IGCS 2023 Annual Global Meeting SEOUL

IGCS 2023 Abstracts: Trials-in-Progress ePosters

Registered delegates will have access to all submitted Trials-in-Progress ePosters via the IGCS 2023 mobile application, IGCS 360 Educational Portal and the ePoster Stations onsite at the meeting venue.

Poster presenters were given the option to submit an audio file with a short presentation together with their ePosters. Submitted audio files will be available together with their ePosters within the ePoster Stations onsite and the IGCS 360 Educational Portal.

TP002 / #1431

Topic: ***AS03. Cervical Cancer***

MULTICENTRIC INTERNATIONAL IMAGING STUDY TO COMPARE THE DAGNOSTIC ACCURACY OF ULTRASOUND, DW/MRI AND PET/CT IN PREOPERATIVE ASSESSMENT OF LYMPH NODE STATUS IN CERVICAL CANCER (CANNES)

Filip Fruhauf[1], Daniela Fischerova[1], Roman Kocian[1], Nicolò Bizzarri[2], Reyes Oliver Peréz[3], David Cibula[1]
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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 (LNs) in cervical cancer. Primary end-point is the overall accuracy of imaging in detection of pelvic LN macrometastases and to prove non-inferioriy 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

Topic: ***AS03. Cervical Cancer***

AN OPEN LABEL, SINGLE ARM, MULTICENTER TRIAL OF DURVALUMAB AND BVAC-C, IN PATIENTS WITH HPV 16 OR 18 POSITIVE CERVICAL CANCER (DURBAC)

Chel Hun Choi[1], Byoung Gie Kim[2], Jeong-Won Lee[2], Tae-Joong Kim[2], Yoo Young Lee[3], Duck Cho[2], Byoung-Kwan Park[3], Sang Yong Song[2], Dae-Yeon Kim[4], Kidong Kim[5], Hee Seung Kim[6], Jung-Yun Lee[7], Myong Cheol Lim[8], Wu_Hyun Kim[9], Chang Yuil Kang[9]
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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: Enrolment 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.

TP004 / #1496

Topic: ***AS03. Cervical Cancer***

SENTINEL LYMPH NODE BIOPSY VERSUS PELVIC LYMPHADENECTOMY IN EARLY- STAGE CERVICAL CANCER: A MULTI-CENTER RANDOMIZED TRIAL

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Introduction: Sentinel lymph node (SLN) biopsy has long been considered as an alternative for pelvic lymphadenectomy in cervical cancer. However, the optimal strategy for applying SLN biopsy in cervical cancer remains lacking.

Methods: We are performing a multicenter, randomized controlled trial to compare the two approaches for lymph node dissection in cervix cancer (PHENIX trial, ClinicalTrials.gov number, NCT02642471). We enroll patients with FIGO 2018 stage IA1 (lymphovascular space involvement), IA2, IB1, IB2 and IIA1 cervical squamous carcinoma, adenocarcinoma, or adenosquamous carcinoma. SLN biopsy were performed at the start of surgery. The SLNs were submitted for frozen section examination and patients were triaged into the PHENIX-I (SLN-negative) or PHENIX-II (SLN-positive) cohort. In each cohort, patients were randomized in a 1:1 ratio into the experimental (SLN biopsy alone) or reference (pelvic lymphadenectomy) arm. This trial was designed with non-inferiority hypothesis and the primary endpoint is disease-free survival. Estimated sample sizes of 830 and 250 are required to fulfill the study objectives of PHENIX-I and II, respectively.

Current Trial Status: Up to June 2023, 826 and 67 patients enrolled PHENIX-I and PHENIX-II cohort, respectively. Twenty-five patients were excluded due to inappropriate postoperative pathology. Among the current data, the bilateral detecting rate of SLN was 82.4%. The frozen section examination was found false-negative in 7 patients and false-positive in 3. Adjuvant therapies were administered in 47.9% patients with pathological risks. The median follow-up time reached 30 months. Neither of the cohorts showed difference in disease-free survival between the arms. The final presentation of results is expected in 2026.

TP005 / #1524

Topic: ***AS03. Cervical Cancer***

THERAPEUTIC EFFECT OF SURGICAL DEBULKING OF METASTATIC LYMPH NODES IN CERVICAL CANCER STAGE IIICR: A PHASE III, RANDOMIZED CONTROLLED CLINICAL TRIAL (KGOG1047; DEBULK TRIAL)

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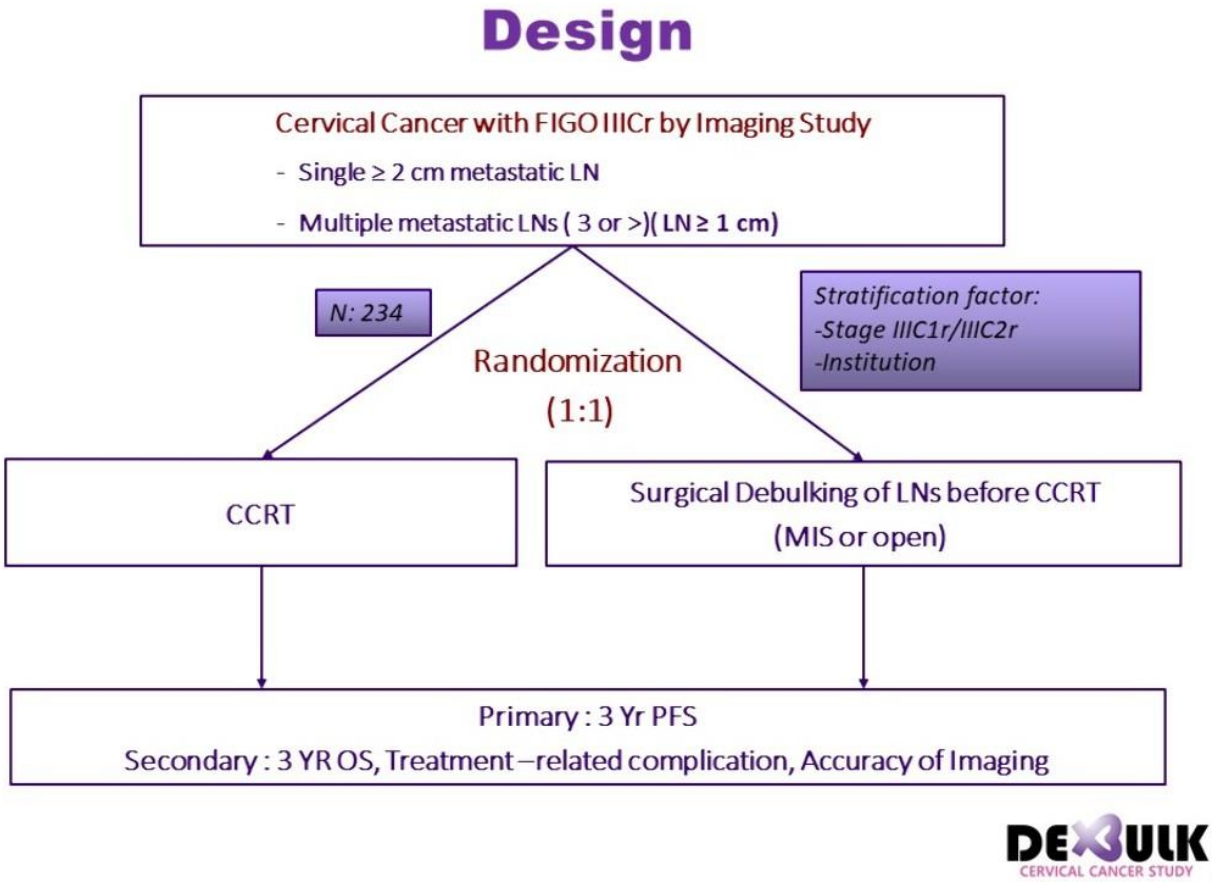
Introduction: Bulky or multiple lymph node (LN) metastasis has been reported to have poor prognosis in cervical cancer and the size or number of LN metastasis is not yet reflected in both the staging system and treatment modality. The therapeutic effect of surgical resection of bulky lymph node before 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, multi-center, 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 ≥ 2cm or more than 3 LNs with a short axis ≥ 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.



TP007 / #1383

Topic: ***AS04. Endometrial/Uterine Corpus Cancers***

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 480mg 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

Topic: ***AS04. Endometrial/Uterine Corpus Cancers***

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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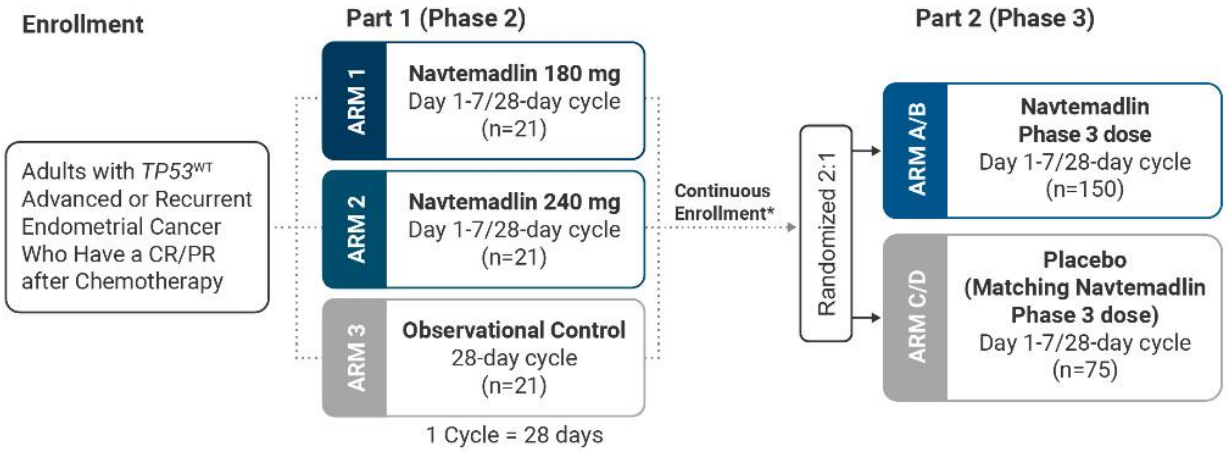
Introduction: Advanced/recurrent endometrial cancer (EC) has poor prognosis with 5-year survival rate of ~17% (Colombo 2016; Siegel 2022). Maintenance treatment may extend the response to initial chemo/chemoimmunotherapy. Mouse double minute 2 (MDM2), a key negative regulator of p53, is upregulated in ~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.

Figure 1: Study Schema of KRT-232-118



*After enrollment completes for Part 1, patients will continue to be enrolled for Part 2 and randomized 2:2:1:1 to one of the 4 treatment arms: navtemadlin 180 mg, navtemadlin 240 mg, placebo 180 mg or placebo 240 mg. Once the SRC determines the navtemadlin Phase 3 dose, enrollment for Part 2 will continue with 2:1 randomization to the navtemadlin Phase 3 dose and matching placebo dose.

Abbreviations: CR, complete remission; PR, partial response; WT; wild type.

TP009 / #1495

Topic: ***AS04. Endometrial/Uterine Corpus Cancers***

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 endocrine resistance. GOG-3007 and other phase 2 studies have demonstrated that the combination of conventional mTOR inhibitors (mTORi) and endocrine therapy provides clinical benefit in patients with EC. nab-Sirolimus is a nanoparticle injectable form of mTORi approved for malignant perivascular epithelioid cell tumor. Preclinical data with nab-sirolimus demonstrated improved tumor accumulation, mTOR inhibition, and tumor growth suppression compared with conventional mTORi. We hypothesize that nab-sirolimus in combination with letrozole may produce synergistic antitumor activity in patients with recurrent EEC.

Methods: In this phase 2, open-label, single-arm, multi-center study (NCT05997017), nab-sirolimus (100 mg/m^2, IV, days 1 and 8 of each 21-day cycle) and letrozole (2.5 mg, oral, daily) are administered to patients (~29 planned) with clinically confirmed, advanced or recurrent EEC. Eligibility criteria include age ≥18 years, 0-1 prior chemo-based regimens, ECOG 0-1, mTORi naïve, and RECIST-measurable disease. The primary endpoint is best ORR by RECIST v1.1; key secondary endpoints include duration of response, PFS, OS, and safety. The relationship between biomarkers and response outcomes is an exploratory endpoint.

Current Trial Status: Open for enrollment.

TP010 / #397

Topic: ***AS04. Endometrial/Uterine Corpus Cancers***

ENGOT-EN20/GOG-3083/XPORT-EC-042 A PHASE 3, RANDOMIZED, PLACEBO-CONTROLLED, DOUBLE-BLIND, MULTICENTER TRIAL OF SELINEXOR IN MAINTENANCE THERAPY FOR PATIENTS WITH P53 WILD-TYPE, ADVANCED OR RECURRENT ENDOMETRIAL CARCINOMA

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Introduction: Selinexor is FDA-approved for use in multiple myeloma and diffuse large B-cell lymphoma. In the ENGOT-EN5/GOG-3055/SIENDO study (NCT03555422), preliminary analysis of a pre-specified exploratory subgroup of patients with TP53wt EC showed a decrease in risk for progression or death with a median PFS of 13.7 months with selinexor vs 3.7 months with placebo. Of the EC molecular subtypes, TP53 wild type (wt) tumors represent 50% of advanced and recurrent tumors.

Methods: XPORT-EC-042 (NCT05611931) is a phase 3 randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of selinexor as maintenance therapy in patients with TP53wt primary stage IV or recurrent EC, who achieved a partial or complete response per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 after completing at least 12 weeks of platinum combination chemotherapy±immunotherapy. Among other inclusion/exclusion criteria, eligible patients must be ≥18 years of age, have histologically confirmed EC, and TP53wt tumor confirmed by NGS sequencing. Patients will be randomized 1:1 with selinexor 60mg or placebo once-weekly in 28-day cycles until progressive disease, toxicity, or 3-years if in complete response. A total of 220 patients are estimated to be enrolled globally. The primary endpoint is PFS based on RECIST v1.1 criteria as assessed by the Investigator. The key secondary endpoint is overall survival. Select secondary endpoints include safety assessments and PFS assessed by a blinded independent central review.

Current Trial Status: Patient enrollment is ongoing.

TP011 / #1536

Topic: ***AS11. Ovarian Cancer***

A DOUBLE-BLIND PLACEBO-CONTROLLED PHASE III CHEMO-IMMUNOTHERAPY (PACLITAXEL-CARBOPLATIN-OREGOVOMAB [PCO]) VS CHEMOTHERAPY (PACLITAXEL-CARBOPLATIN-PLACEBO [PCP]) IN PATIENTS WITH NEWLY DIAGNOSED, ADVANCED EPITHELIAL OVARIAN CANCER (EOC): FLORA-5/GOG-3035 STUDY

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Introduction: Oregovomab, a murine IgGκ1 MAb, binds to the circulating tumor associated antigen CA125, resulting in development of immunogenic complexes with CA125, which are subsequently processed by dendritic cells and macrophages leading to downstream CA125-specific antitumor activity by T and B lymphocytes. In a randomized Phase 2 study in previously untreated EOC patients, immunization with oregovomab with paclitaxel and carboplatin (PC) demonstrated significant improvement in mPFS (months) 41.8 for PCO and 12.2 for PC ($p = 0.0027$, HR 0.46) and mOS has not yet been reached (NE) for PCO and was 43.2 months for PC ($p = 0.043$, HR 0.35).

Methods: This Phase 3, double-blind, placebo-controlled, multicenter trial, has enrolled patients from 14 countries. Patients with optimally debulked with FIGO III/IV EOC and serum CA125 ≥ 50 U/ml receiving adjuvant (Cohort 1) or neoadjuvant (Cohort 2) chemotherapy were randomized post-surgery to PCO or PCP. Patients with germline BRCA1/2 mutations were excluded. Chemotherapy will be administered every 3 weeks in both cohorts. In cohort 1, oregovomab/placebo is administered simultaneously at cycles 1, 3, and 5 of chemotherapy with an additional dose at 12 weeks following cycle 5. In cohort 2, oregovomab/placebo is administered post interval debulking surgery at cycles 4 and 6 with an additional dose at 6- and 18-weeks following cycle 6. The primary objective is PFS determined by RECIST 1.1 criteria.

Current Trial Status: At the time of abstract submission, 618 patients were enrolled and target enrolment Cohort 1 (378) and Cohort 2 (240) was achieved.

TP012 / #1530

Topic: ***AS11. Ovarian Cancer***

PHASE 2, SINGLE ARM CLINICAL TRIAL TO EVALUATE THE SAFETY AND ACTIVITY OF OREGOVOMAB AND NIRAPARIB IN SUBJECTS WITH PLATINUM SENSITIVE RECURRENT OVARIAN CANCER: FLORA-4

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Introduction: Oregovomab, a murine IgGκ1 MAb, with high affinity binding ($1.16 \times 10^{10}/M^{-1}$) to the tumor associated antigen CA125, acts as a therapeutic vaccine inducing indirect immunization by cellular and humoral immune responses directed against CA125. In a randomized phase II study in patients with previously untreated EOC, immunization with oregovomab in a schedule-dependent combination with paclitaxel and carboplatin (PC) demonstrated significant improvement in mPFS (months) 41.8 for PCO and 12.2 for PC ($p = 0.0027$, HR 0.46) and mOS has not yet been reached (NE) for PCO and was 43.2 months for PC ($p = 0.043$, HR 0.35).

Methods: This is a single arm Phase 2 evaluation of the combination of oregovomab and niraparib in subjects who have been previously treated with 1 to 3 lines of platinum-based chemotherapy and have platinum sensitive EOC. All subjects will receive the combination of niraparib and oregovomab. The daily dose of niraparib will be 300 mg taken orally from Day 1 Week 1 to at least the end of Week 12. For subjects whose baseline weight is <77 kg or baseline platelet count is <150,000 µL the daily dose of niraparib will be 200 mg. Oregovomab (2 mg) will be administered at Day 1 of Weeks 1, 4, 7, 12, and 20. This study will assess DCR, ORR, early humoral response, and safety of concomitant administration of oregovomab and niraparib.

Current Trial Status: At the time of abstract submission, 10 subjects were enrolled, and the target enrollment was completed.

TP013 / #1025

Topic: ***AS11. Ovarian Cancer***

ADVERSE EVENT MANAGEMENT IN PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER TREATED WITH NIRAPARIB AND ANLOTINIB: UPDATES FROM THE PHASE II, MULTI-CENTER ANNIE STUDY

Ting Deng[1], Lei Yan[2], Jing Li[1], Guochen Liu[1], Aijun Yin[3], Yanling Feng[1], Min Zheng[1], Chuyao Zhang[1], He Huang[1], Qidan Huang[1], An Lin[4], Jie Jiang[3], Beihua Kong[3], Jihong Liu[1]
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Introduction: The primary analysis of the ANNIE study demonstrated promising anti-tumor activity of the niraparib-anlotinib combination in platinum-resistant recurrent ovarian cancer (PROC). We report updated overall survival (OS) and safety data and the management of key treatment-emergent adverse event (TEAE) from the ANNIE study.

Methods: In the multi-center, single-arm, phase 2 ANNIE study, enrolled patients received oral niraparib 200 mg or 300 mg (baseline bodyweight-directed) once daily and anlotinib 10 mg (12 mg before protocol amendment) once daily on days 1–14 of each 21-day cycle. Safety management involved a multidisciplinary team comprising specialist physicians, who performed monitoring and intervention for key comorbidities and TEAEs.

Current Trial Status: Results: Forty patients were enrolled. After a median follow-up of 19.0 months, the updated median OS was 18.2 months (95% CI: 12.1–not evaluable). The most common TEAEs were hypertension (n=22, 55%), leukopenia (n=18, 45%), hand foot syndrome (n=17, 43%), thrombocytopenia (n=15, 38%), neutropenia (n=14, 35%), and hypertriglyceridemia (n=12, 30%). Hypertension and cardiovascular events were mostly managed by early interventions using beta-blockers. Hypertriglyceridemia was mostly managed using atorvastatin and simvastatin.Hematological toxicities were consistent with prior studies and no severe hematologic events occurred. Protocol amendment was implemented to reduce the incidence of hand-foot syndrome, while topical glucocorticoids and non-steroidal anti-inflammatory drugs were used in patients with apparent symptoms. Conclusions: The updated OS analysis showed sustained long-term efficacy of niraparib-anlotinib in PROC patients. The safety data reflected satisfactory tolerability and adverse event management, supporting the involvement of a multidisciplinary disease management team in ovarian cancer care.

TP014 / #1034

Topic: ***AS11. Ovarian Cancer***

A PROSPECTIVE RANDOMIZED MULTICENTER TRIAL FOR LYMPHADENECTOMY IN EARLY-STAGE OVARIAN CANCER: LOVE STUDY

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Introduction: The Lymphadenectomy in Ovarian Neoplasms (LION) study revealed that systemic lymphadenectomy did not bring survival benefit for advanced ovarian cancer patients with clinically normal lymph nodes and was associated with a higher incidence of operative complications. However, there is no consensus on whether lymphadenectomy has survival benefit or not in early epithelial ovarian cancer (EOC).

Methods: We designed the LOVE study, a multicenter, randomized controlled, phase III trial to compare the efficacy and safety of comprehensive staging surgery with or without lymphadenectomy in stages IA-IIB EOC and fallopian tube carcinomas (FTC). The hypothesis is that the oncological outcomes provided by comprehensive staging surgery without lymphadenectomy are non-inferior to those of conventional completion staging surgery in early-stage EOC and FTC patients who have indications for post-operative adjuvant chemotherapy. Patients assigned to experimental group will undergo comprehensive staging surgery, but lymphadenectomy. Patients assigned to comparative group will undergo completion staging surgery including systematic pelvic and para-aortic lymphadenectomy. All subjects will receive 3–6 cycles of standard adjuvant chemotherapy. Major inclusion criteria are pathologic confirmed stage IA-IIB EOC or FTC, and patients have indications for adjuvant chemotherapy either confirmed by intraoperative fast frozen section or previous pathology after an incomplete staging surgery. Major exclusion criteria are non-epithelial tumors and low-grade serous carcinoma. Patients with severe rectum involvement which lead to partial rectum resection will be excluded. The sample size is 656 subjects. Primary endpoint is disease-free survival.

Current Trial Status: The LOVE trial is in progress, 17 participating centers in China are recruiting subjects, 130 patients were randomized.

TP015 / #1539

Topic: ***AS11. Ovarian Cancer***

A DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE II CHEMOIMMUNOTHERAPY (PACLITAXEL-CARBOPLATIN-OREGOVOMAB) VS CHEMOTHERAPY (PACLITAXEL-CARBOPLATIN-PLACEBO) AS NEOADJUVANT THERAPY IN PATIENTS WITH ADVANCED EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PERITONEAL CARCINOMA

Niraj Bhatt[1], Rajesh Korant[2], Mahesh Kalloli[3], Anita Ramesh[4], Vijay Kumar[5], T S Ganesan[6], B Ravishankar[7], K Pavithran[8], Shilpa Kandipalli[9], Evelyn (Ye Ran) Yoon[10], Ben (Byung Hak) Yoon[10], Tl Raj Teja[10], Sunil Gupta[10], Srinivasa Rao Jada[10]
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Introduction: Oregovomab, a murine IgGκ monoclonal antibody binds to tumor-associated antigen, CA125, rendering target antigen CA125 more immunogenic through enhanced antigen processing and presentation to specific T cells, bypassing tumor-associated suppression and resulting in enhanced efficacy of chemotherapy. In a randomized phase II study, oregovomab (O) in combination with paclitaxel and carboplatin (PC) demonstrated significant improvement in mPFS (months) 41.8 PCO vs 12.3 PC, HR=0.46, p=0.0027 and OS median N.E. PCO vs 43.2 PC, HR=0.35, p=0.043.

Methods: This is a phase 2, double-blind, placebo-controlled, multi centered clinical trial. Patients with FIGO III/IV EOC and serum CA125 ≥ 50 U/ml receiving neoadjuvant chemotherapy will be randomized. In each arm patients will receive oregovomab/placebo at cycles 1 and 3 in combination with chemotherapy prior to interval debulking surgery, followed by oregovomab/placebo at cycles 4 and 6 in combination with chemotherapy, and oregovomab/placebo monotherapy at cycle 6 plus12 weeks. The objective of this study is to confirm that the presence of primary tumor and its immune suppressive biology does not interfere with chemoimmunotherapy when oregovomab is administered with initiation (Cycle 1) of chemotherapy did not delay timing of cytoreductive surgery. The primary objective of the study is to evaluate the PFS Rate at 12 months. Secondary objectives include investigator assessed ORR and DCR by RECIST v1.1, PFS, OS, Response to surgery, safety and tolerability.

Current Trial Status: Of the 88 patients enrolment target of the study, 31 patients have been enrolled from 14 centers at the time of submission.

TP016 / #1542

Topic: ***AS11. Ovarian Cancer***

A MULTICENTER STUDY OF NIRAPARIB AS MAINTENANCE THERAPY IN BRCA WILD-TYPE, NEWLY DIAGNOSED ADVANCED OVARIAN CANCER (POLO TRIAL)

Se Ik Kim[1], Chel Hun Choi[2], Ji Hyun Kim[3], Yong Jae Lee[4], Jeong-Yeol Park[5], Dong Hoon Suh[6], Yong Beom Kim[6], Jung-Yun Lee[4], Myong Cheol Lim[3], Byoung Gie Kim[2], Jae-Weon Kim[1]
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Introduction: Poly(adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitors have revolutionized the management of ovarian cancer. However, the optimal treatment of BRCA wild-type patients with advanced ovarian cancer remains controversial. The POLO trial aims to investigate the efficacy of niraparib maintenance therapy in patients with BRCA wild-type, newly diagnosed, low-risk advanced ovarian cancer.

Methods: The POLO is a multi-center, investigator-initiated, single-arm, phase IV trial of patients with FIGO stage III-IV high-grade serous or endometrioid ovarian cancer. This study includes patients having both germline and somatic wild-type BRCA1/2 genes, no visible residual tumor after primary cytoreductive surgery, and responses to the postoperative platinum-based combination chemotherapy. Patients who received neoadjuvant chemotherapy are excluded. All enrolled patients are treated with niraparib maintenance therapy for three years or until disease progression, unacceptable toxicity, or withdrawal of patient consent. The primary endpoint is 12-month progression-free survival (PFS) rate. The secondary endpoints are overall survival, PFS, time to first subsequent treatment, time to second progression, time to second subsequent treatment, and safety. All patients should provide tumor slides obtained during cytoreductive surgery for a prospective examination of somatic homologous recombination deficiency and homologous recombination repair gene alterations. Pre- and post-niraparib blood samples will be collected for circulating cell-free DNA analyses. Molecular biomarkers that may indicate clinical response to niraparib will be identified. In total, 102 patients will be recruited from six sites. An interim analysis is planned after recruitment of 68 participants.

Current Trial Status: Accrual is expected to be completed in December 2023, followed by the presentation of results in 2025.

TP017 / #812

Topic: ***AS11. Ovarian Cancer***

A PHASE III RANDOMIZED CONTROLLED TRIAL IN PRIMARY STAGE THREE AND FOUR OVARIAN CANCER AFTER INTERVAL CYTOREDUCTIVE SURGERY (FOCUS/KOV-HIPEC-04)

Ji Hyun Kim[1], Boram Park[2], Jeong-Yeol Park[3], Jung-Yun Lee[4], Suk-Joon Chang[5], Yoo Young Lee[6], Dae Gy Hong[7], Hyun Woong Cho[8], Jae Yun Song[9], Jung-Yun Kim[1], Sang-Yoon Park[10], Myong Cheol Lim[10]
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Introduction: The addition of hyperthermic intraperitoneal chemotherapy (HIPEC) during interval cytoreductive surgery increases progression-free and overall survival for patients with advanced-stage epithelial ovarian cancer in two randomized controlled trials (OV-HIPEC-01 and KOV-HIPEC-01). The aim of this trial is to identify the survival benefit of HIPEC in advanced ovarian cancer in the era of maintenance therapy of bevacizumab and/or PARP inhibitor.

Methods: The KOV-HIPEC-04 is a multicenter, 1:1 randomized, phase III trial that will enroll 520 patients with primary epithelial ovarian cancer who completed neoadjuvant chemotherapy. Patients will be randomized at the time of interval cytoreductive surgery with achieving complete cytoreduction or cytoreduction with no more than 2.5mm depth of residual disease to receive HIPEC (experimental arm, 41.0-42.0°C cisplatin 75mg/m^2, 90 minutes) or not (control arm). After recovery from surgery, patients will receive postoperative platinum-based adjuvant chemotherapy followed by maintenance therapy with PARP inhibitor or bevacizumab. The primary endpoint is to evaluate overall survival (OS); secondary objectives are progression-free survival (PFS), cancer-specific survival, time to first subsequent therapy, safety, and quality of life. Assuming that the enrollment period is 5 years and the follow-up period is 3 years, the total number of events required is 263. Based on the log-rank test, the total number of subjects required to prove HR 0.67 with a two-sided alpha of 0.05 and 90% power is 494. 520 patients are finally

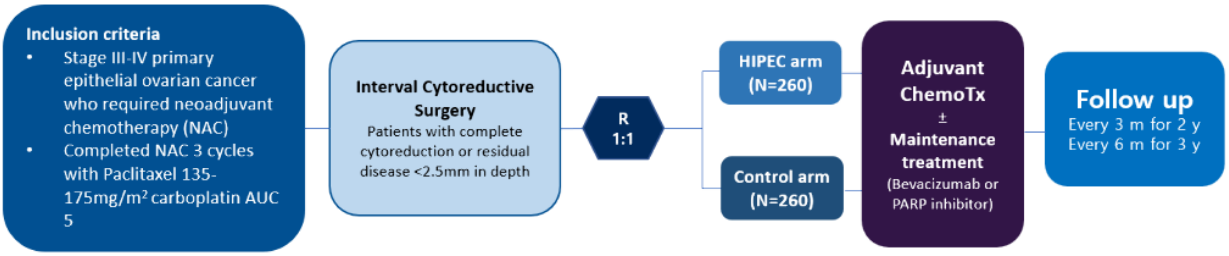
studied, considering 5% drop-out. ClinicalTrials.gov (NCT05827523)

A Phase III Randomized Controlled Trial in Primary Stage Three and Four Ovarian Cancer After Interval Cytoreductive Surgery (FOCUS/KOV-HIPEC-04)

ClinicalTrials.gov (NCT05827523)

Primary endpoint: **Overall survival**

Secondary endpoint: progression-free survival (PFS), cancer-specific survival, time to first subsequent therapy (TFST), safety, and quality of life



Stratification factors

1. Stage
2. Use of PARP inhibitor or not
3. Size of residual disease

HIPEC regimen

- Cisplatin 75mg/m²
- 90 minutes, 41.5 ℃ (range, 41-42℃)

Current Trial Status: Not yet Recruiting

TP018 / #822

Topic: ***AS11. Ovarian Cancer***

A RANDOMIZED, MULTICENTER, OPEN-LABEL PHASE III TRIAL OF HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY IN PLATINUM-RESISTANT RECURRENT OVARIAN CANCER

Ji Hyun Kim[1], Eun-Young Park[2], Dae Hoon Jeong[3], Yoo Young Lee[4], Chel Hun Choi[5], Tae-Joong Kim[6], Hyun Hoon Chung[7], Taek Sang Lee[8], Shin Wha Lee[9], Jeong-Yeol Park[9], Sung Jong Lee[10], Seob Jeon[11], Ki Hyung Kim[12], Hyeong In Ha[13], Youngbok Ko[14], San-Hui Lee[15], Suk-Joon Chang[16], Sang-Yoon Park[17], Myong Cheol Lim[17]
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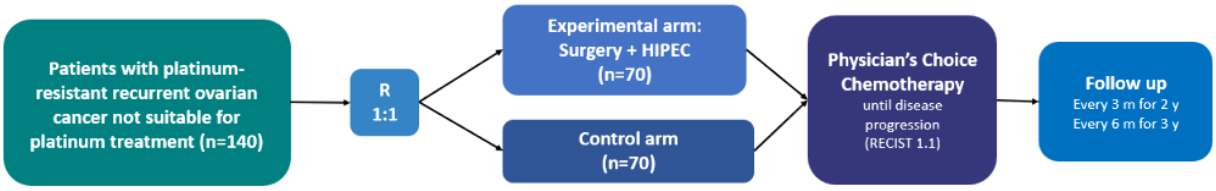
Introduction: Recent randomized trials (OV-HIPEC-01 and KOV-HIPEC-01) and meta-analyses reveal survival benefits of HIPEC after recent exposure of systemic chemotherapy exposure in ovarian cancer.

Methods: This trial (KOV-HIPEC-02) is a multicenter, open-label, 1:1 randomized, phase III trial that will enroll 140 patients in platinum-resistant recurrent epithelial ovarian cancer. The trial is registered on ClinicalTrials.gov (NCT05316181). The experimental arm will receive HIPEC (41.0-42.0°C, doxorubicin 35mg/m^2 and mitomycin 15mg/m^2, 90 min) followed by physician's choice chemotherapy, and the control arm will receive physician's choice chemotherapy without HIPEC until disease progression or unacceptable toxicities. The primary objective of the trial is to evaluate progression-free survival (PFS). Secondary objectives are overall survival (OS), cancer-specific survival, safety, and quality of life. Assuming that the enrollment period is 3 years and the follow-up period is 2 years, the total number of events required is 121. Based on the log-rank test, the total number of subjects required to prove HR 0.6 with a two-sided alpha 0.05 and 80% power is 126. 140 patients are finally studied considering 10% drop-

out.

Randomized Phase III Trial of HIPEC in Platinum-Resistant Recurrent Ovarian Cancer (KOV-HIPEC-02)

ClinicalTrials.gov (NCT05316181)
Primary endpoint: Progression-free survival (PFS)



Stratification factors

1. Histology (HGSOC vs non-HGSOC)
2. Number of prior lines of chemotherapy (≤ 1 line vs ≥ 2 lines)

HIPEC regimen

- Doxorubicin 35mg/m² + Mitomycin C 15mg/m²
- 90 minutes, 41.5 ℃ (range, 41-42℃)

Current Trial Status: Active Recruiting

TP019 / #1387

Topic: ***AS11. Ovarian Cancer***

ROSELLA (GOG-3073, ENGOT-OV72/MITO): A PHASE 3 STUDY OF RELACORILANT + NAB PACLITAXEL VS. NAB-PACLITAXEL IN PLATINUM-RESISTANT OVARIAN CANCER

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Introduction: Single-agent chemotherapies are commonly used in platinum-resistant ovarian cancer (OC), but outcomes are generally poor. Cortisol, which binds to the glucocorticoid receptor (GR), can suppress apoptotic pathways used by chemotherapy. The selective GR modulator relacorilant may reverse cortisol's anti-apoptotic effects to enhance chemotherapy efficacy. In a phase 2 study in patients with recurrent, platinum-refractory/resistant OC (NCT03776812), intermittently dosed relacorilant + nab-paclitaxel showed clinically meaningful improvement in progression-free survival (PFS), duration of response (DoR), and overall survival (OS) without increased side effect burden vs. nab-paclitaxel monotherapy. The ROSELLA study aims to confirm these findings in a larger patient population.

Methods: ROSELLA (NCT05257408) is a randomized, phase 3, 2-arm, open-label study of relacorilant + nab-paclitaxel vs. nab-paclitaxel monotherapy. Approximately 360 women with platinum-resistant ovarian, primary peritoneal, or fallopian tube cancer who have received 1–3 prior systemic anticancer therapies, including prior bevacizumab, and ≥1 platinum-based therapy are being enrolled. Patients with primary platinum-refractory disease are excluded. Patients are being randomized 1:1 to relacorilant (150 mg the day before, of, and after nab-paclitaxel) + nab-paclitaxel (80 mg/m^2) or nab-paclitaxel monotherapy (100 mg/m^2); stratified by prior lines of therapy (1 vs >1) and region of world (North America vs. Europe vs. rest of world). Nab-paclitaxel is administered on days 1, 8, and 15 of each 28-day cycle. The primary endpoint is PFS by blinded independent central review. Key secondary and exploratory endpoints include OS, PFS by investigator assessment, objective response rate, best overall response, DoR, safety, pharmacokinetics, pharmacodynamics, patient-reported outcomes, and quality of life.

Current Trial Status: Currently enrolling

TP020 / #1513

Topic: ***AS11. Ovarian Cancer***

FIRST-IN-HUMAN PHASE 1/2 STUDY OF UBAMATAMAB, A MUC16XCD3 BISPECIFIC ANTIBODY, ADMINISTERED ALONE OR IN COMBINATION WITH CEMIPLIMAB IN PATIENTS WITH RECURRENT OVARIAN CANCER

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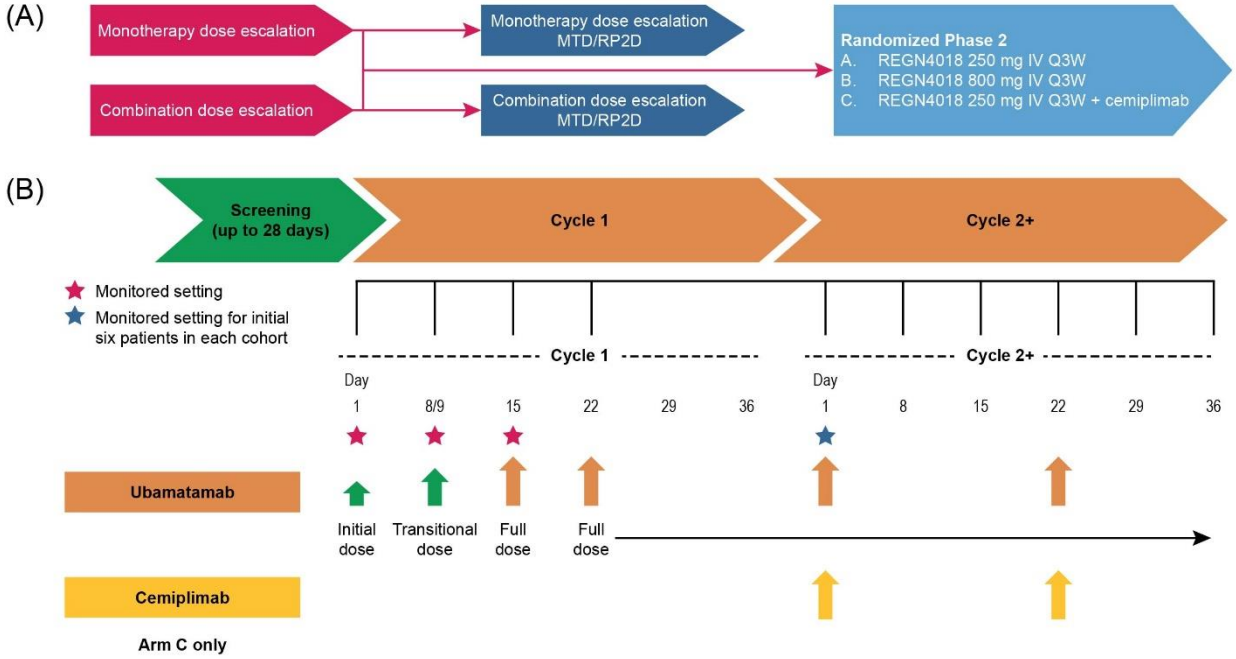
Introduction: Ubamatamab (REGN4018) is a MUC16xCD3 bispecific antibody that promotes T cell-mediated cytotoxicity by facilitating contact between cancer cells and T cells. In a Phase 1 study (NCT03564340) in patients with recurrent ovarian cancer (OC), ubamatamab monotherapy demonstrated an acceptable safety profile and durable clinical activity at doses of 20 mg to 800 mg IV weekly (by RECIST and CA-125 response rates), and linear pharmacokinetics up to 800 mg IV weekly.

Methods: In Phase 2, up to 150 patients with advanced platinum-resistant OC and elevated serum CA-125 will be randomized 1:1:1 to IV Q3W treatment: ubamatamab 250 mg; ubamatamab 800 mg; or ubamatamab 250 mg plus cemiplimab 350 mg (Figure 1). All treatment arms will include weekly step-up dosing of ubamatamab (1 mg week 1, 20 mg week 2, and full dose weeks 3 and 4) to limit risk of cytokine release syndrome before proceeding to Q3W dosing. Expansion cohorts will use a Simon 2-stage study design, with interim analysis after 20 patients. Any arm with ≥3 objective responses will be expanded to 50 patients. The primary endpoint for each treatment arm is ORR per RECIST 1.1 criteria. Secondary endpoints include DOR, PFS, safety, and pharmacokinetics of ubamatamab with/without cemiplimab. Exploratory endpoints include evaluation of baseline tumor MUC16 expression and other biomarkers as predictors of response. The impact of ubamatamab on QOL and physical functioning will be assessed.

Current Trial Status: The study is currently recruiting patients to combination dose escalation, monotherapy dose expansion, and the randomized Phase 2

cohort.

Figure 1. (A) Phase 1 dose escalation and Phase 2 dose expansion including randomized Phase 2 cohort and (B) study schema for randomized Phase 2 cohort



Monotherapy dose escalation is complete. Combination dose escalation, monotherapy dose expansion, and randomized Phase 2 cohorts are currently open for enrollment.
IV, intravenous; MTD, maximum tolerated dose; Q3W, every 3 weeks; RP2D, recommended Phase 2 dose.

TP021 / #1540

Topic: ***AS11. Ovarian Cancer***

REFRAME-O1/ENGOT-OV79/GOG-3086: A PHASE 2/3 OPEN-LABEL STUDY EVALUATING THE EFFICACY AND SAFETY OF LUVELTAMAB TAZEVIBULIN VERSUS INVESTIGATOR'S CHOICE CHEMOTHERAPY IN RELAPSED PLATINUM-RESISTANT EOC EXPRESSING FOLATE RECEPTOR-ALPHA

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Introduction: Folate receptor alpha (FolRα) is a validated target in the treatment of platinum resistant ovarian cancer (PROC) expressing high-FolRα. There remains a high unmet need to treat PROC with low to moderate FolRα expression. Luveltamab tazevibulin (luvelta), a novel FolRα-targeting ADC with a hemiasterlin warhead (DAR4), is designed using site-specific conjugation technology to target a broad range of FolRα-expressing cancers. Luvelta demonstrated preliminary efficacy data (ORR of 37.5%; mDOR of 5.5 months; mPFS of 6.1 months) in 32 patients with advanced/relapsed EOC with FolRα expression of >25% (any intensity) in a Ph1 study (NCT03748186). ORR was higher at 5.2 mg/kg (43.8% versus 31.3%, n=32) compared to 4.3 mg/kg. Luvelta showed a manageable safety profile, with the most common grade 3+ adverse events of neutropenia, arthralgia, and anemia. This data forms the basis for a pivotal study of luvelta in patients with PROC with broad FolRα expression levels.

Methods: REFRaME-O1/ENGOT-Ov79/GOG-3086 is a 2-part Phase 2/3 study of luvelta in subjects with relapsed PROC expressing FolRα. Part 1 is the dose-optimization stage, with ~50 subjects randomized 1:1 at 4.3 mg/kg Q3W or 5.2 mg/kg Q3W + prophylactic pegfilgrastim for 2 cycles followed by 4.3 mg/kg Q3W. Part 2 will commence with the selected optimized dose versus investigator's choice chemotherapy, with a 2:1 randomization schedule. Key inclusion criteria: progressive PROC, up to 3 prior regimens, TPS of ≥25% for FolRα expression, and measurable disease. Key exclusion criteria: primary platinum refractory disease and prior treatment with a FolRα ADC or ADC-containing tubulin inhibitor.

Current Trial Status: Currently enrolling

TP022 / #997

Topic: ***AS11. Ovarian Cancer***

SENTINEL-NODE BIOPSY IN EARLY STAGE OVARIAN CANCER: PRELIMINARY RESULTS OF A PROSPECTIVE MULTICENTRE STUDY (SELLY)

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Introduction: Sentinel-lymph node biopsy has safely replaced lymphadenectomy in the staging of many solid cancers. The aim of this study was to evaluate the sensitivity and specificity of sentinel-lymph-node mapping compared with the gold standard of complete lymphadenectomy in detecting metastatic disease for early stage ovarian cancer.

Methods: In the SELLY multicentre, prospective, phase II trial (EUDRACT 2019-001088-58) patients with presumed stage I-II epithelial ovarian cancer and planned for immediate or delayed minimally-invasive comprehensive staging were eligible for study inclusion. Patients received an injection of indocyanine green and sentinel-lymph-node mapping followed by pelvic and para-aortic lymphadenectomy. Seven centers from in Italy participated in the trial. Negative sentinel lymph nodes (by haematoxylin and eosin staining on sections) were ultra-staged with immunohistochemistry for cytokeratin. The primary endpoint, sensitivity of the sentinel-lymph-node-based detection of metastatic disease, was defined as the proportion of patients with node-positive disease with successful sentinel-lymph-node mapping who had metastatic disease correctly identified in the sentinel lymph node.

Current Trial Status: Between March 2018 and July 2022, 176 patients were enrolled but only 174 received complete study interventions. 100 (58%) patients had successful mapping of at least one sentinel lymph node and 15 of them (15.0%) had positive nodes. Of the latter, 11 of 15 (73.3%) patients had a correct identification of the disease in the SLN. In detail, 7 out of 11 patients required ultrastaging protocol. 4 patients with node-positive disease had a negative SLN. Enrollment was closed on January 2023. Data analysis is about to be completed.

TP023 / #61

Topic: ***AS11. Ovarian Cancer***

AN PROSPECTIVE, SINGLE-ARM, PHASE Ⅱ STUDY OF ALTERNATING REGIMENS OF FLUZOPARIB AND ORAL ETOPOSIDE MAINTENANCE THERAPY, IN NEWLY DIAGNOSED ADVANCED OVARIAN CANCER: FARE TRIAL

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Introduction: Most patients with ovarian cancer (OC) are diagnosed in advanced stages. A current therapy option for advanced OC patients is debulking surgery; followed by platinum-based chemotherapy ± bevacizumab; followed by maintenance therapy with bevacizumab or monotherapy with PARP inhibitors. The expense of OC maintenance therapy might be substantial. However, the potential benefits of alternating regimens of PARP inhibitors and chemotherapy have not yet been explored. In the alternating regimens of fluzoparib and oral etoposide, both drugs function by directly targeting the DNA of tumour cells. Additionally, the adverse effects of each treatment may be controlled separately without any additive effects. The FARE trial aims to evaluate the efficacy and safety of alternating regimens maintenance therapy in Chinese patients with newly diagnosed advanced OC who are not at high risk of recurrence.

Methods: The FARE trial is a single-center, investigator-initiated, single-arm, phase II trial of patients with FIGO stage III-IV high-grade serous or high-grade endometrioid OC. This study includes patients with tumors sample had to be available for central testing to determine BRCA mutation status and homologous-recombination deficiency (HRD) status, no visible residual tumor after primary cytoreductive surgery, and responses to the postoperative platinum-based combination chemotherapy. All enrolled patients are treated with this alternating regimens maintenance therapy for 24 months, until disease progression or unacceptable toxicity, or withdrawal of patient consent. Primary endpoint is progression-free survival (PFS).

Current Trial Status: Trial in progress: there are no available results at the time of submission, and there are no available conclusions at the time of submission.

TP024 / #1560

Topic: ***AS11. Ovarian Cancer***

STANDARD OF CARE THERAPY WITH OR WITHOUT STEREOTACTIC ABLATIVE RADIATION THERAPY FOR RECURRENT OVARIAN CANCER (SABR-ROC): A PROSPECTIVE RANDOMIZED PHASE III TRIAL (KGOG 3064/KROG 2204)

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Introduction: Despite the controversial role of radiotherapy (RT) in recurrent ovarian cancer (ROC), there might be a survival benefit irrespective of favorable clinical features according to a preliminary analysis. This prospective study was designed to compare the survival outcomes between standard of care (SOC) with or without stereotactic ablative RT (SABR) to all recurrent sites in ROC.

Methods: Patients with recurrent epithelial ovarian cancer with 10 or less metastatic sites at recurrence based on the number of SABR fields are eligible. Those who have a history of RT, single lesion sized >5 cm, or diffuse peritoneal carcinomatosis are not eligible. Patients will be stratified by factors as the followings; number of favorable factors (absence of ascites, platinum-sensitivity, CA-125, and ECOG performance), location of the lesion (lymph node vs. non-lymph node), and use of PARP inhibitor. Patients will be randomized (1:2) into SOC salvage treatment (arm 1) vs. SOC plus metastasis-directed SABR (arm 2). The primary endpoint is 3-year overall survival rate (58.5% for arm 1 and 74.4% for arm 2). A total of 270 patients will be required.

Current Trial Status: A dummy-run study involving 4 representative clinical scenarios is under progress. To enhance compliance with the protocols, a three-tiered RT quality assurance (QA) process consisting of general credentialing, trial-specific credentialing with dummy run plus phantom QA, and individual case review has been performed. Currently, 32 patients from 16 sites are enrolled as of August 21st, 2023.

TP025 / #1492

Topic: ***AS15. Rare Tumors***

PHASE 2, MULTICENTER, GLOBAL, OPEN-LABEL BASKET TRIAL OF NAB-SIROLIMUS FOR PATIENTS WITH INACTIVATING ALTERATIONS IN TSC1 AND TSC2 (PRECISION I)

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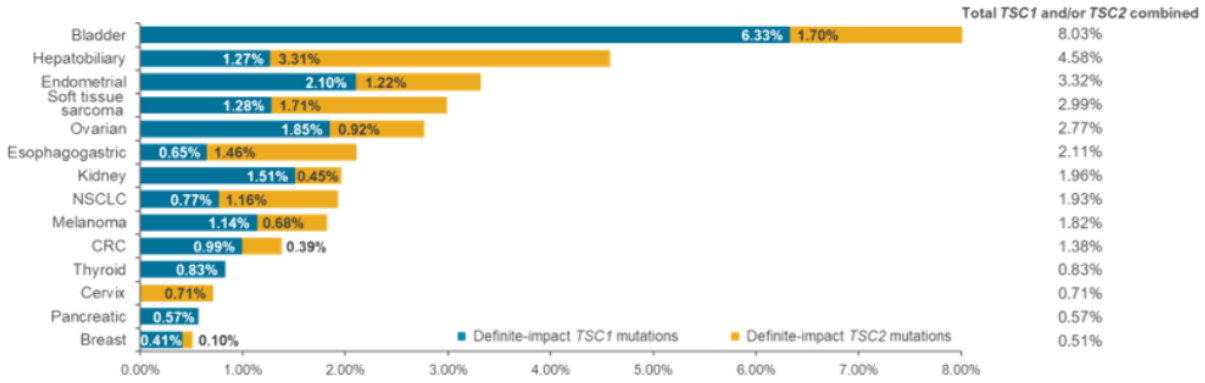
Introduction: TSC1 and TSC2 alterations have been observed in many cancers and lead to mTOR pathway activation. nab-Sirolimus is a novel albumin-bound mTOR inhibitor approved in the US for adult patients with malignant PEComa. In an exploratory analysis of the AMPECT trial of nab-sirolimus in advanced malignant PEComa (NCT02494570), 64.3% (9/14) of patients with pathogenic inactivating TSC1 or TSC2 alterations had confirmed response (Cranmer et al, Cancer Res, 2023:LB288). Treatment-related adverse events (TRAEs) in AMPECT were mostly grade 1/2 (no grade ≥4; discontinuation rate due to TRAEs: 6%). PRECISION I (NCT05103358) will evaluate efficacy and safety of nab-sirolimus in patients with TSC1 (Arm A) or TSC2 (Arm B) pathogenic inactivating alterations.

Methods: Eligible patients are ≥12y (US) or ≥19y (Korea), mTORi-naïve, have advanced or metastatic malignant solid tumors harboring TSC1 or TSC2 inactivating alterations identified using next-generation sequencing (NGS) in tumor tissue or liquid biopsy, and have received appropriate standard treatments, per investigator. Approximately 120 patients (60 per arm) will be enrolled globally. nab-Sirolimus 100 mg/m^2 will be given intravenously over 30 min on Days 1 and 8 of each 21-day cycle. Primary endpoint: overall response rate per independent radiographic review (IRR) using RECIST v1.1. Secondary endpoints: duration of response, time to response, progression-free survival by IRR, overall survival, patient-reported QOL, and safety.

Current Trial Status:

Figure. Estimated frequency of inactivating *TSC1* or *TSC2* alterations by tumor type[a]



[a]The proportion of patients with definite impact alterations (ie, mutations known to have a biological impact, including frameshift, nonsense, splice-site mutations, and deep deletions) derived from analysis of TCGA and cBioPortal by Gulati et al (Data on file). *TSC1, TSC2*, tuberous sclerosis complex subunit 1, 2.

Enrollment began in March 2022 and is expedited through collaboration with leading NGS providers. Patients with urothelial, endometrial, ovarian, and cervical cancers are expected to be enrolled based on the frequency of TSC1 and TSC2 inactivating alterations (Figure).

TP026 / #1436

Topic: ***AS16. Screening/Early Detection***

COMPARING VISUAL INSPECTION WITH ACETIC ACID, WITH AND WITHOUT LUGOL'S IODINE FOR TRIAGE OF HPV SELF-SAMPLE POSITIVE WOMEN IN ETHIOPIA – A RANDOMISED CONTROLLED TRIAL.

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Introduction: HPV vaginal self-sampling is more acceptable by women than health-provider cervical cancer screening methods. However, only a minority of HPV positive women will need treatment for pre-cancerous lesions, which requires an effective triage test. Visual inspection with acetic acid (VIA) is recommended as a triage, but the sensitivity and specificity are questioned. The aim of this randomised controlled study is to compare the accuracy of VIA with and without Lugol's Iodine (VILI).

Methods: All women from an urban Ethiopian cohort with a cervix are eligible. Participants each collect two vaginal self-samples for HPV DNA analysis at Addis Ababa University laboratory. HPV positive women are stratified according to age and pregnancy status, and then randomized to either VIA or VIA with VILI (RedCap software). They are then examined at a clinic according to the allocated triage test. All women, except those pregnant, have a biopsy taken from the lesion or at 12 and 6 o'clock. If a lesion is visualized, they are immediately treated, unless pregnant. All biopsies are evaluated by a senior pathologist.

Current Trial Status: 940 participants have been screened with an HPV vaginal self-sample (Date 16/7/2023). 131 were hrHPV positive and have visited the VIA clinic. 175 HPV positive women are needed to be examined at the clinic to get enough statistical power for the analyses we hope to reach in September 2023. Final results will be presented at IGCS.