<table>
<thead>
<tr>
<th>PROTOCOLES</th>
<th>PTES S/R/Tx/FUP</th>
<th>PHASE</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>IND228</td>
<td>URCOH</td>
<td>II</td>
<td>A phase II study of durvalumab and tremelimumab in patients with advanced rare tumours</td>
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</tbody>
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- Histologically and/or cytologically confirmed cancer that is advanced / metastatic / recurrent or unresectable and for which no curative therapy exists as follows: Clear cell carcinoma of the ovary
- At least one measurable lesion as defined by RECIST 1.1 that has not been the site of the protocol mandated biopsy.
- Previous Therapy
  - Cytotoxic Chemotherapy:
    - Patients may have received prior chemotherapy – no limit on number of prior regimens.
  - Other Systemic Therapy:
    - May have received other prior therapies including, angiogenesis inhibitors, PARP inhibitors or signal transduction inhibitors (tyrosine kinase inhibitors). Prior therapy with PD-1/PDL1 or CTLA-4 inhibitors is not allowed.
    - Must have recovered from all reversible toxicity related to prior chemotherapy or systemic therapy and have adequate washout as follows (Longest of one of the following):
      - Two weeks
      - 5 half-lives for investigational agents
      - Standard cycle length of standard therapies
  - Radiation:
    - Prior external beam radiation is permitted provided a minimum of 28 days (4 weeks) have elapsed between the last dose of radiation and date of registration. Exceptions may be made for low-dose, non-myelosuppressive radiotherapy after consultation with CCTG senior investigator. Concurrent radiotherapy is not permitted. Patients planned for concurrent chemotherapy-radiation are not eligible.
  - Surgery:
    - Previous surgery is permitted provided that a minimum of 28 days (4 weeks) have elapsed between any major surgery and date of registration, and that wound healing has occurred.
### CHECKMATE-848

**URCOH**
Francine Richard au 24853

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| **A Randomized, Open-Label, Phase 2 Study of Nivolumab in Combination with Ipilimumab or Nivolumab Monotherapy in Participants with Advanced or Metastatic Solid Tumors of High Tumor Mutational Burden (TMB-H)** (CheckMate 848: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 848) | II | - Patients with a refractory, metastatic, or unresectable TMB-H solid tumors including standard of care, if available.
- Treatment with botanical preparations alone (e.g. herbal supplements or traditional Chinese medicines) are not considered a line of therapy.
- The IRT must be provided with the results of both tissue and blood TMB-H testing for eligible participants prior to randomization. Both results are utilized for stratification purposes
- Participants must have either fTMB or bTMB ≥ 10 mut/Mb
- Prior TMB-H results obtained with F1CDx assay (tissue) or assay from Foundation Medicine (blood) are acceptable for eligibility purposes. When these prior results are not available, tissue and blood samples must be provided for central TMB-H testing, and results must be available prior to randomization.
- TMB results obtained from any other assays are not acceptable for eligibility.
- Participants must have an ECOG Performance Status of ≤1 (participants > 16 years old with solid tumors), KPS ≥ 80 (participants > 16 years old with primary CNS tumors) or LPS ≥ 80 (participants 12 to 16 years old ONLY).
- Participants must have measurable disease for response assessment as per RECIST 1.1 for solid tumors other than CNS, and RANO criteria for primary CNS malignancies. |

### ESPS-001

**DP/IUT/IUT/IUT**

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| **A Phase 1 / 2 Study of LY2880070 in Patients with Advanced or Metastatic Cancer** (Part A, Arm 1 (LY monotherapy) is now closed to accrual. However Part A, Arm 2 (LY + GEM) and Part A, Arm 3 (poor metabolizers only) are currently active. There are currently no slots available in Arm 2, however I will send out a notice to all sites should any slots in this cohort open for competitive enrollment.) | I/II | - Patients must have histological or cytological evidence of cancer (solid tumors, excluding glioblastoma and primary brain tumor) that is advanced and/or metastatic.
- For Arm 3 of Part A, patients must be poor metabolizers for CYP2D6. |

### OVAIRES

#### PRÉVENTION

**OV25**

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| **A Randomized Phase II Double-Blind Placebo-Controlled Trials of Acetylsalicylic Acid (ASA) in Chemoprevention of Ovarian Cancer with BRCA 1 and 2 Mutations (STICs and STONES)** | II | - Previously documented germline BRCA1/2 pathogenic mutation or likely pathogenic variant based on the ACMG 2015 guidelines.
- Risk-reducing surgery (bilateral salpingo-oophorectomy or bilateral salpingectomy inclusive of fimbria) scheduled for within 6 months to 2 years after the date of randomization as standard of care.
- Surgery should not be delayed to allow subjects to participate in the trial.
- Subjects with a previous unilateral salpingectomy/oophorectomy for other reasons will be eligible. |

### NEO

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<tbody>
<tr>
<td><strong>A Phase II, Open-Label, Randomized, Multi-Centre Study, of Neoadjuvant Olaparib in Patients with Platinum Sensitive Recurrent High Grade Serous Ovarian/Primary Peritoneal or Fallopian tube</strong></td>
<td>II</td>
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<tr>
<td>Study</td>
<td>Details</td>
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<td>--------------------------------------------</td>
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<tr>
<td><strong>FORWARD2</strong> DP/NG/ET/AV</td>
<td>A Phase 1b/2 Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Mirvetuximab Soravtansine (IMGN853) in Combination with Bevacizumab, Carboplatin, Pegylated Liposomal Doxorubicin, Pembrolizumab, or Bevacizumab + Carboplatin, in Adults with Folate Receptor Alpha Positive Advanced Epithelial Ovarian Cancer, Primary Peritoneal Cancer, or Fallopian Tube Cancer</td>
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<tr>
<td><strong>OVC2</strong> DP/ST/CT/AV</td>
<td>A Randomized Phase II/III study of the combination of Cediranib and Olaparib compared to Cediranib or Olaparib alone, or Standard of care chemotherapy in women with recurrent platinum-resistant or - refractory ovarian, fallopian tube, or primary peritoneal cancer (COCOS)</td>
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**Cancer**

- Histologically proven recurrent high grade serous ovarian/primary peritoneal or fallopian tube cancer.
- Patients must have disease amenable to pre-operative biopsy.
- Patients must have disease deemed suitable for surgical debulking.
- Patients must have had at least one line of platinum based therapy, with a progression free interval of at least 6 months.
- Patients must have shown platinum sensitivity to their last line of platinum therapy.

≥ 1 LIGNE mais ≤ 3 LIGNES (sensible ou résistant)

- Patients must have had at least one line of platinum based therapy, with a progression free interval of at least 6 months.
- Patients must have shown platinum sensitivity to their last line of platinum therapy.

≥ 1 LIGNE mais ≤ 3 LIGNES (résistant ou réfractaire)

- Patients may have either platinum-resistant disease or platinum-sensitive disease, where a non-platinum doublet is an appropriate next line of therapy.
- Number of prior therapies (where adjuvant ± neoadjuvant will be considered one regimen and maintenance therapy will be considered to be part of the preceding regimen; hormonal therapy counts as a separate line of therapy unless given as maintenance):
cell carcinoma histologies are also eligible, provided that the patient has a known deleterious germline BRCA1 or BRCA2 mutation identified through testing at a clinical laboratory.

- Have recurrent platinum-resistant or refractory disease - defined as disease that has progressed by imaging while receiving platinum or had recurrence within 6 months of the last receipt of platinum-based chemotherapy. Rising CA125 only is not considered as platinum-resistant or refractory disease.

- Evaluable disease – defined as RECIST 1.1 measurable disease OR non-measurable disease (defined as solid and/or cystic abnormalities on radiographic imaging that do not meet RECIST 1.1 definitions for target lesions OR ascites and/or pleural effusion that has been pathologically demonstrated to be disease-related in the setting of a CA125 > 2x ULN).

- No more than 3 prior treatment regimens (including primary therapy; no more than 1 prior non-platinum based therapy in the platinum-resistant/-refractory setting). Hormonal therapies used as single agents will not count towards this line limit.

- Patients may not have had a prior anti-angiogenic agent in the recurrent setting. Prior use of bevacizumab in the upfront or upfront maintenance setting is allowed.

- Patients may not have previously received a PARP-inhibitor.

**MAINTENANCE POST 1ère LIGNE**

**ATHENA**

| DP/JT/SDS/AV | 0/0/0/0 | III |

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy

- Have newly diagnosed, histologically confirmed, advanced (FIGO stage III-IV), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer.
- Completed cytoreductive surgery, including at least a bilateral salpingo-oophorectomy and partial omentectomy, either prior to chemotherapy (primary surgery) or following neoadjuvant chemotherapy (interval debulking).
- Have received 4 to 8 cycles of first line platinum-doublet treatment per standard clinical practice, including a minimum of 4 cycles of platinum/taxane combination.
- A patient with best response of PR must have received at least 6 cycles.
- Bevacizumab is allowed during the chemotherapy phase, but not during maintenance, during therapy directed by this protocol.
- Have completed first-line platinum-based chemotherapy and surgery with a response, in the opinion of the investigator, defined as no evidence of disease progression or rising CA-125 at any time during front-line treatment; and:
  - No evidence of measurable disease by RECIST 1.1 (if complete resection/R0 at primary or interval cytoreductive surgery); or
  - A partial or complete response per RECIST 1.1 (if measurable disease was present after surgery and prior to chemotherapy) (Appendix 1); or
  - A GCIG CA-125 response (if only non-measurable disease was present prior to chemotherapy)

**≥ 2 LIGNES (sensible 1ère ligne)**

**ARIEL4**

| DP/ST/ET/AV | 2/2/0/1 1DC | III |

A Phase 3 Multicenter, Randomized Study of Rucaparib versus Chemotherapy in Patients with Relapsed, BRCA-Mutant, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

- Have a histologically confirmed diagnosis of high-grade serous or
Grade 2 or Grade 3 endometrioid epithelial ovarian, fallopian tube, or primary peritoneal cancer
  - If mixed histology, > 50% of the primary tumor must be confirmed to be high-grade serous or endometrioid upon review by local pathology
  - Patients with a histology of other than serous or endometrioid are also eligible if they are known to harbor a deleterious germline or somatic BRCA1/2 mutation

- Received min 1 platin sensible
- Pas de taxol Hebdo, sensible au 1er platin.
- Received ≥ 2 prior chemotherapy regimens and have relapsed or progressive disease as confirmed by radiologic assessment
  - Had documented treatment-free interval of ≥ 6 months following the first chemotherapy regimen received
  - Hormonal agents (eg, tamoxifen, letrozole, etc), anti-angiogenic agents (eg, bevacizumab, pazopanib, cediranib, etc), and other non-chemotherapy agents will not be counted as a chemotherapy regimen for the purpose of determining patient eligibility
  - Agents administered in the maintenance setting will not be counted as a separate regimen
- Have either a deleterious BRCA1/2 mutation as confirmed by the central laboratory.

Note: patients known to harbor a deleterious germline or somatic BRCA1/2 mutation based on local assessment may be enrolled without central tissue analysis provided there is confirmation that tumor tissue is available to be provided to the central laboratory.

**COL**

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**KEYNOTE-826**

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A Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial of Pembrolizumab (MK-3475) Plus Chemotherapy Versus Chemotherapy Plus Placebo for the First-Line Treatment of Persistent, Recurrent, or Metastatic Cervical Cancer

- Have persistent, recurrent, or metastatic squamous cell carcinoma, adenosquamous carcinoma, or adenocarcinoma of the cervix which has not been treated with systemic chemotherapy and is not amenable to curative treatment (such as with surgery and/or radiation).

  **NOTE:** Prior chemotherapy utilized as a radiosensitizing agent and completed at least 2 weeks prior to randomization with resolution of all radiation-related toxicities is allowed.

**EMPOWER R2810-ONC-1676**

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An Open Label, Randomized, Phase 3 Clinical Trial of REGN2810 vs Therapy of Investigator’s Choice Chemotherapy in Recurrent or metastatic Platinum-Refractory Cervical Carcinoma

- Recurrent, persistent, and/or metastatic cervical cancer, for which there is not a curativeintervention option (surgery or radiation therapy with or without chemotherapy). Acceptable histologies are squamous carcinoma, adenocarcinoma, and adenosquamous carcinoma. Sarcomas and neuroendocrine carcinomas are not eligible histologies.

- Tumor progression or recurrence within 6 months of last dose of platinum therapy that was used to treat metastatic, persistent or recurrent cervical cancer

- Patients must meet at least one of the following criteria regarding prior bevacizumab therapy:
  - Received prior bevacizumab-containing therapy, which was discontinued due to progression of disease
  - Received prior bevacizumab-containing therapy, which was discontinued...
due to toxicity
  o Was deemed unsuitable for prior bevacizumab therapy for one of the following reasons:
    • Unacceptable risk of fistula formation,
    • poorly controlled hypertension,
    • “low risk” disease according to the Moore Criteria
    • Refused prior bevacizumab therapy.
    • Did not have access to bevacizumab therapy due to logistical reasons
  • Patients must meet at least one of the following criteria regarding prior paclitaxel therapy:
    o Received prior paclitaxel-containing therapy, which was discontinued due to progression of disease
    o Received prior paclitaxel-containing therapy, which was discontinued due to toxicity
    o Was deemed unsuitable for prior paclitaxel therapy for one of the following reasons:
      • Neuropathy
      • allergy to paclitaxel or its components
    o Refused prior paclitaxel therapy

| CX.5      | 34 | III |
| VS/ST/ET/FG |    |    |
| Cancer du col précoce et à faible risque |
| Comparer hystérectomie radicale ou simple combinés à la dissection des ganglions pelviens |

ENDOMÈTRE

≥ 1ière LIGNE, ≤2ième LIGNE

GARNET

| 7/5/2/1 | III |
| VS/ST/ET/AV |    |
| A Phase 1 Dose Escalation and Cohort Expansion Study of TSR-042, an anti-PD-1 Monoclonal Antibody, in Patients with Advanced Solid Tumors |
| Part 2B: Histologically or cytologically proven recurrent or advanced solid tumor with measurable lesion(s) per RECIST v.1.1 and meets one of the following disease types: |
| o Cohort A1 (MSI-H endometrial cancer) |
| o Cohort A2 (MSS endometrial cancer) |
| Patients must have progressed on or after platinum doublet therapy |
| ≤2 lines for recurrent/advanced (≥Stage IIIb) disease. |
| Prior Tx with hormone therapies is acceptable and does not count towards the number of anti-cancer therapies noted in the criterion above for this cohort. |
| All endometrial cancer histologies are allowed except endometrial sarcoma (including carcinosarcoma). |
| Pt must submit 2 scans demonstrating increase in tumor measurement that meet criteria for PD based on RECIST v.1.1 |
| Presence of at least 1 measurable lesion on baseline scan will be confirmed by central radiology review. |
| MSI (MSI-H vs MSS) should be known via local or central lab testing before patients receive the first dose of TSR-042. |
| o Cohort B: SqCC of anus, penis, cervix, vagina, or vulva who have progressed on or after at least 1 prior systemic Tx for recurrent or advanced disease. |
| o Cohort C - Patients with serous or clear cell ovarian, fallopian tube, or primary peritoneal cancer who have recurrent disease and were previously treated with chemotherapy for recurrent or advanced disease and who are currently considered platinum-resistant or refractory. |
| o Cohort D - Patients with breast cancer that is human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-negative, and progesterone receptor-negative (TNBC) who have progressed on or after at least 1 prior regimen for recurrent or advanced disease |

01-MAI-2019
or who relapsed/progressed while on or within 1 month from completion of adjuvant chemotherapy.

- Cohort E - Patients with NSCLC who progressed after at least 1 prior platinum-based systemic chemotherapy regimen for recurrent or advanced disease. Chemotherapy regimen in the adjuvant or neoadjuvant setting following surgery and/or radiation is acceptable if recurrent or advanced disease develops within 6 months from completion of therapy

- Patients with a known epidermal growth factor receptor (EGFR) mutation must have received a chemotherapy regimen and an EGFR tyrosine kinase inhibitor (TKI) (e.g., erlotinib, gefitinib, afatinib, or experimental)

- Patients with a known anaplastic lymphoma kinase (ALK) translocation must have received a chemotherapy regimen and an ALK inhibitor (e.g., crizotinib, ceritinib, or experimental)

- Cohort F – Patients with recurrent or advanced MSI-H solid tumors or POLE-mut solid tumors, except endometrial cancers, that have progressed following up to 2 prior lines of systemic therapy for recurrent or advanced (≥Stage IIIB) disease and who have no alternative treatment options.

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<th>LUNCHBOX</th>
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<tbody>
<tr>
<td>A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel Vs. Sandwich Therapy of Carboplatin and Paclitaxel Followed by Tumor Volume Directed Irradiation Then Further Carboplatin and Paclitaxel for Optimally Debulked Advanced Endometrial Carcinoma</td>
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- All patients with Surgical Stage III or IVA endometrial carcinoma per FIGO 2009 staging criteria, including clear cell and serous papillary and undifferentiated carcinomas

- Surgical Stage III disease includes those patients with positive adnexa, parametrial involvement, tumor invading the serosa, positive pelvic and/or para-aortic nodes, or vaginal involvement

- Surgical Stage IVA includes patients with bladder or bowel mucosal involvement, but no spread outside the pelvis

- Patients with FIGO 2009 surgical Stage I or II endometrial clear cell or serous carcinoma and with positive peritoneal cytology

- Surgery must have included a hysterectomy and bilateral salpingo-oophorectomy. Pelvic lymph node sampling and para-aortic lymph node sampling are optional.

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<tbody>
<tr>
<td>MK3475 Protocol 775 A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Pembrolizumab Versus Treatment of Physician’s Choice in Participants with Advanced Endometrial Cancer</td>
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- Histologically confirmed diagnosis of endometrial carcinoma.

- Documented evidence of advanced, recurrent or metastatic EC.

- Radiographic evidence of disease progression after 1 prior systemic, platinum-based chemotherapy regimen for recurrent, metastatic or primary unresectable disease.

- Participants who progress <1 year after completion of prior adjuvant or neoadjuvant platinum-based chemotherapy are eligible without further systemic treatment.

- Participants who progress ≥1 year after completion of prior adjuvant or neoadjuvant platinum-based chemotherapy must receive 1 additional cytotoxic systemic treatment prior to enrollment in this study.