IGCS 2024 Annual Global Meeting DUBLIN
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IGCS 2024 Abstracts: E-Poster Viewing (Trials-in-Progress)

Registered delegates will have access to all submitted Trial-in-Progress E-Posters via the IGCS 2024 mobile application, IGCS 360 Educational Portal, and the onsite E-Poster Stations.

Poster presenters were given the option to submit an audio file with a short presentation together with their E-Posters. Submitted audio files will be available together with their E-Posters via the IGCS 360 Educational Portal.

TP001 / #1584

Topic: *AS03. Cervical Cancer*

GOG-3043 (NCT04831580): A RANDOMIZED NON-INFERIORITY TRIAL OF ROBOTIC VERSUS OPEN SURGERY FOR EARLY STAGE CERVICAL CANCER (ROCC)

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Introduction: Minimally invasive surgery (MIS) for early stage cervical cancer was associated with an increased risk of recurrence and death from disease in the LACC trial. The ROCC trial is designed to re-examine the oncologic safety of MIS for early stage cervical cancer when performed with robotic assistance utilizing comprehensive tumor containment.

Methods: This is an international, multi-center prospective randomized, non-inferiority trial for patients with FIGO 2018 stage IA2-IB2 cervical cancer undergoing radical hysterectomy and lymph node assessment. Patients will be randomized 1:1 to robotic vs open arm. Squamous cell (SCC), adenocarcinoma (AC), and adenosquamous (AS) histologies are eligible. Pre-operative MRI is required. Transcervical manipulators are prohibited and tumor containment prior to colpotomy using pre-specified surgical techniques is mandatory. The primary objective is 3-year disease free survival (DFS). Secondary objectives include disease specific survival (DSS), overall survival (OS), patterns of recurrence, complications, and patient reported outcome measures. 60 sites are currently activated and we anticipate opening at 11 additional sites. Interim analyses for futility planned after 370/640 patients enrolled.

Current Trial Status: 156/840 patients have been enrolled (79 in the robotic arm and 77 in the open arm). The majority of patients have SCC (56.9%), have had a prior CKC

(62.7%), and have a tumor size of <2cm (60.8%). 60.3% of patients are white, 15.4% black, and 24.4% identify as Hispanic or Latino.

TP002 / #1419

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

GOG 3088: A RANDOMIZED PHASE II STUDY OF LETROZOLE VERSUS OBSERVATION IN PATIENTS WITH NEWLY DIAGNOSED UTERINE LEIOMYOSARCOMA

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Introduction: Approximately 85% of women with uterine leiomyosarcomas (uLMS) present with stage I disease. NCCN guidelines for stage I uterine confined disease recommend observation; however, recurrence risk of uLMS overall is quite high at 50-70% within the first two years. The estrogen receptor (ER) is expressed in 40-87% of leiomyosarcomas. Because of this high expression, estrogen may act as a growth factor that stimulates cell proliferation and tumor growth. Subsequently, there have been several evaluations for the use of aromatase inhibitors as single agent therapy for uLMS. These trials have each shown varying degrees of clinical activity. We hypothesize that by decreasing systemic estrogen using an aromatase inhibitor we will prolong the time to recurrence for patients with this disease.

Methods: This is a GOG Foundation led phase II randomized controlled trial comparing letrozole (2.5mg PO daily) to observation in newly diagnosed patients with uterine confined stage I uLMS. Forty patients will be randomized 1:1. Patients will be eligible post operatively if they have no measurable disease and will be required to be estrogen receptor (ER) positive. The primary endpoint of the trial is investigator-assessed progression free survival. Exploratory translational evaluation will occur to 1) correlate response based on IHC hormone receptor status, 2) evaluate gene expression signatures of hormone receptor activity, tumor biology, and tumor microenvironment, 3) evaluate the contribution of single nucleotide polymorphism rs3820282 to tumor biology and response to letrozole.

Current Trial Status: GOG 3088 activated in January of 2024 and expects to enroll across 20 US sites. Clinicaltrials.gov Identifier: NCT05649956.

TP003 / #1538

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

PHASE 3 ENGOT-EN23/GOG-3095/MK-2870-005 STUDY: SACITUZUMAB TIRUMOTECAN (SAC-TMT) MONOTHERAPY VS TREATMENT OF PHYSICIAN'S CHOICE CHEMOTHERAPY IN PATIENTS WITH ENDOMETRIAL CANCER WHO RECEIVED PRIOR CHEMOTHERAPY AND IMMUNOTHERAPY

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Introduction: Trophoblast cell surface antigen 2 (TROP2) is overexpressed in endometrial cancer (EC) patients and is associated with worse prognosis. Sac-TMT (also known as MK-2870/SKB264) is a novel antibody-drug conjugate composed of an anti-TROP2 antibody coupled to a cytotoxic belotecan derivative via a novel linker (average drug/antibody ratio, 7.4). ENGOT-en23/GOG-3095/MK-2870-005 evaluates sac-TMT

monotherapy versus chemotherapy at physician's choice (TPC) in EC patients who had received prior chemotherapy and/or anti–PD-(L)1 therapy.

Methods: This phase 3, randomized, open-label study (NCT06132958) is enrolling patients ≥18 years with histologically confirmed endometrial carcinoma or carcinosarcoma, radiographically measurable or nonmeasurable disease (RECIST v1.1 by BICR), ECOG PS ≤1, and tumor tissue for MMR, TROP2, and histology assessment (central testing). Patients received prior platinum-based chemotherapy and anti–PD-(L)1 therapy, either separately or in combination. Up to 3 prior lines of therapy are allowed. Patients are randomized 1:1 to receive intravenous sac-TMT 4 mg/kg Q2W or TPC (doxorubicin 60 mg/m^2 Q3W [21-day cycle] or paclitaxel 80 mg/m^2 on days 1, 8, and 15 Q4W [28-day cycle]) until radiographic PD, unacceptable toxicity, or patient withdrawal. Randomization is stratified by MMR status (dMMR vs pMMR), TROP2 expression (low vs medium/high), number of prior lines of therapy (≤2 vs 3), and baseline disease status (measurable vs nonmeasurable). Primary endpoints are PFS (RECIST v1.1 by BICR) and OS. Secondary endpoints include ORR and DOR (RECIST v1.1 by BICR), safety, and PROs. Imaging assessments occur Q8W from randomization through week 56 and Q12W thereafter.

Current Trial Status: Enrollment began in Dec 2023

TP004 / #1561

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

A PHASE 2, OPEN-LABEL, SINGLE-ARM, PROSPECTIVE, MULTICENTER STUDY OF NAB-SIROLIMUS PLUS LETROZOLE IN ADVANCED OR RECURRENT ENDOMETRIOID ENDOMETRIAL CANCER

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Introduction: Dysregulation of mTOR signaling is implicated in the pathology of endometrial carcinoma (EC), particularly in endometrioid EC (EEC) in which >80% harbor PTEN or PI3K/AKT/mTOR pathway alterations. Crosstalk between mTOR and estrogen signaling pathways is associated with endocrine therapy resistance, and mTOR inhibition combined with endocrine therapy has shown benefit in patients with recurrent EC in previous phase 2 studies. *nab*-Sirolimus, an intravenous nanoparticle albumin-bound mTOR inhibitor (mTORi), is approved in the US for adults with advanced malignant perivascular epithelioid cell tumors. Preclinical data demonstrated improved tumor accumulation, mTOR target inhibition, and tumor growth suppression of *nab*-sirolimus versus other mTORis. This trial will evaluate the antitumor activity of combined mTOR and estrogen signaling pathway inhibition with *nab*-sirolimus and letrozole, respectively, in patients with advanced or recurrent EEC.

Methods: In this phase 2, open-label, single-arm, multicenter study (NCT05997017), *nab*-sirolimus (100 mg/m^2, intravenous, on days 1 and 8, 21-day cycle) and letrozole (2.5 mg, oral, daily) are administered to patients (~30 planned, Simon's 2-stage design) with clinically confirmed, advanced or recurrent EEC. Eligibility criteria

include age ≥18 years, ≤1 prior chemotherapy-based regimen in the advanced, metastatic, or recurrent setting (prior adjuvant chemotherapy additionally permitted), ECOG performance status 0 or 1, mTORi-naïve, and measurable disease. The primary endpoint is best overall response rate (per RECIST v1.1). Key secondary endpoints include duration of response, disease control rate, progression-free survival, overall survival, and safety. Exploratory endpoints include correlation of biomarkers with clinical outcomes.

Current Trial Status: The trial is currently open for enrollment.

TP005 / #1564

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

GOG-3069: PHASE 2 STUDY OF ALPELISIB AND FULVESTRANT FOR PIK3CA-MUTATED ESTROGEN RECEPTOR-POSITIVE ENDOMETRIOID ENDOMETRIAL CANCERS

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Introduction: Knowledge of the molecular landscape of endometrial cancer is driving novel treatment development for persistent, metastatic, or recurrent disease. Endocrine-based combinations such as aromatase inhibitors with mTOR or CDK4/6 inhibitors have shown benefit especially in patients not previously treated with chemotherapy. Oncogenic *PIK3CA* mutations impact response to aromatase inhibitors in breast cancer. Alpelisib + fulvestrant is approved for treatment of metastatic hormone receptor-positive, HER2-negative breast cancer harboring *PIK3CA* mutations after progression on endocrine therapy. *PIK3CA* mutations are common in endometrial cancers and may similarly confer endocrine resistance. GOG3069 is a phase II trial evaluating the efficacy and safety of alpelisib + fulvestrant in biomarker-selected endometrial cancer patients.

Methods: GOG-3069 is a phase II non-randomized, open-label, multicenter, two-stage study. Eligible patients have advanced (FIGO2014 Stage III/IV), persistent, or recurrent endometrial carcinoma with RECISTv1.1 measurable disease. Patients cannot be curable by surgery or radiotherapy. Other criteria: endometrioid histology with estrogen

receptor expression (≥1% of tumor cells) and oncogenic *PIK3CA* mutation, ≤3 prior lines of therapy including 1 systemic chemotherapy. Enrolled patients will receive alpelisib 300mg orally daily and fulvestrant 500mg IM Cycle 1 Day 1 and Day 15, then 500mg IM on Day 1 of each 28-day cycle. The primary endpoint is overall response rate by RECISTv1.1. Secondary endpoints include safety, tolerability, progression-free survival, duration of response, and 24-month overall survival rate. The statistical plan uses a conditional-stratified design factoring differing probabilities of response based on prior chemotherapy exposure.

Current Trial Status: GOG-3069 activated in November 2023 and will enroll across 15 US sites.

TP006 / #1565

Topic: *AS04. Endometrial/Uterine Corpus Cancers*

DOSE-EXPANSION PART OF A PHASE 1B GLOBAL STUDY OF E7386 PLUS LENVATINIB IN PATIENTS WITH HEPATOCELLULAR CARCINOMA AND OTHER SOLID TUMORS INCLUDING ENDOMETRIAL CANCER

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Introduction: E7386 is a first-in-class anticancer agent that modulates Wnt/β-catenin signaling. We describe the ongoing dose-expansion of study 102 (phase 1b): E7386+lenvatinib in hepatocellular carcinoma (HCC) or endometrial cancer (EC).

Methods: Eligible patients (≥18 years) should have a confirmed diagnosis of advanced/unresectable/recurrent solid tumor. HCC patients should have CPS A, BCLC Stage B/C, and progression on/after immune-oncology (IO)-based therapy or no prior therapy (IO-ineligible). EC patients should have progression after platinum-based chemotherapy (PBT) and an EC IO-based therapy; if IO-ineligible, patients may have ≤1 additional line of PBT (neoadjuvant/adjuvant setting). HCC patients (n≈60) will be randomized (2:1) to E7386 100mg BID+lenvatinib (12mg/day, BW≥60kg; 8mg/day, BW<60kg) or lenvatinib (monotherapy; same dose) in 28-day cycles. HCC patients will

be stratified by geographical region (Western Europe/North America vs Japan vs other countries). EC patients (n≈30) will receive E7386 120mg BID+lenvatinib 14mg QD. The primary objective aims to assess safety/tolerability of E7386+lenvatinib; secondary objectives will assess pharmacokinetics/efficacy of E7386+lenvatinib, and efficacy of lenvatinib monotherapy in HCC. Tumors will be assessed by investigator (RECIST v1.1) Q8W from first dose. AEs will be monitored/recorded. Study sites include: United States/France/Republic of Korea/Japan/Taiwan. The protocol is being amended to assess the optimal dose of E7386 when used in combination with lenvatinib, and the efficacy of E7386+lenvatinib relative to treatment of physician's choice, and lenvatinib monotherapy, in patients with advanced EC and progression following anti-PD(L)1 therapy.

Current Trial Status: As of June 28, 2024, 61 patients with HCC and 30 patients with EC have enrolled; dose optimization and regional expansion in EC is planned.

TP007 / #1413

Topic: *AS10. Ovarian Cancer*

PROSPECTIVE MULTICENTRE STUDY ON THE VALUE OF SECONDARY CYTOREDUCTIVE SURGERY IN THE ERA OF PARP-INHIBITORS (CONCEPT)

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Introduction: Secondary cytoreductive surgery (SCS) for epithelial ovarian cancer (EOC) relapse is being increasingly adopted following the favourable outcomes of recent multicentre prospective randomised trials (RCT) in tumorfree operated patients. However, these RCTs were conducted at times when Poly (ADP-ribose) polymerase inhibitor (PARPi) therapy was not part of routine practice. It is therefore difficult to determine whether the positive impact of SCS is retained when PARPi maintenance is available. Since a new RCT combining SCS and PARPi does not seem feasible, we wished to conduct a “real life” prospective observational study to evaluate the utilisation and impact of SCS in the PARPi era.

Methods: All consecutive high-grade EOC-patients (>18 years of age) who are treated in an ESGO- or nationally accredited cancer centre for a relapse >6 months from 1st line platinum-based chemotherapy will be registered. Patients will be registered prospectively for 1 year and followed-up at 6, 12 and 24 months. ECOG-status, AGO-score and tumour patterns will be described to categorize patients and correlate survival with SCS and PARPi-use. Key outcomes will include: adherence to ESGO-ESMO-ESP consensus recommendations; AGO score calculation at relapse; rate of relapsed OC-patients deemed inoperable; PFS and OS in regards to ultilisation of SCS; rate of patients undergoing SCS with a negative AGO score; and use of maintenance therapy at primary and recurrent disease.

Current Trial Status: This study is now open for site registration from April to October 2024. Due to favourable regulatory conditions this will be conducted as an audit in the UK.

TP008 / #1422

Topic: *AS10. Ovarian Cancer*

ALEPRO: A PHASE II, MULTICENTRE, OPEN-LABEL STUDY OF ABEMACICLIB AND LETROZOLE IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE RARE OVARIAN CANCER

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Introduction: Low-grade serous ovarian cancer (LGSOC) and adult-type granulosa cell tumor (AGCT) are rare ovarian malignancies, accounting for about 8% and 5% of all ovarian cancers, respectively. These subtypes of ovarian cancer will often be treated with conventional chemotherapy, although response rates are disappointing. Therefore, the search for alternative treatment strategies is crucial. The cyclin-dependent kinase 4/6 (CDK4/6) inhibitor abemaciclib in combination with endocrine therapy remarkably improved the outcome of patients with estrogen receptor-positive (ER+) breast cancer.

Methods: This study is a phase 2, multicentre, open-label, single-arm clinical trial (NCT05872204) of abemaciclib and letrozole in patients with advanced, recurrent and/or metastatic ER+ ovarian cancer. One cohort will include LGSOC patients and another cohort AGCT patients. Up to 50 patients with ER+ tumors will be included per cohort. The primary endpoint is ORR according to RECIST v1.1. Secondary endpoints include DOR, CBR, PFS, OS and adverse event profile. Additionally, patient-reported quality of life will be assessed by applying EQ-5D-5L and EORTC QLQ-C30 questionnaires. Exploratory aims include assessing blood and tissue biomarkers for association with clinical benefit and response rate. An interim analysis will be performed on 15 patients per cohort after 24 weeks of treatment to assess efficacy. Thirty additional patients per cohort will be included when the response rate is more than 1 in 15 evaluable patients.

Current Trial Status: Enrolment will take place at 3 Belgian, 6 French and 3 Dutch sites. At the time of abstract submission, 13 patients were included in the LGSOC cohort and one patient in the AGCT cohort.

TP009 / #1424

Topic: *AS10. Ovarian Cancer*

PRESSURISED INTRAPERITONEAL AEROSOLISED CHEMOTHERAPY IN THE MANAGEMENT OF CANCERS OF THE COLON, OVARY AND STOMACH: PHASE II RANDOMISED CONTROLLED TRIAL OF EFFICACY IN PERITONEAL METASTASES.

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Introduction: Up to 13%, 50% and 14% of patients with bowel, ovarian and stomach cancer respectively, present with peritoneal metastases (PM) which is difficult to treat with conventional chemotherapy. Pressurised IntraPeritoneal Aerosol Chemotherapy (PIPAC) which delivers chemotherapy into the peritoneal cavity, directly to the tumour site, as an aerosol during keyhole surgery is emerging as a potential new strategy. This trial aims to determine if PIPAC given with (colorectal, stomach) or instead of (ovarian) systemic anti-cancer therapy (SACT) improves Peritoneal Progression Free Survival (pPFS) compared to standard SACT.

Methods: PICCOS trial (PIPAC In Cancers of the Colon, Ovaries and Stomach) is a multi-arm, prospective randomised controlled trial (RCT) in the UK designed to provide high quality evidence regarding the efficacy of PIPAC in improving pPFS. Each cancer type will have individual eligibility criteria and protocols to allow for the necessary variations in treatment. In all cancer types, patients will be randomised in a 1:1 ratio to receive either standard SACT or a combination of standard SACT and/or PIPAC, where three PIPAC procedures are performed. We aim to recruit 78 colorectal, 66 ovarian and 72 stomach cancer patients over 2.5 years and follow-up will last for a minimum of 6 months.

Current Trial Status: This is the largest RCT in the world that is investigating the efficacy and impact on quality of life of PIPAC in the treatment of PM. PICCOS aims to provide high quality evidence to guide clinical practice and further research. The trial is currently recruiting.

TP010 / #1537

Topic: *AS10. Ovarian Cancer*

EFFICACY AND SAFETY OF LUVELTAMAB TAZEVIBULIN IN PATIENTS WITH RECURRENT PLATINUM-RESISTANT OVARIAN CANCER: THE REFRAME-01 (GOG-3086, ENGOT-79OV, AND APGOT-OV9) PHASE 2/3 STUDY

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Introduction: Patients with recurrent platinum-resistant ovarian cancer (PROC) with low to moderate levels of folate receptor alpha (FRα) expression remain an underserved population. Luveltamab tazevibulin (luvelta) is a FRα-targeting antibody-drug conjugate designed to treat cancers with a broad range of FRα expression. In a phase 1 study in recurrent epithelial ovarian cancer, luvelta demonstrated encouraging antitumor activity (ORR: 37.5%; mDOR: 5.5 months; mPFS: 6.1 months) and a manageable safety profile in patients with >25% FRα expression (Tumor Proportion Score [TPS] >25% regardless of

staining intensity). These results supported the initiation of the phase 2/3 trial described herein.

Methods: Randomized, open-label, phase 2/3 study evaluating the efficacy and safety of luvelta vs investigator's choice chemotherapy (ICC; gemcitabine, paclitaxel, pegylated liposomal doxorubicin, or topotecan) in patients with recurrent PROC expressing FRα (NCT05870748). Eligible patients (≥18 years) have measurable disease, 1–3 prior lines of therapy, ECOG PS ≤1, and TPS of ≥25%. Patients with primary platinum-refractory disease are excluded. Part 1 (phase 2) consisted of a dose-optimization stage with patients randomized 1:1 to receive IV luvelta Q3W at 4.3 mg/kg or 5.2 mg/kg with prophylactic G-CSF for 2 cycles followed by 4.3 mg/kg for cycles ≥3. In Part 2 (phase 3), patients are randomized 1:1 to the optimal luvelta dose or ICC. Primary objectives are to determine PFS and ORR. Secondary objectives include evaluation of OS, DOR, safety, and quality of life.

Current Trial Status: Part 1 is closed and part 2 has recently opened enrolment, planning to recruit approx. 550 patients.

TP011 / #1539

Topic: *AS10. Ovarian Cancer*

PHASE II STUDY TO ASSESS THE EFFICACY OF NIRAPARIB RECHALLENGE TREATMENT AFTER COMPLETE SECONDARY CYTOREDUCTION IN OVARIAN CANCER PATIENTS WITH OLIGOMETASTATIC PROGRESSION: THE ANALLISA STUDY

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Introduction: Maintenance therapy with PARP inhibitors (PARPi) is the standard of care for frontline platinum-sensitive high-grade ovarian cancer (OC) patients, particularly those with BRCA mutations or homologous recombination deficiency (HRD). Some BRCA and HRD patients could also benefit from adding bevacizumab. However, most patients progress during or after PARPi, with over 75% experiencing oligometastatic progression (OMP), defined as ≤5 lesions per ASCO/ESTRO consensus. The optimal treatment strategy for OC patients with OMP remains unclear, representing an unmet medical need. The ANALLISA study evaluates the efficacy and safety of niraparib rechallenge in patients with OC and OMP after complete secondary cytoreduction, progressing during or after first maintenance PARPi.

Methods: This multicenter, single-arm, phase II trial (NCT06180356) will enroll 30 patients with advanced high-grade or endometrioid OC experiencing OMP during or after first PARPi maintenance therapy, with no residual disease after complete secondary cytoreductive surgery. Patients will receive oral niraparib (300-200-100 mg based on weight, platelet count and previous dose) once daily in 28-day cycles. Primary endpoint is PFS as per RECIST v.1.1. Secondary endpoints include PFS by biomarker status, PFS2, time to first subsequent therapy, OS, and safety. Tumor samples will be collected at secondary surgery, and blood samples at baseline, every 3 cycles and at

the end of treatment, for biomarker analysis. Sample size was determined using an exponential maximum likelihood estimation test with one-sided H1 of median PFS≥9 months and H0 of median PFS≤5 months, requiring 18 events to achieve 80% power at a 5% Type I error.

Current Trial Status: Not yet recruiting

TP012 / #1581

Topic: *AS10. Ovarian Cancer*

ROMA VERSUS CA125 IN COMMUNITY SETTING FOR DIAGNOSIS OF OVARIAN CANCER – PROSPECTIVE DIAGNOSTIC TEST ACCURACY STUDY. SONATA STUDY - TRANSFORMING OVARIAN CANCER DIAGNOSTIC PATHWAYS

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Introduction: Women with non-specific abdominal symptoms in the community currently undergo testing with CA125 tumour marker. The Risk of Ovarian Malignancy Algorithm (ROMA) combines CA125 and HE4 in an algorithm with menopause adjusted thresholds. A Cochrane systematic review showed ROMA is more sensitive than CA125 and ultrasound for the diagnosis of Ovarian Cancer (OC) in secondary care settings. This cohort study will determine ROMA diagnostic accuracy and cost-efficiency in community settings, where ovarian cancer presents less often while also investigating implementation challenges of ROMA in parallel studies . Robust evidence on the diagnostic accuracy and cost-effectiveness of ROMA versus CA125 in community settings, will inform future diagnostic pathways, potentially improving OC early detection and outcomes.

Methods: Prospective diagnostic test accuracy cohort study with consecutive sample testing. 37,400 blood samples from symptomatic women in community /primary care setting comparing CA125 with ROMA. NHS laboratory data will be linked with routinely collected clinical outcomes data from NHS cancer hospitals. Data will be and stored and analysed in a Trusted Research Environment. The study is powered to detect a 20% difference in sensitivity between ROMA and CA125 for early-stage OC. Interim analysis of 25,000 samples available January 2025. Primary Outcome : sensitivity/specificity of ROMA versus CA125 in early-stage OC. Secondary Outcome Measures: Sensitivity/specificity of ROMA versus CA125 in all stages of OC. Cost-effectiveness: model-based cost consequence analysis from an NHS perspective.

Current Trial Status: All approvals to test samples and for outcome data linkage to be obtained without patient level consent in place (23/CAG/0086, Research 23/WS/0107). Sample accrual 31/03/24: 5803.

TP013 / #1585

Topic: *AS10. Ovarian Cancer*

SB221: A PROOF-OF-CONCEPT STUDY TO ASSESS THE COMBINATION OF SON-1010 (IL12-FHAB) AND ATEZOLIZUMAB IN PATIENTS WITH PLATINUM-RESISTANT OVARIAN CANCER (PROC): TRIAL IN PROGRESS

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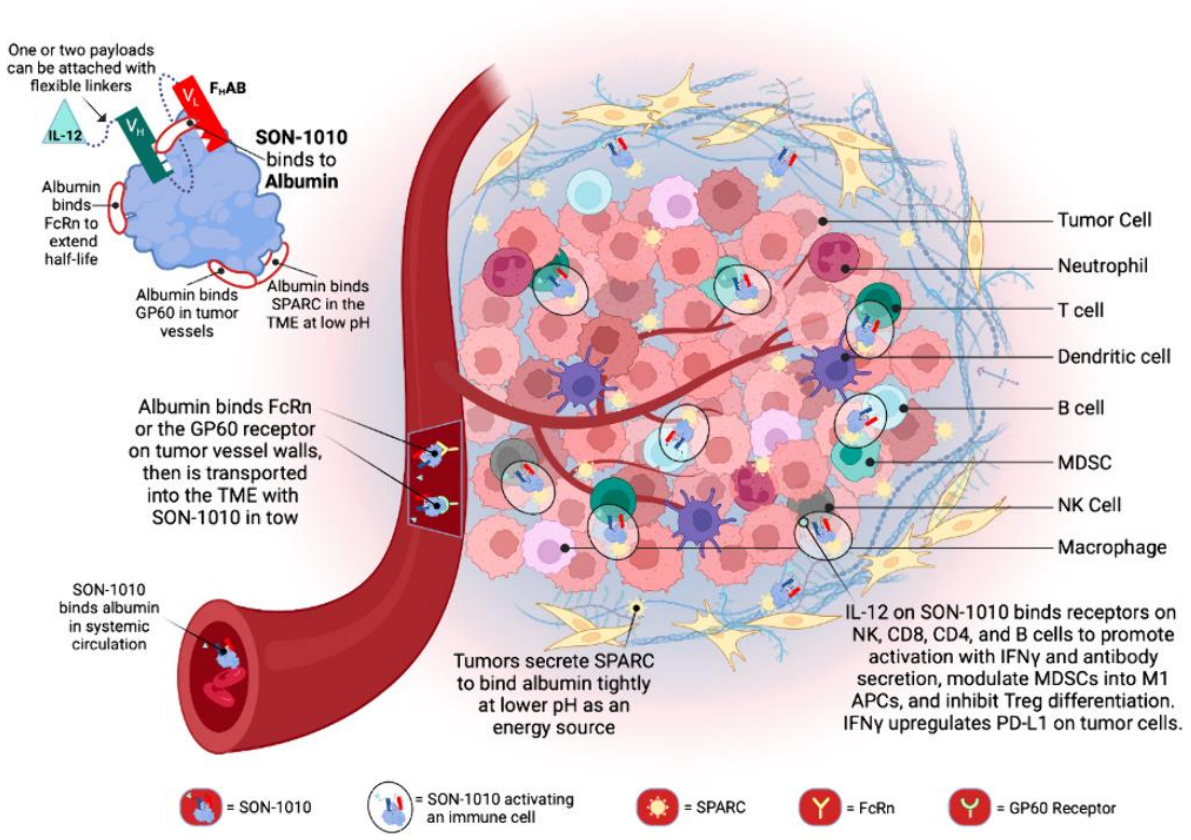
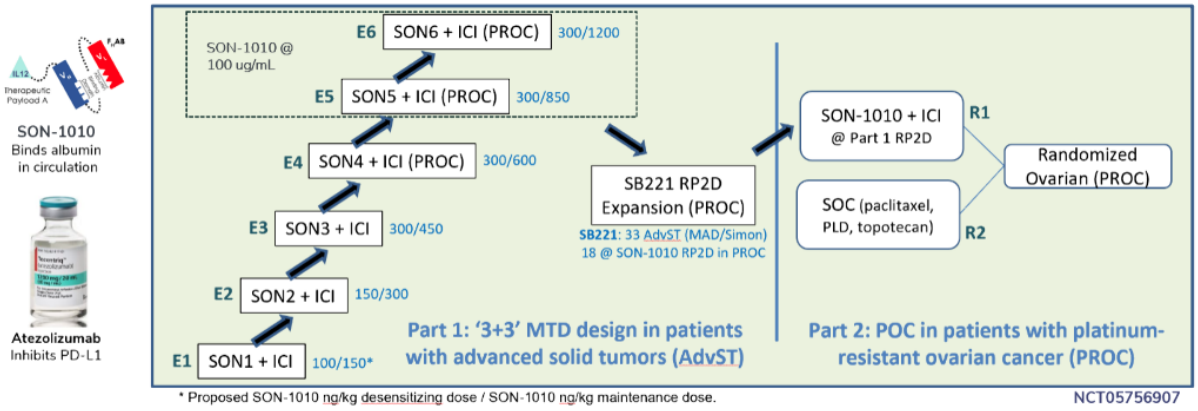
Introduction: Interleukin 12 (IL-12) strongly activates T and NK cells to produce IFNγ and kill tumor cells, yet has had limited success as an immunotherapeutic drug due to inefficient tumor targeting, short PK, and subsequent toxicity. We developed SON-1010, a single-chain native IL-12 genetically linked to a fully-human albumin binding (F_HAB®) domain that targets the tumor microenvironment (TME) through albumin binding to over-expressed FcRn, GP60, and SPARC. This results in improved PK, decreased toxicity, and a broader therapeutic index. A 'cold' mouse melanoma model showed efficacy and significant increases in activated NK, NKT, Th1, and cytotoxic CD8 T cells. We hypothesize that SON-1010 may 'warm up' the TME to improve checkpoint inhibitor effectiveness in immunologically-active tumors like PROC that have high levels of

SPARC.



Methods: Study SB221 is a Phase 1b/2a multicenter study to assess the safety, tolerability, PK, PD, and efficacy of SON-1010 administered SC, either alone or in combination with a fixed dose of atezolizumab (Tecentriq®) given IV (NCT05756907). Part 1 determines the maximum tolerated dose (MTD) of the combination in advanced solid tumors with expansion in PROC to establish the Recommended Phase 2 Dose (RP2D). Once the likelihood of efficacy is shown with a Simon 2-stage design, Part 2 will then assess the potential for improved efficacy of the combination of SON-1010 with atezolizumab versus the standard of care (SOC) in PROC.



Current Trial Status: The first dose-escalation cohorts have been enrolled and additional sites are being added to help with recruitment of patients with PROC.

TP014 / #1586

Topic: *AS10. Ovarian Cancer*

PHASE I CLINICAL TRIAL OF AUTOLOGOUS T-CELLS GENETICALLY ENGINEERED WITH A CHIMERIC RECEPTOR TO TARGET THE FOLLICLE-STIMULATING HORMONE RECEPTOR (FSHR) IN RECURRENT OVARIAN CANCER (OVCA)

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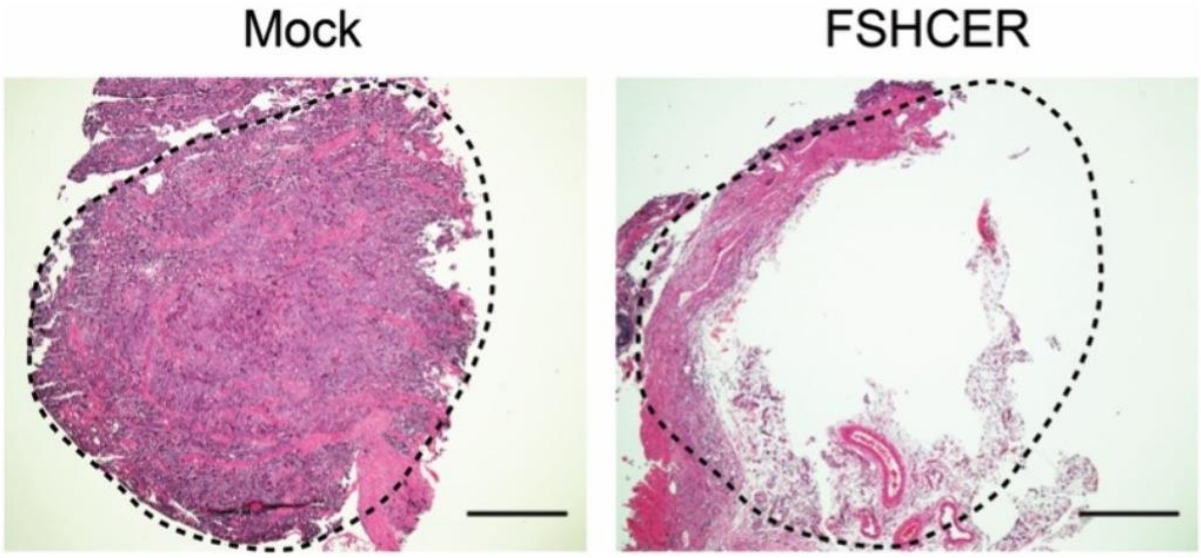
Introduction: FSHR is a tissue specific antigen expressed in >55% of high-grade epithelial OVCAs with negligible FSHR expression in non-ovarian tissues. OVCA xenografts treated with FSHCER T (FSH-Chimeric Endocrine Receptor+ T-Cell (CER-T) (Fig.1)) cells demonstrated cytotoxic activity against patient-derived FSHR+ ovarian carcinomas (Fig.2). We hypothesize targeting FSHR in women with FSHR+ OVCA will result in responses due to engraftment, expansion, and survival of these adoptively transferred FSHCER T-cells and will have acceptable toxicity.



Methods: The primary objective of this phase 1 dose-escalation study (NCT05316129) in high-grade epithelial OVCA using T-cells genetically modified to express CER targeting FSHR is to assess the safety of the intraperitoneal (IP) and intravenous (IV) infusions of FSHCER T-cells. Secondary objectives include antitumor efficacy, persistence of transferred FSHR T cells, expansion of endogenous tumor-targeted cells, and comparison of IP and IV administration routes. Patients unable to be treated in the IP arm may be treated in the IV arm in the lowest unfilled cohort for that arm. Cohorts of 3 to 6 patients will be infused with escalating doses of FSHCER T-cells to establish the maximum tolerated dose (MTD) with 6 planned dose levels from 1 $x10^5$ to 1 x 10^7 (cells/kg) with the 5^{th} level receiving lymphodepleting chemotherapy. Following MTD determination, an expansion phase will be initiated.

Current Trial Status: Six patients have been enrolled and have received FSHR T-cells in the first two dose-level cohorts. Five have cleared the DLT period and one patient is within the DLT window but without DLT.

TP015 / #1529

Topic: *AS13. Patient Advocacy*

ASK QUESTIONS IN GYNECOLOGIC ONCOLOGY (ASQ-GYO): A RANDOMIZED CONTROLLED TRIAL OF A QUESTION PROMPT LIST COMMUNICATION INTERVENTION IN OUTPATIENT GYNECOLOGIC ONCOLOGY CLINICS

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Introduction: Several professional US cancer organizations have highlighted the benefits of utilizing communication tools to increase patient engagement during cancer consultations. Question Prompt Lists (QPLs) are an example of such a tool. QPLs are a list of questions tailored to specific medical contexts to empower patients to participate more actively in their care. QPL use increases patient self-efficacy, number of questions asked and recall of information, and decreases anxiety at follow-up. The Ask Questions in Gynecologic Oncology (ASQ-GYO) QPL is a novel tool created to highlight surgery, chemotherapy, and radiation oncology questions that patients may have during their initial outpatient gynecologic oncology consultation. We will assess the acceptability and effectiveness of the ASQ-GYO QPL at improving patient self-efficacy, distress, trust in physicians, and knowledge about their diagnosis and care plan.

Methods: In this randomized controlled trial, we will recruit 70 patients to receive either the intervention (ASQ-GYO QPL) or usual care (no QPL) prior to their first visit with a gynecologic oncologist. Eligibility criteria include age ≥18 years, able to consent, English speaking, have a confirmed or likely diagnosis of a gynecologic cancer. Participants will complete a pre-visit survey assessing sociodemographic characteristics, self-efficacy, distress, and trust in physicians. Participants then complete a post-visit survey again assessing those domains, and also knowledge about their diagnosis and perceptions of the QPL. Planned analyses include pre/post-visit changes in the domains assessed, post-visit differences between groups and perceived acceptability of the QPL.

Current Trial Status: Open to active accrual with 14 patients enrolled as of 6/19/24.

TP016 / #1431

Topic: *AS15. Radiation Oncology*

STUDY OF 3D-PRINTED CUSTOM APPLICATORS FOR INTRACAVITARY HIGH DOSE RATE (HDR) GYNAECOLOGICAL BRACHYTHERAPY

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Introduction: Adjuvant radiotherapy following definitive surgery for intermediate and high-intermediate risk endometrial cancers provides significant reduction in local recurrence. Vaginal brachytherapy is used as monotherapy for intermediate risk malignancies and may be used in conjunction with external beam radiotherapy if there is cervical stromal involvement. Delivery of prescribed dose critically depends on close apposition of the applicator to the vaginal mucosa. While in many cases a cylindrical applicator may suffice, if the vault topography is irregular, close apposition may not be possible. We are conducting a feasibility study to develop an efficient and robust clinical workflow for a personalised 3D-printed vaginal applicator generated from a simulation CT.

Methods: Patients identified at the Northern Sydney Cancer Centre Gynaeoncology multidisciplinary tumour board requiring intracavitary vaginal brachytherapy are eligible. Eligible and consenting patients are CT simulated using a standard fixed diameter cylinder followed by a CT simulation with a gel or alginate distended vaginal cavity. A model for the custom applicator is generated and sent for 3D printing. Brachytherapy plans are produced for both the cylinder and custom applicator and patients are treated using the best tolerated technique and dosimetrically superior plan. Patient reported quality of life outcomes and clinician reported outcomes are collected as well as dosimetric data. Clinical follow up extends to 5 years.

Current Trial Status: The trial is open and we are actively recruiting patients with a target of 10 patients. To date four patients have been screened, one patient is for clinical assessment and one patient is in the planning stage for treatment.