

treatment. On studying acceptability of self-sampling, 943 (96.72%) participants were ‘very satisfied’, 918(94.15%) found it to be ‘very comfortable’ and 863(88.51%) stated that they will strongly recommend it to other eligible women.

Conclusion/Implications HR-HPV testing with limited genotyping showed a prevalence of 4.6%, 60% of these were HPV 16/18 positive. Point of care testing was feasible in the community and self-sampling was acceptable. Roughly 50% declined treatment, and reasons need to be looked into.

PR088/#198

EZH2/EZH1 INHIBITOR TULMIMETOSTAT (CPI-0209): PRELIMINARY PHASE II RESULTS AND FIRST BIOMARKER FINDINGS IN PATIENTS WITH ARID1A-MUTANT OVARIAN CLEAR CELL OR ENDOMETRIAL CARCINOMAS (OCCC/EC)

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Introduction ARID1A mutation (ARID1Amut) has a high incidence in OCCC (up to 60%) and EC (up to 40%), with evidence as a negative prognostic marker for treatment resistance and outcomes. EZH2 inhibition in ARID1Amut solid tumors results in tumor growth inhibition (Bitler et al. Nat Med 2015;21:231–238). Preliminary Phase II (NCT04104776) efficacy, safety, and biomarker findings from OCCC and EC cohorts receiving tulmimetostat are reported.

Methods The Phase II study is evaluating tulmimetostat 350 mg once daily in 6 disease-based cohorts, including ARID1A-mut OCCC/EC. Per Simon 2-stage design, expansion of enrolment (plus n=19 patients per cohort in Stage 2) requires objective response rate (ORR) $\geq 1/10$ in Stage 1. Primary endpoint is ORR; secondary endpoints include safety. Evaluation of two additional dose levels was implemented for both cohorts, per FDA recommendation of Project Optimus, to inform on optimal tulmimetostat dose.

Results 24 patients were enrolled (OCCC, n=14; EC, n=10); 50% of each cohort have received ≥ 3 prior treatment lines. Both cohorts are eligible for Stage 2 expansion, with 1 and 2 confirmed partial responses in patients with OCCC and EC, respectively (table 1). The manageable safety profile across all 6 tumor cohorts (n=81) was consistent with known class effects; Grade ≥ 3 related adverse events ($\geq 10\%$ of patients) included thrombocytopenia, anemia, neutropenia, and diarrhea. Next generation sequencing did not reveal a specific hotspot for ARID1Amut locations impacting clinical outcome in patients with OCCC/EC.

Conclusion/Implications These preliminary findings in heavily pre-treated patients with ARID1Amut OCCC/EC support continued investigation of tulmimetostat monotherapy.

PR089/#862

ARTIFICIAL INTELLIGENCE-BASED DIAGNOSTIC SYSTEM FOR THE DETECTION OF ABNORMAL COLPOSCOPIC FINDINGS

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Introduction Colposcopic examination requires sufficient training to detect cervical intraepithelial neoplasia (CIN) with (1) high diagnostic accuracy and (2) minimizing time and reducing tissue biopsies. This study aimed to develop an artificial intelligence (AI) based system which replicates expert colposcopic examination techniques, independent of examiner skill.

Abstract PR088/#198 Table 1 Best responses*

		OCCC	EC
Efficacy evaluable, N		14	8
Best confirmed response, † n	CR	0	0
	PR	1	2
	SD	7	2
Best confirmed or unconfirmed response, † n	CR	0	0
	PR	4	3
	SD	4	1
No response, n	Progressive disease	6	2
	Not evaluable	0	1†
	Discontinued without response assessment	0	1

CR, complete response; EC, endometrial carcinoma; OCCC, ovarian clear cell carcinoma; PR, partial response; SD, stable disease.

*data cut-off 14 February 2023; †Per RECIST 1.1; ‡Patient had a radiological assessment (stable disease) prior to the required protocol-specified window (at least 28 days).