (95% CI) differences of 4.1 (2.2–5.8) and 6.5 (3.9–8.9) in the ITT and HRd cohorts, respectively.

Conclusion: In patients with ovarian cancer, first-line niraparib maintenance was associated with significant gains in QA-TWiST and QA-PFS vs. placebo, confirming the benefit of niraparib in the ITT population and HRd cohort.

Miscellaneous

Oral (OMi1)

Gestational Trophoblastic Neoplasia

<https://doi.org/10.3802/jgo.2021.32.S1.OMi1>

Phase II trial for Chemo-Resistant Gestational Trophoblastic Neoplasias with Pembrolizumab (CR-GTP)

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Background: Gestational trophoblastic neoplasia (GTN) represents a group of rare tumors that accounts for less than 1% of gynecologic cancers which arising from malignant transformation of trophoblast, a cell originating from placenta. Most patients with GTN are cured with chemotherapy, however 0.5%–5.0% of them die as a result of multi-drug resistance, necessitating novel approaches. Placental expression of paternal antigens make placenta a target for maternal immune recognition during pregnancy, and programmed death-ligand 1 (PD-L1) expression maintains gestational immune tolerance. Not known the exact mechanism, there is possible explanation by immune tolerance associated/derived from pregnancy. Therefore, targeting programmed cell death protein 1 (PD-1) inhibitory signaling with PD-1 inhibitor might be effective in

chemo-resistant GTN.

Methods: Participants are eligible to be included in the study. Female participants who are at least 18 years of age with histologically confirmed diagnosis of gestational trophoblastic neoplasia (hydatidiform-mole, invasive mole, gestational choriocarcinoma, placental site trophoblastic tumor, and epithelioid trophoblastic tumor) refractory or chemo-resistant to multi-agent chemotherapy (such as EMA-CO, EMA-EP, BEP, TP-TE, etc.) status will be enrolled in this study. Pembrolizumab 200 mg will be administered as a 30-minute intravenous infusion every 3 weeks. Radiological response assessed by the overall response according to iRECIST criteria every 3 cycles, and serologic response assessed by serum b-hCG at every 3 weeks. The serologic response is expected to show a decrease at least 50% of patients. We will test for four immunohistochemistry mismatch repair deficiency (MLH1/MSH2/MSH6/PMS2), microsatellite instability test, and PD-L1 expression, and we will further analyze the other immune response proteins (CD3, CD8, Granzyme B).

Oral (OMi2)

Gestational Trophoblastic Neoplasia

<https://doi.org/10.3802/jgo.2021.32.S1.OMi2>

Comparison of immuno-histochemical staining of programmed cell death ligand-1 (PD-L1) in placental site trophoblastic tumor and epithelioid trophoblastic tumor using 22C3, SP263, and SP142

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Objective: This study aims to evaluate programmed death-ligand 1 expression and concordance between 3 commercially available antibodies in placental site trophoblastic tumor (PSTT)/epithelioid trophoblastic tumor (ETT).

Methods: Serial histology sections from 14 patients diagnosed with PSTT or ETT underwent following immunohistochemistries; 22C3, SP263, SP142 on Ventana

Benchmark. Slides were scanned and counted for the number of tumor and immune cells expressing PD-L1 in 3 parts in each slide by one pathologist. Tumor cell proportion score (TC) and immune cell proportion score (IC) were calculated.

Results: Median of TC in 22C3, SP263, and SP142 was 35.0%, 50.7%, and 9.1%, respectively. Median of IC in 22C3, SP263, and SP142 was 1.7%, 1.8%, and 1.8%, respectively. Those 3 antibodies showed a high correlation in TC of PD-L1 staining. The percentage agreement was 85.7% between 22C and SP263 ($\kappa=0.440$, $p=0.047$). The percentage agreement was 92.9% and 85.7% between 22C3 and SP142 using 1% ($\kappa=0.811$, $p=0.002$) of TC, respectively. Using clinically relevant cut-off, the percentage agreement between SP263 and 22C3, and 22C3 and SP142 was 71.4% ($\kappa=0.152$, $p=0.571$) and 92.9% ($\kappa=0.811$, $p=0.002$), respectively. Intratumoral agreement of positivity of PD-L1 expression among different 3 parts in the same slide was 100% in 22C3 and SP263.

Conclusion: Those 3 antibodies showed a good correlation in TC of PD-L1 expression. 22C3 and SP142 may be interchangeable to determine PD-L1 due to its high agreement to evaluate the positivity for PD-L1 in PSTT/ETT. SP263 showed a higher positivity rate than others, and the agreement was acceptable with 22C3.

Oral (OMi3)

Endometrial Hyperplasia, Endometrial Intra-epithelial Neoplasia, and Endometrial Cancer

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Feasibility of identifying circulating tumor DNA based on cervical smear samples in endometrial cancer patients

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Objective: Cervical smear samples are easy to obtain and may effectively reflect the tumor environment in the pelvis due to anatomic proximity. Thus, we have investigated the feasibility of using cervical smear samples for tumor DNA analysis in endometrial cancer patients.

Methods: Patients undergoing endometrial cancer staging were prospectively enrolled since January 2021. Cervical smear samples were obtained preoperatively via vaginal sampling. Cell-free DNA was extracted and analyzed with a custom panel which covers 101 endometrial cancer-related genes. Prepared

libraries were sequenced using NovaSeq 6000 System (Illumina) and analyzed using Piseq analysis (Dxome).

Results: Cervical smear samples were obtained from 13 patients, and among them whole blood was available for ctDNA analysis in 12 patients. This predominantly early-stage cohort consisted of stage IA (n=7), stage IB (n=3), and stage II, III, and IV patients (n=1 for each). Overall, the detection rate for cervical cytology-based tumor DNA was 8 out of 13 patients (62%), whereas only 2 out of 13 patients (15%) had detectable ctDNA based on blood. Specifically, for stage IA patients, ctDNA was detected in 3 out of 7 patients, despite that all 7 patients had normal PAP smear result. Based on cytology-based tumor DNA analysis of cervical smear samples, the most frequently identified gene mutations were PTEN (n=6), PIK3CA (n=4), ARID1A (n=3), KRAS (n=3), TP53 (n=2), MSH6 (n=2), and ATM (n=2).

Conclusion: In this pilot study with predominantly early-stage endometrial cancer patients, cervical smear was more sensitive than whole blood or conventional PAP smear in terms of detecting tumor DNA.

Oral (OMi4)

Gynecologic Cancer Screening

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Pilot study on biomarkers for screening endometrial hyperplasia and early-stage endometrioid cancer

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Objective: Endometrial cancer is the most common malignancy of the female reproductive system in developed countries including Taiwan. Ways to screen precancerous endometrial lesion and early-stage endometrial cancer are mandatory. We performed proteomics study on endometrioid endometrial cancer and proteinase-3 (PRTN-3) showed significant expression in cancerous tissue compared with normal endometrial tissue. High expression of vascular endothelial growth factor (VEGF) and interleukin-6 (IL-6) was noted through literature review. We then conducted a pilot study to check if these are effective markers in vaginal discharge for the detection of early-stage endometrial cancer and its precancerous lesion.

Methods: After granted by Institutional Review Board, vaginal discharge samples of 133 patients between 2015 and 2017 at