

Etudes cliniques

Service d'Oncologie - Radiothérapie

Janvier 2019

SEIN NEO ADJUVANT

- **Neo-RHEA** : NEOadjuvant Biomarker Research Study of Palbociclib in Estrogen Receptor Positive HER2 Negative Breast Cancer "NeoRHEA.
- **TOUCH** : Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with letrozole and trastuzumab versus paclitaxel in combination with trastuzumab for patients with hormone receptor positive/HER2 positive early breast cancer.

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.
- **MONARCHE/JPCF** : A randomized, open-label, phase 3 study of Abemaciclib combined with standard adjuvant endocrine therapy versus standard adjuvant endocrine therapy alone in patients with high risk, node positive, early stage, hormone receptor positive, human epidermal receptor 2 negative, breast cancer.

SEIN METASTASE

- **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.
- **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.
- **NEKTAR** : A phase 3 open-label, randomized, multicenter study of NKTR-102 versus treatment of physician's choice (TPC) in patients with metastatic breast cancer who have stable brain metastases and have been previously treated with an anthracycline, a taxane, and capecitabine.
- **VIOLETTE/D5336C00001** : A Phase II, Open Label, Randomised, Multi-Centre Study to Assess the Safety and Efficacy of Agents Targeting DNA Damage Repair in Combination with Olaparib versus Olaparib Monotherapy in the Treatment of Metastatic Triple Negative Breast Cancer Patients Stratified by Alteration in Homologous Recombinant Repair (HRR)-related Gene (including BRCA1/2).
- **CASCADIAN/ONT-380-206** : Phase 2 Randomized, Double-Blinded, Controlled Study of ONT-380 vs. Placebo in Combination with Capecitabine and Trastuzumab in Patients with Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma (HER2CLIMB).
- **SYNERGY** : A Phase I/II Study of Paclitaxel plus Carboplatin and Durvalumab (MEDI4736) with or without Oclelumab (MEDI9447) for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer.

NSCLC et SCLC

OVAIRE – ENDOMETRE

- **BGOG-cx2/SHAPE**: A randomized phase III trial comparing radical hysterectomy and pelvic node dissection vs simple hysterectomy and pelvic dissection in patients with low-risk early stage cervical cancer.
- **BGOG-cx6 GCT1015-04**: A Single arm, Multicenter, International Trial of Tisotumab Vedotin (HuMax®-TF-ADC) in Previously Treated, Recurrent or Metastatic Cervical Cancer.
- **BGOG-cx3/BGOG-cx101**: Prospective randomized Phase II trial comparing doxorubicin alone versus atezolizumab alone versus doxorubicin and atezolizumab in recurrent cervical cancer.
- **PRIMMO** : A phase II Investigation of Pembrolizumab (Keytruda) in combination with radiation and an immune modulatory cocktail in patients with cervical and uterine cancer.
- **OREO** : A Phase IIIb, Randomised, Double-blind, Placebo-controlled, Multicentre Study of Olaparib Maintenance Retreatment in Patients with Epithelial Ovarian Cancer Previously Treated With a PARPi and Responding to Repeat Platinum Chemotherapy.
- **B9991030** : A randomized, open-label, multicenter, phase 3 study to evaluate the efficacy and safety of avelumab in combination with chemotherapy followed by maintenance therapy of avelumab in combination with the poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor talazoparib in patients with previously untreated advanced ovarian cancer.

- **D0816C00020/OPINION** : OPINION - Étude de phase IIIb multicentrique, en ouvert, à bras unique, portant sur l'olaparib en monothérapie d'entretien chez des patientes atteintes d'un cancer de l'ovaire à mutation BRCA non germinale, en rechute sensible au platine, qui présentent une réponse complète ou partielle suite à une chimiothérapie à base de platine.

MELANOME

- **PABLO – CDRB436BBE03** : A Belgian prospective study assessing PD-L1 expression in BRAFV600 mutated metastatic melanoma patients at low risk of early progression, before the initiation of first line therapy.

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).
- **PEACE2/GETUC-AFU23**: A randomized Phase III, factorial design, of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse.
- **PEACE3/EORTC 1333**: A Randomized multicenter phase III trial comparing enzalutamide vs. a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone.
- **PEGASUS/EORTC 1414-ROG-GUCG**: Phase III randomized trial comparing irradiation plus long term adjuvant androgen suppression with LHRH antagonist versus LHRH agonist plus flare protection in patients with very high risk localized or locally advanced prostate cancer. A joint study of the EORTC ROG and GUCG.
- **TRITON3/CO-338-063**: Open label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration-Resistant Prostate Cancer Associated with a Homologous Recombination deficiency.

THYROÏDE

- **E7080-G000-211** : A Multicenter, Randomized, Double-blind Phase 2 Trial of Lenvatinib (E7080) in Subjects with I-131 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

- **CASSIOPE** : Prospective non interventional study of cabozantinib tablets in adults with advanced renal cell carcinoma following VEGF targeted therapy.
- **AURA** : Avelumab as neoadjuvant therapy in subjects with urothelial muscle invasive bladder cancers.

ORL

- **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.
- **KOTK/SBRT-Hypofractionnement** : Combined hypofractionated stereotactic body radiotherapy with immunomodulating systemic therapy for inoperable recurrent head and neck cancer.
- **HNC-LS: SPECT---CT Lymphoscintigraphy For Individualized Superselective Prophylactic Nodal Irradiation in cNO Head and Neck Squamous Cell Carcinomas : a Phase I/II Study.**
- **UPSTREAM/EORTC1559:** A pilot study of personalized biomarker-based treatment strategy or immunotherapy in patients with recurrent/metastatic HNSCC.
- **MK3475-689** : A Phase III, Randomized, Open-label Study to Evaluate Pembrolizumab as Neoadjuvant Therapy and in Combination With Standard of Care as Adjuvant Therapy for Stage III-IVA Resectable Locoregionally Advanced Head and Neck Squamous Cell Carcinoma (LA HNSCC).

COLON – RECTUM – ESTOMAC – PANCREAS

- **CA209-577** : A randomized, multicenter, double blind, phase III study of adjuvant Nivolumab or placebo in patients with resected oesophageal, or gastrooesophageal junction cancer.
- **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.
- **ADAGE** : Randomised phase III study evaluating adjuvant chemotherapy after resection of stage III colon adenocarcinoma in patients aged 70 and older.

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.
- **MIME-A** : Multiorgan Metabolic imaging response assessment of Abemaciclib The MiMe-A Trial.

CERVEAU

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

HEMATOLOGIE

AUTRE

- CA209-234 NIVO : NIVO Pass Study Information/ Pattern of Use and Safety/Effectiveness of Nivolumab in Routine Oncology Practice. (Lung cancer and melanoma).

*New study