## SERVICE DE GYNÉCOLOGIE-ONCOLOGIE

### PROTOCOLES EN RECRUTEMENT

### OVAIRES

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<th>PROTOCOLES</th>
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| OV25 DP/GSO/GSO/FG | 6 | II | 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)  
- 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. |

≥ 1 LIGNE ≤ 2 LIGNES

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| FORWARD2 DP/NG/ET/AV | 2 | Ib | A Phase 1b Study to Evaluate the Safety, Tolerability and Pharmacokinetics of Mirvetuximab Soravtansine (IMGN853) in Combination with Bevacizumab, Carboplatin, Pegylated Gy014Liposomal Doxorubicin, Pembrolizumab, or Bevacizumab + Carboplatin, in Adults with Folate Receptor Alpha Positive Advanced Epithelial Ovarian Cancer, Primary Peritoneal Cancer, or Fallopian Tube Cancer  
- Advanced EOC  
- Primary peritoneal cancer  
- Fallopian tube cancer  
- Patients must have confirmation of FRα +  
- Patients must have at least one lesion that meets the definition of measurable disease according to RECIST 1.1.  
- Patients must have received ≥1 but not more than 2 prior systemic treatment regimens; prior systemic treatment regimens may include VEGF inhibitors (including BEV), and must include at least one platinum-based chemotherapy.  
  - Adjuvant ±Neoadjuvant will be considered as one regimen  
  - Maintenance therapy will be considered to be part of the preceding regimen  
  - Patients who have received IMGN853 are excluded.  
- Patients must have potentially platinum sensitive disease. Platinum sensitive disease is disease that responded to platinum therapy and did not progress within 6 months of completing the treatment.  
- Time from prior therapy:  
  - Systemic anti-neoplastic therapy: five half-lives or four weeks, whichever is shorter  
  - Radiotherapy: wide-field radiotherapy (e.g. > 30% of marrow-bearing bones) completed at least four weeks, or focal radiation |
completed at least two weeks, prior to starting study treatment.

≥ 2 LIGNES (sensible 1ère ligne)

| 9 | II | Non-Randomized, Open-Label Phase II Study to Assess Olaparib Tablets as a Treatment for Subjects with Different HRD Tumor Status and with Platinum-Sensitive, Relapsed, High-Grade Serous or High-Grade Endometrioid Ovarian, Fallopian Tube, or Primary Peritoneal Cancer That Have Received at Least 1 Prior Line of Chemotherapy  
- HSerous/HGEndometrioid  
- At least 1 lesion (RECIST v1.1) that can be accurately assessed at baseline by CT/MRI and is suitable for repeated assessment;  
- At least 1 prior platinum-based line of chemotherapy for ovarian cancer. Note: There is no limit on the number of lines of chemotherapy  
Partially-platinum-sensitive (defined as progression 6 to 12 months after the end of the last platinum-based chemotherapy) or platinum-sensitive (defined as progression > 12 months after the end of the last platinum-based chemotherapy) |

| 2 | 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. |

MAINTENANCE

COL

MAINTENANCE

06-NOV-2018
### ≥ 1 LIGNE

**Regeneron (empower)**  
R2810-QNC-1676 VS/ST/CT/FG  
11 III  

**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 curative/intertvention 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
  - 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:
  - Received prior paclitaxel-containing therapy, which was discontinued due to progression of disease
  - Received prior paclitaxel-containing therapy, which was discontinued due to toxicity
  - Was deemed unsuitable for prior paclitaxel therapy for one of the following reasons:
    - Neuropathy
    - Allergy to paclitaxel or its components
  - Refused prior paclitaxel therapy

**AIM2CERV**  
1

**CX.5**  
VS/ST/ET/FG  
34 III

- Cancer du col précoce et à faible risque
- Comparer hystérectomie radicale ou simple combinés à la dissection des ganglions pelviens

### ENDOMÈTRE

#### ≥ 1ère LIGNE, ≤2ième LIGNE

**GARNET**  
VS/ST/ET/AV  
5 III

**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:
  - Cohort A1 (MSI-H endometrial cancer)
  - 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.
- 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.
- 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.
- 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 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.
- 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.

### TAK-C31004 DP/NG/SDS/AV

A Phase 2, Randomized Study of MLN0128 (a Dual TORC1/2 Inhibitor), MLN0128+MLN1117 (a PI3Kα Inhibitor), Weekly Paclitaxel, or the Combination of Weekly Paclitaxel and MLN0128 in Women With Advanced, Recurrent, or Persistent Endometrial Cancer
- Histologic or cytologic diagnosis of endometrial carcinoma
  - Endometrioid
  - Serous
  - Mixed adenocarcinoma
  - Clear-cell carcinoma
  - Carcinosarcoma.
- Evidence that the endometrial cancer is advanced, recurrent, or persistent and has relapsed or is refractory to curative therapy or established treatments.
- At least 1 prior platinum-based regimen, not more than 2 prior. Prior treatment may include chemotherapy, chemotherapy/radiation therapy, and/or consolidation/maintenance therapy. Chemotherapy administered in conjunction with primary radiation as a radio-sensitized therapy will be considered a systemic chemotherapy regimen.

### LUNCHBOX BC/NG/ET/AV

A Randomized Phase III Trial of Carboplatin 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
- 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

06-NOV-2018
• 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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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

- 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.