Etudes cliniques
Service d’Oncologie - Radiothérapie

Juillet 2017

SEIN NEO ADJUVANT

- **Neo-RHEA**: NEOadjuvant Biomarker Research Study of Palbociclib in Estrogen Receptor Positive HER2 Negative Breast CAnCer “NeoRHEA.”

SEIN ADJUVANT

- **OLYMPIA**: A Phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant therapy in BRCA mutated high-risk HER2-neg primary breast cancer patients who have completed definitive local and systemic neoadjuvant/adjuvant.

- **UNIRAD**: Phase III trial evaluating the safety and benefit of adding everolimus to adjuvant hormone therapy in women with poor prognosis, ER+ and HER2- primary breast cancer who remain free of disease after receiving 3 years of adjuvant HT.

- **POSITIVE**: A study evaluating the pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine responsive breast cancer who desire pregnancy.

- **PALLAS**: PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of Palbociclib with adjuvant endocrine therapy versus endocrine therapy alone for hormone receptor positive (HR+)/ human epidermal growth factor receptor 2 (HER2)-negative early breast cancer.

SEIN METASTASE

- **BROCADE III / M12-914**: A phase 3 randomized, placebo-controled trial of carboplatin and paclitaxel with or without the pARP inhibitor Veliparib (ABT-888) in HER2- neg metastatic or locally advanced unresectable BRCA-associated breast cancer.

- **UZB-MO-CF-01**: A phase II, open label study of everolimus with fulvestrant in postmenopausal women with hormone receptor-positive HER-2 negative AI and fulvestrant treated, locally advanced or metastatic breast cancer, who progressed on or after mTor inhibitor based treatment.

- **FRIDA**: A Phase 2, randomized, double-blind, placebo-controlled study of paclitaxel in combination with reparixin compared to paclitaxel alone as front-line therapy for Metastatic Triple-Negative Breast Cancer.

- **SOPHIA**: A Phase 3, Randomized Study of Margetuximab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy in the Treatment of Patients with HER2+ Metastatic Breast Cancer Who Have Received Two Prior Anti-HER2 Therapies and Require Systemic Treatment.
SMS-031: AIPAC (Active Immunotherapy PAClitaxel): A multicentre, Phase IIb, randomised, double blind, placebo-controlled study in hormone receptor-positive metastatic breast carcinoma patients receiving IMP321 (LAG-3Ig fusion protein) or placebo as adjunctive to a standard chemotherapy treatment regimen of paclitaxel.

MonarcHER/I3Y-MC-JPBZ: A Phase 2, Randomized, Multicenter, 3-Arm, Open-Label Study to Compare the Efficacy of Abemaciclib plus Trastuzumab with or without Fulvestrant to Standard-of-Care Chemotherapy of Physician’s Choice plus Trastuzumab in Women with HR+, HER2+ Locally Advanced or Metastatic Breast Cancer.

AURORA: EORTC1408/BIG14-01: Aiming to Understand the MOlecular Aberrations in Metastatic Breast Cancer.

PYTHIA: A Phase II Study of Palbociclib plus Fulvestrant versus Placebo plus Fulvestrant for pretreated patients with ER+/HER2- Metastatic Breast Cancer - Palbociclib in molecularly characterized ER-positive/HER2-negative metastatic breast cancer.


COMPLEEMENT-1: An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and postmenopausal women with hormone receptorpositive (HR+) HER2-negative (HER2-) advanced breast cancer (aBC) with no prior hormonal therapy for advanced disease. Amendment 1: premenopausal women allowed.

PEARL: Pet imaging as a biomarker of Everolimus added value in hormone refractory postmenopausal women.

NSCLC et SCLC

SPLENDOUR -EORTC 08111/ETOP 5-12: A randomized, open-label phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC.

M14-361: A Phase 2, Randomized, Double-Blind Study of Veliparib in Combination with Carboplatin and Etoposide as a Therapy of Treatment Naïve Extensive Stage Small Cell Lung Cancer.

OVAIRE – ENDOMETRE

ENGOT-cx1/BGOG-cx1: Double-blind Phase II study comparing 3-weekly carboplatin (AUC 5 or 6) + paclitaxel 175 mg/m2 with or without concomitant and maintenance Nintedanib (BIBF 1120) in advanced or recurrent cervical carcinoma.

BGOG-ov8/Inovatron: Phase III international, randomized study of Trabectedin plus Pegylated Liposomal Doxorubicin (PLD) versus Carboplatin plus PLD in patients with ovarian cancer progression within 6-12 months of last platinum.

BELOVA ML29515: A non-interventional study to collect data on the safety and efficacy data of the frontline Bevacizumab treatment in ovarian cancer >= 70 years.
 **BGOG-ov17/MITO16**: A Multicenter Phase III Randomized Study with Second Line Chemotherapy plus or minus Bevacizumab in Patients with Platinum Sensitive Epithelial Ovarian Cancer Recurrence After a Bevacizumab/Chemotherapy First Line.

 **PRIMA**: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with HRD-Positive Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy.

 **PRIMMO**: A phase II Investigation of Pembrolizumab (Keytruda) in combination with radiation and an immune modulatory cocktail in patients with cervical and uterine cancer.

**MELANOME**

 **COBIRAF/ ML29471**: A single arm, open label, phase II, multicenter study to assess the detection of the bRAF V600 mutation of cDNA from plasma in patients with advanced melanoma.

**PROSTATE**

 **GALAHAD / 64091742PCR2001**: A Phase 2 Efficacy and Safety Study of Niraparib in Men with Metastatic Castration-Resistant Prostate Cancer and DNA-Repair Anomalies. (temporarily closed).

 **BAYER 17777**: A Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer.

**THYROIDE**

 **E7080-G000-211**: A Multicenter, Randomized, Double-blind Phase 2 Trial of Lenvatinib (E7080) in Subjects with 131 I-Refractory Differentiated Thyroid Cancer to Evaluate Whether an Oral Starting Dose of 20 mg or 14 mg Daily Will Provide Comparable Efficacy to a 24 mg Starting Dose, But Have a Better Safety Profile.

**REIN – VESSIE**

 **METASUN**: A proof of concept study to evaluate the use of metabonomics and lipidomics in predicting toxicity and efficacy of anti-VEGF therapy in patients with metastatic clear cell renal cell carcinoma.

**ORL**

 **UCL-ONCO 2013-01**: Prospective collection of plasma samples from patients treated with molecular targeted therapies for squamous cell carcinoma of H N.

 **C-ART**: A two-arm phase II randomized study comparing adaptive biological imaging-voxel intensity-based radiotherapy (adaptive dose escalation) versus standard radiotherapy for head and neck cancer.
- **UCL ONCO 2015-01**: Study of LEE011 plus Cetuximab in patients with recurrent or metastatic squamous cell carcinoma of the Head and the Neck.

- **SCORES-D5660C00004**: A Phase 1b/2, Open-Label, Multicentre Study Assessing the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumour Activity of MEDI4736 in Combination With AZD9150 or AZD5069 in Patients With Advanced Solid Malignancies and Subsequently Comparing AZD9150 and AZD5069 Both as Monotherapy and in Combination With MEDI4736 as Second Line Treatment in Patients With Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck.

- **MK-3475 (pembrolizumab) Protocol 412**: Study of pembrolizumab given concomitantly with chemoradiation and as maintenance therapy versus chemoradiation alone in subjects with locally advanced head and neck squamous cell carcinoma.

- **Javelin 16/Pfizer B9991916**: A randomized double-blind phase 3 of Avelumab in combination with standard of care chemoradiotherapy (cisplatin plus definitive radiation therapy) vs standard of care chemoradiotherapy in the front-line treatment of patients with Locally Advanced Squamous Cell Carcinoma of the Head and Neck.

**COLON – RECTUM – ESTOMAC**

- **BEV-ONCO**: Randomized Phase 2 study comparing pathological responses observed on colorectal cancer metastases resected after preoperative treatment combining bevacizumab with FOLFOX or FOLFIRI.

- **REACH IN**: Regorafenib after failure of gemcitabine and platinum-based chemotherapy for locally advanced (non resectable) and metastatic intrahepatic or hilar cholangiocarcinoma: a randomized double-blinded phase II trial.

- **CA209-577**: A randomized, multicenter, double blind, phase III study of adjuvant Nivolumab or placebo in patients with resected oesophageal, or gastrooesophageal junction cancer.

- **HepSTAR**: Randomized controlled phase II trial comparing Trans-Arterial Chemo-Embolization With TACE plus Stereotactic Ablative Radiotherapy in stage BCLC B Hepatocarcinoma.

- **ARMO AM0010-301/ARTIST**: A Randomized Phase 3 Study of AM0010 in Combination with FOLFOX Alone as Second-line Therapy in patients with metastatic pancreatic cancer that has progressed during or following a first-line gemcitabine containing regimen.

**TUMEURS SOLIDES**

- **CTMT212X2102**: A Phase I, Open-Label Study to Determine the Effect of Repeat Dosing of Trametinib on the Pharmacokinetics and Safety of a Combined Oral Contraceptive (Norethindrone plus Ethinyl Estradiol) and to Characterize the Pharmacokinetics of Trametinib’s Metabolite M5 in Female Subjects with Solid Tumors.
CERVEAU

- **ROAM / EORTC 1308**: Radiation versus Observation following surgical resection of atypical meningioma: a randomized controlled trial (the ROAM study).

- **M13-813** (via Site de Godinne): A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 with Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects with Newly Diagnosed Glioblastoma (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification (Intellance 1).

HEMATOLOGIE

- **SENIOR**: Sub-cutaneous Rituximab-miniCHOP versus Sub-cutaneous Rituximab-miniCHOP + lenakidomide (R2-miniCHOP) in diffuse large B Cell lymphoma for patients of 80 years old or more. A multicentric phase II study of the LYSA.