and the size or number of LN metastasis is not yet reflected in both the staging system and treatment modality. The therapeutic effect of surgical resection of bulky lymph node before standard treatment has been reported in several retrospective studies. However, there are lack of well-planned randomized clinical study. Therefore, the aim of the Korean Gynecologic Oncology Group (KGOG) 1047/DEBULK trial is to investigate whether the debulking surgery of bulky or multiple LNs prior to concurrent chemoradiation therapy (CCRT) improves the survival rate in cervical cancer IIICr as diagnosed by imaging.

Methods The KGOG 1047/DEBULK trial is a phase III, multicenter, randomized clinical trial of patients with bulky or multiple lymph node metastasis in cervical cancer IIICr. This study included patients with a short-axis of a pelvic or paraaortic LN $\geq$ 2 cm or more than 3 LNs with a short axis $\geq$ 1 cm and for whom CCRT is planned. The treatment arms will randomly be allocated to undergo either CCRT (control arm) or surgical debulking of bulky or multiple LNs prior to CCRT (experimental arm). Total 234 patients will be included (117 patients per each group) within 4 years. The primary endpoint is 3-year progression free survival. The secondary endpoints are the treatment-related complications and the radiologic accuracy.

Current Trial Status Twenty-two Korean institutions have confirmed their participation, and are preparing for international joint research with India, Vietnam, and Malaysia. There are currently 15 patients enrolled.

AS04. Endometrial/Uterine corpus cancers

TP007/#1383 A PHASE II STUDY OF INDUCTION PD-1 BLOCKADE (NIVOLUMAB) IN PATIENTS WITH SURGICALLY COMPLETELY RESECTABLE MISMATCH REPAIR DEFICIENT ENDOMETRIAL CANCER (NIVEC)

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Introduction Mismatch repair deficient endometrial cancer (MMRd-EC) is a subtype of endometrial carcinoma which exhibits aggressive characteristics and poor prognosis. MMRd tumors are known to be highly immunogenic and of great interest for immune checkpoint inhibitor. There is lack of data regarding the efficacy of nivolumab as induction monotherapy in completely resectable MMRd-ECs . In this regard, we suggest a window of opportunity study of induction PD-1 blockade (nivolumab) in patients with surgically resectable MMRd-EC .

Methods This multi-center, non-randomized, open-label Phase II study plans to enroll 30 patients with surgically resectable MMRd-EC. Additional inclusion criteria include clinical stage I-IIIC2, tumor specimen that demonstrates MMRd by immunohistochemistry or microsatellite instability as demonstrated by NGS or PCR. Exclusion criteria include multiple primary cancers, residual adverse effects of prior therapy or history of severe hypersensitivity to any antibody products . Patients will receive nivolumab at a dose of 480 mg IV, every 4 weeks as induction therapy for six cycles. Subsequently, patients will undergo surgery and/or receive adjuvant treatment following standard institutional guidelines. The primary endpoint is complete response rate of PD-1 blockade and surgery. Secondary endpoints include objective response rate, progression-free survival, overall survival, and adverse events. Correlative studies include genomic characterization of tumors, assessment of immune infiltration of tumor microenvironment, and serial circulating cell-free DNA and immune biomarkers.

Current Trial Status Open enrollment period: Dec/2022, to Dec/2024. The Target number: 30 patients. The study intends to provide valuable insights into the efficacy and safety of nivolumab as induction therapy for surgically resectable MMRd-EC.

TP008/#1500 TRIAL IN PROGRESS: PHASE 2/3 STUDY OF NAVTEMADLIN AS MAINTENANCE THERAPY IN PATIENTS WITH ADVANCED OR RECURRENT ENDOMETRIAL CANCER WHO RESPONDED TO CHEMOTHERAPY (ENGOT-EN21; GOG-3089)

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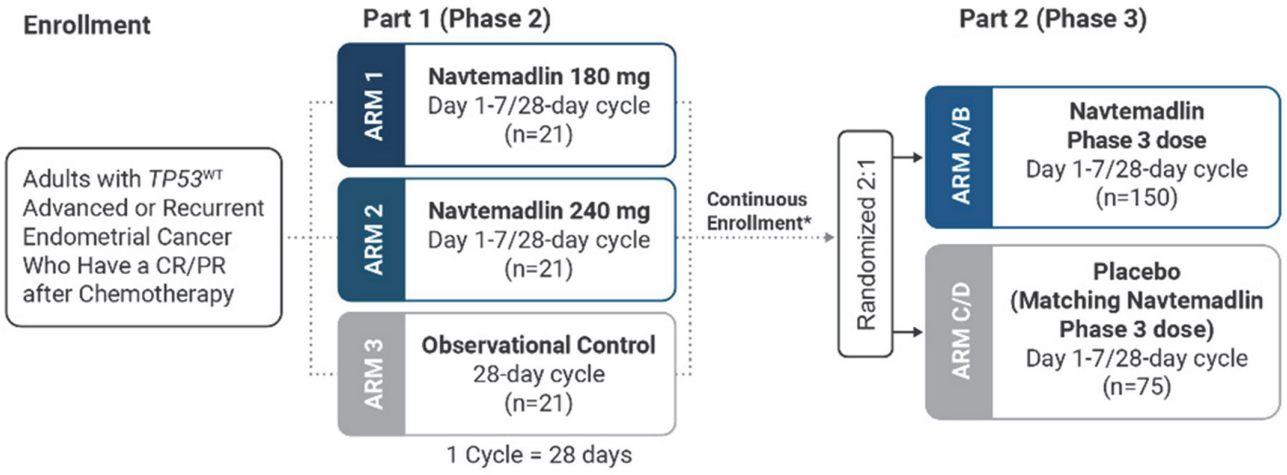
Introduction Advanced/recurrent endometrial cancer (EC) has poor prognosis with 5-year survival rate of ~17% (Colombo 2016; Siegel 2022). Maintenance treatment may extend the response to initial chemo/chemoimmunotherapy. Mouse



Abstract TP008/#1500 Figure 1 Study schema of KRT-232–118

double minute 2 (MDM2), a key negative regulator of p53, is upregulated in ~50% of EC patients (Jeczen 2007) due to loss of $p14^{ARF}$, a critical modulator of intranuclear MDM2 levels, thus preventing p53 tumor suppressor function. Navtemadlin is a potent, selective MDM2 inhibitor that restores p53-mediated apoptosis in $TP53^{WT}$tumors. The sensitivity of EC to genotoxic chemotherapy (Miller 2020) suggests susceptibility to p53-mediated apoptosis. Post-chemotherapy maintenance with navtemadlin may provide a non-genotoxic way to maintain p53-driven activity and tumor cell control in the ~50% of $TP53^{WT}$EC patients (Nakamura 2019). KRT-232–118 is a Global 2-part Phase 2/3 study evaluating the safety and efficacy of navtemadlin maintenance therapy in $TP53^{WT}$ advanced/recurrent EC patients following response to chemotherapy (EudraCT 2022–5002196-31; NCT05797831).

Methods Adults with ECOG PS 0–1 who completed up to 6 cycles of chemotherapy excluding adjuvant/neo-adjuvant therapy and achieved CR or PR (RECIST v1.1) are eligible. The open-label Phase 2 randomizes patients to oral navtemadlin at a dose of 180 mg or 240 mg QD (Day 1–7/28-day cycle), or observation; primary endpoint is recommended Phase 3 dose (RP3D). The double-blind Phase 3 will randomize patients (2:1) to the RP3D vs placebo QD (Day 1–7/28-day cycle); stratification is by response and disease stage. Primary endpoint for Phase 3 is PFS by blinded independent review.

Current Trial Status This study is now open to enrollment.

TP009/#1495 A PHASE 2, OPEN-LABEL, SINGLE-ARM, PROSPECTIVE, MULTI-CENTER STUDY OF NAB-SIROLIMUS PLUS LETROZOLE IN ADVANCED OR RECURRENT ENDOMETRIOID ENDOMETRIAL CANCER

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Introduction Despite recent pivotal data demonstrating improved outcomes with immunotherapy plus chemotherapy, regardless of mismatch repair status, alternative treatment options for advanced or recurrent endometrial carcinoma (EC) remain necessary. Dysregulation of mTOR signaling is implicated in the pathology of EC, particularly in endometrioid EC (EEC) in which >80% harbor PTEN or PI3K/AKT/mTOR pathway alterations. Moreover, crosstalk between mTOR and estrogen receptor signaling pathways is associated with