may be enrolled based on emerging data. The primary end-
points are safety and tolerability, overall response rate, disease
control rate, and duration of response. Patients are not
selected by B7-H4 status but baseline tumors samples are col-
lected for retrospective analysis. The trial is currently enrolling
patients. NCT05377996
Results Trial in progress
Conclusions Trial in progress

TP013/#1437 ENGOT-EN19/NSGO-CTU/ALPACA: A RANDOMISED
PHASE II TRIAL OF ALPELISIB IN COMBINATION
WITH LETROZOLE FOR PATIENTS WITH
ADVANCED OR RECURRENT ENDOMETRIAL
CANCER
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10.1136/ijgc-2022-igcs.522

Objectives Patients with advanced or recurrent EC have few
treatment options and succumb to the cancer rapidly. Approx-
imately 40% of patients with ER-positive, endometrial cancer have
activating mutations in the gene PIK3CA, inducing hyperactivation of the alpha isofrom of phosphatidylinositol 3-
kinase (PI3K). Endocrine therapy is the standard treatment for
patients with ER-positive advanced endometrial cancer. How-
ever, acquired resistance to endocrine-based therapy remains a
challenge. Targeted therapies, such as PI3K inhibitors, have
been developed to overcome resistance to existing therapies
This prospective, multicenter, open-label, randomized phase II
study is evaluating the activity of alpelisib, a PIK3CA inhibitor
in combination with letrozole in relapsed endometrial cancer.

Methods Patients with PIK3CA mutated, G1–2 endometriod
adenocarcinoma relapsed after first-line systemic therapy are
eligible. Patients must have measurable disease and ECOG per-
formance status 0–1. Patients are randomized into one of the
two treatment arms, (A:B), in a 1:1 randomization (n=86):
Arm A (letrozole): Arm B (letrozole plus alpelisib. Primary
ependpoint is investigator assessed progression-free survival.
Study sponsor is the Nordic Society of Gynaecological Oncol-
ogy – Clinical Trial Unit and is being conducted in six cooper-
ative groups (MaNGO, BGOG, DGOG, PMHC, NOGGO & NSGO).
Results Study is expected to start enrolment in Q4 2022
Conclusions The positive outcome will further improve the
outcome of our patients and phase III validation trial will
follow.

TP014/#1529 RANDOMIZED COMPARISON BETWEEN SENTINEL
LYMPH NODE MAPPING USING INDOCYANINE
GREEN PLUS A FLUORESCENT CAMERA VERSUS
LYMPH NODE DISSECTION IN CLINICAL STAGE I-II
ENDOMETRIAL CANCER (KGOG2029/SELYE)
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10.1136/ijgc-2022-igcs.523

Objectives Sentinel lymph node (SLN) mapping has been sug-
gested as an alternative surgical technique to lymph node dis-
section (LND) for early-stage endometrial cancer. However, the
survival outcomes of SLN mapping compared with LND have not been established via prospective randomized con-
trolled trials. The primary endpoint of the Gynecologic Oncol-
ogy Group 2029 trial (KGOG2029/SELYE) is the 3-year
disease-free survival (DFS) of SLN mapping versus LND. The
secondary endpoints are 3-year overall survival (OS), 5-year
DFS, 5-year OS, pattern of recurrence, immediate surgical out-
comes, SLN mapping success rate, postoperative lymph-related
complications, postoperative QOL, and the cost-effectiveness
of SLN mapping versus LND.

Methods The KGOG2029/SELYE trial is a multi-center, single-
blind, randomized controlled trial which has been designed to
determine the prognostic value of SLN mapping alone com-
pared with conventional lymphadenectomy for patients with
clinical stage I-II endometrial cancer of any histologic type and
any histologic grade. Study patients will be classified into low/intermediate-risk and high-risk groups according to the
risk of lymph node metastasis. A low/intermediate-risk group
will undergo pelvic SLN mapping in SLN group and will
undergo pelvic lymph node dissection in LND group. A high-
risk group will undergo a 2-step SLN mapping procedure con-
sisting of para-aortic SLN mapping (first step) and pelvic SLN
mapping (second step) in SLN group and will undergo pelvic
and para-aortic lymph node dissection in LND group. Eighty-
one of planned 810 patients have been enrolled at the time of
submission.

Results There are no available results at the time of
submission.

Conclusions There are no available conclusions at the time of
submission.

TP015/#1566 A PHASE 2, TWO-STAGE, STUDY OF
MIRVETUXIMAB SORAVTANSINE (IMGN853) IN
COMBINATION WITH PEMBROLIZUMAB IN
PATIENTS WITH MICROSATELLITE STABLE (MSS)
RECURRENT OR PERSISTENT ENDOMETRIAL
CANCER (EC)
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1Susana Campos, 1Carolyn Krasner, 1Elizabeth Lee, 1Joyce Liu, 1Elizabeth Stover,
1Jennifer Veneis, 1Alexi Wright, 1Ursula Matulonis, 1Panagiotis Konstantinopoulos, 1Dana-
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Objectives Folate receptor-alpha (FRα) expression is associated with poor prognosis in endometrial cancer (EC). Mirvetuxi-
mab soravtansine (MIRV), an antibody drug conjugate (ADC)
comprising a FRα-binding antibody, cleavable linker, and the
tubulin-disrupting maytansinoid DM4, showed tolerability and
single agent activity in a Phase 1 dose expansion study in
FRα+ advanced/recurrent EC (NCT01609556). In addition to
direct target-mediated cytotoxicity, MIRV activates monocytes
and promotes phagocytosis of tumor cells through Fc-Fcγ
receptor interactions. We hypothesized that addition of MIRV may
improve the low response to immunotherapy in MSS EC.

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Conclusions There are no available conclusions at the time of
submission.
Methods This is a Phase 2, single cohort study of MIRV with pembrolizumab in recurrent/persistent EC (NCT03835819). Patients must have advanced or recurrent MSS serous EC with FReT expression (≥50% of cells with ≥2+ by IHC performed at Ventana, Inc) and have received 1–3 prior lines of therapy. Prior receipt of ICi is allowed. Patients receive MIRV 6 mg/kg AIBW and pembrolizumab 200 mg every 21 days. The co-primary endpoint is progression-free survival at 6 months and objective response rate by RECIST 1.1. Translational objectives include assessment of tumor-infiltrating immune cells, expression of immune checkpoint markers, and whole exome sequencing. Statistical considerations are for a Simon two-stage optimal design with 16 patients in Stage 1 and 19 patients in Stage 2, to a total of 35. Prespecified activity for the first stage of accrual was met; second stage accrual began November 2020.

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

Conclusions Trial in progress: no available results at time of submission.

TP016/#1442 KEYNOTE-C93/GOG-3064/ENGOT-EN15: PHASE 3, RANDOMIZED, OPEN-LABEL STUDY OF FIRST-LINE PEMBROLIZUMAB VERSUS PLATINUM-DOU BLET CHEMOTHERAPY IN MISMATCH REPAIR DEFICIENT ADVANCED OR RECURRENT ENDOMETRIAL CARCINOMA

1Brian Slomovitz*, 2David Cibula, 3Murat Gultekin, 4Mansoor Mirza, 5Beata Maciakowska-Mateczyna, 6Alexandra Taylor, 7Ignacio Romero, 8Nicoleta Colombo, 9Jacob Korach, 10Jianqing Zhu, 11Lucy Gilbert, 12Kosei Hasagawa, 13Jae-Weon Kim, 14Sally Baron-Hay, 15Vicky Makker, 16Robert L Coleman, 17Robert J Ortoski, 18Kuan Zhou, 19Ivan Khemka, 20Sandor Pignata, 21Division of Gynecologic Oncology, Mount Sinai Medical Center, Miami Beach, USA; 22Department of Obstetrics and Gynecology, General Faculty Hospital in Prague, First Faculty of Medicine, Charles University, Prague, Prague, Czech Republic; 23Department of Obstetrics and Gynecology, Division of Gynecological Oncology, Faculty of Medicine, Hacettepe University, Ankara, Turkey; 24NCGO-CTU and Department of Cancer Treatment Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark; 25Department of Gynecologic Oncology, Biastyl Oncology Center, Biastyl, Poland; 26Department of Gynecology Oncology, Royal Marsden Hospital Nhs Trust, London, UK; 27Department of Medical Oncology, Fundación Instituto Valenciano De Oncología, Calle Del Profesor Beltrán Báguena, Valencia, Spain; 28Department of Medicine and Surgery, University of Milan-Bicocca and Division of Gynecologic Oncology, European Institute of Oncology (Ieo) Ircs, Milan, Italy; 29Gynecologic Oncology Department, Sheba Medical Center, Tel Aviv University, Tel Aviv, Israel; 30Department of Gynecologic Oncology, Cancer Hospital of The University of Chinese Academy of Sciences (zhijiang Cancer Hospital), Hangzhou, China; 31Division of Gynecologic Oncology, McGill University Health Centre, Montreal, Canada; 32Department of Gynecologic Oncology, Saitama Medical University International Medical Center, Hidaka, Japan; 33Department of Obstetrics and Gynecology, Seoul National University College of Medicine, Seoul, Korea, Republic of; 34Northwestern Sydney Cancer Centre, Royal North Shore Hospital, Sydney, Australia; 35Department of Medicine, Memorial Sloan Kettering Cancer Center, Weill Cornell Medical Center, New York, USA; 36Gynecologic Oncology, Texas Oncology-the Woodlands, The Woodlands, USA; 37Global Clinical Development, Merck and Co., Inc., Rahway, USA; 38Biostatistics and Research Decision Sciences, Merck and Co., Inc., Rahway, USA; 39Department of Uro-Gynecological Oncology, Instituto Nazionale Tumori Ircs Fondazione G Pascale, Naples, Italy

TP017/#1455 A PHASE 2 UMBRELLA STUDY OF RETIFANILMAB (INCMGA00012) ALONE OR IN COMBINATION WITH OTHER THERAPIES IN PATIENTS WITH ADVANCED OR METASTATIC ENDOMETRIAL CANCER (POD1UM-204)

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Objectives Managing advanced endometrial cancer (EC) after platinum therapy remains a challenge. Retifanilimab is an investigational humanized monoclonal antibody against programmed cell death 1 (PD-1) with demonstrated efficacy in advanced tumors, including EC.