Abstracts

Objectives The prognosis for women with recurrent or persistent EC after progressing on first-line chemotherapy is poor. The humanized monoclonal anti-programmed cell death ligand 1 (PD-L1) inhibitor, Atezo has demonstrated monotherapy antitumor activity with an acceptable safety profile in recurrent EC. The AFT-50 EndoMAP trial is a platform trial designed to evaluate the efficacy and safety of Atezo in combination with biomarker-defined targeted agents in pts with recurrent or persistent EC.

Methods This is a phase IB/II non-randomized, multicenter, multicohort, biomarker-driven platform study for pts with recurrent/persistent EC having received no more than 2 prior lines of therapy. Based on genomic profile per FoundationOne® CDx (F1CDx) NGS assay, pts may be eligible for one of the following doublets: Atezo+ipatasertib (PIK3CA/PTEN/ AKT1-altered cancers), Atezo+talazoparib (genomic loss of heterozygosity (LOH) ≥16%), Atezo+Trastuzumab emtansine (ERBB2/HER2 mutated and/or amplified tumors), Atezo+Tiragolumab (MSI-H and/or TMB>10 mut/MB), and Atezo+bevacizumab (biomarker unmatched). Pts will receive Atezo and the targeted agent until progression, unacceptable toxicity, withdrawal from the study, death, or study termination. The primary endpoint is confirmed overall response rate (ORR) for each biomarker. Secondary endpoints include 6-month PFS, disease control rate, duration of response, OS, and safety and tolerability. Additional arms may be added, as supported by evolving understanding of EC and molecular targets. EndoMAP is actively enrolling at 4 sites with a target of 25 sites in the US.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.

TP011/#1527 GOG 3039 A PHASE II STUDY OF ABEMACICLIB IN COMBINATION WITH LETROZOLE IN ADVANCED, RECURRENT OR METASTATIC ENDOMETRIOD ENDOMETRIAL CANCER

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Objectives Primary Objective: To evaluate the efficacy in terms of the probability of surviving progression free for at least 6 months (PFS at 6 mo). Secondary Objective: To determine the proportion responding by RECIST v1.1 in patients with advanced, persistent, or recurrent endometrioid endometrial cancer. To estimate the time to disease progression or death (PFS and OS endpoints). To describe the toxicities in patients receiving combination therapy with letrozole and abemaciclib with advanced/metastatic endometrial cancer.

Methods Key Eligibility Criteria:-Advanced (FIGO 2014 Stage III or IV), persistent, or recurrent endometrial carcinoma.

Must have endometrioid histology (all grades allowed) (Hormone receptor status is not required for enrollment). -Must have measurable disease by RECIST v1.1. -Prior chemotherapy in the adjuvant setting for Stage I, II, or III is permitted. -Prior chemoradiotherapy for a pelvic recurrence is permitted. -Prior immunotherapy and/or targeted therapy is allowed in addition to, in combination with, in lieu of, or subsequent to prior chemotherapy. Regardless of circumstances, no more than one prior chemotherapy regimen (including chemoradiotherapy) is permitted, and no more than one additional systemic therapy is permitted. Hence, eligible patient may have received 0, 1, or 2 prior lines of systemic therapy and one of them may have included chemotherapy. -ECOG performance status of 0–1. -Must be able to swallow oral medications.

Results Trial in progress: there are no available results at the time of submission.

Conclusions Trial in progress: there are no available conclusions at the time of submission.

TP012/#1420 XMT-1660: A PHASE 1B TRIAL OF A B7-H4 TARGETING ANTIBODY DRUG CONJUGATE (ADC) IN ENDOMETRIAL, OVARIAN, AND BREAST CANCERS

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Objectives Endometrial (EC) and ovarian cancers (OC) are some of the leading causes of cancer death in women. Despite therapeutic advances, many patients eventually develop resistance to available standard of care (SOC) therapies. B7-H4 is a poor prognostic factor and is overexpressed in several cancers including endometrial, ovarian, and breast. As a member of the CD28/B7 family of cell surface proteins, it promotes tumorogenesis by suppressing anti-tumor immunity XMT-1660 is a B7-H4-targeted Dolasynthen ADC with a precise, optimized drug-to-antibody ratio and a DolaLock microtubule inhibitor payload with controlled bystander effect. In the preclinical setting, XMT-1660 has demonstrated anti-tumor activity in EC and OC PDX models.

Methods The Ph1 trial includes a first-in-human dose escalation (DES) portion followed by a dose expansion (EXP) evaluating XMT-1660 in patients with EC, OC, and BC following progression on SOC. In the DES, BOIN design will be used to determine the MTD. The DES will assess safety and preliminary efficacy, and establish recommended phase 2 dose (RP2D). In the EXP portion, cohorts enrolling EC/OC, TNBC, ER+/HER2- BC, are planned and additional patients...