

## Etudes cliniques

### Service d'Oncologie - Radiothérapie

Juillet 2016

#### SEIN-NEO ADJUVANT

- **LORELEI -GO28888- 1319 BCG** : A phase II randomized, double-blind, parallel cohort study of neoadjuvant letrozole + GDC-0032 vs Letrozole + placebo in post-menopausal women with ER+/HER2- primary breast cancer
- **BSMO-2014-01** : A prospective, Belgian multi-center, single-arm, phase II study of neoadjuvant weekly paclitaxel and carboplatin followed by dose dense Epirubicin and cyclophosphamide in stage II and III triple negative breast cancer.
- **NEOPAL** : Phase II study, comparing 3 FEC-3 Docetaxel chemotherapy to letrozole + palbociclib combination as neoadjuvant treatment of stage II-III A PAM 50 ROR-defined low or intermediate risk Luminal breast cancer, in postmenopausal women
- **NEOMOARCH /I3Y-MC-JPBY**: A Multicenter, Open Label, Randomized Phase II Neoadjuvant Trial Comparing the Biological Effects of 2 Weeks of Anastrozole In Combination with Abemaciclib to those of Abemaciclib Monotherapy and Anastrozole Monotherapy and the Clinical Activity and Safety of a subsequent 14 weeks of therapy with Abemaciclib in combination with Anastrozole in Postmenopausal Women With Hormone Receptor positive, HER2 negative Breast Cancer.

#### SEIN ADJUVANT

- **EORTC 90091-10093-big 1-12- Treat CTC trial**: Trastuzumab in HER2-negative Early breast cancer as adjuvant treatment for Circulating Tumor Cells (CTC)
- **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.

#### SEIN METASTASE

- **EORTC10085p** : Clinical and biological characterization of Male Breast Cancer.
- **PUMA** : A study of Neratinib + capecitabine vs lapatinib + capecitabine in patients with HER2+ MBC who have received 2 or more prior HER2-directed regimens in the metastatic setting.
- **BROCADE III / M12-914** : A phase 3 randomized, placebo-controlled 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.
- **BRAVO/EORTC1307-PAREXEL#210715** : A phase 3, randomized, open label, multicenter, controlled trial of Niraparib vs physician's choice in previously treated, HER2 negative, germline BRCA mutation positive breast cancer patients.
- **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.
- **BI1280.4** : A phase Ib/II Randomized study of BI 836845 in Combination with Exemestane and Everolimus versus Exemestane and Everolimus alone in women with locally and advanced or metastatic breast cancer.
- **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.
- **IPSOC mamma** : Prospective, non-interventional, non-controlled multicenter observational study to evaluate aspects of pharmaceutical care and the treatment of postmenopausal patients with hormone-receptor positive, HER2-receptor negative, advanced breast cancer treated with everolimus and exemestane.
- **AURORA** : EORTC1408/BIG14-01 : Aiming to Understand the MOlecular Aberrations in Metastatic Breast Cancer

## 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.

## TUMEURS SOLIDES

- **LEOS** : Phase IV of Lonquex® (Lipegfilgrastim) in solid and hematologic tumors.

## 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.
- **EAGLE / D4193C00002 (AZU41931-419302)** : A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Therapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)
- **KESTREL study – D419LC00001**: “A Phase III Randomized, Open-Label, Multi-center, Global Study of MEDI4736 in Combination with Tremelimumab versus Standard of Care (EXTREME) in the Treatment of First-line Recurrent or Metastatic Squamous Cell Head and Neck Cancer Patients
- **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.

## 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.
- **I4T-MC-JVCZ** : Randomized phase II trial evaluating Alternative Ramucirumab Doses in Combination with Paclitaxel in 2nd Metastatic or Locally Advanced, Unresectable Gastric or Gastroesophageal Junction Adenocarcinoma

## NSCLC

- **FIELT- 2** : Treating lung cancer in non-smokers : the next step
- **GEM Study EORTC 08114**: Genetics of EGFR Mutation study: a translational study of the EORTC lung Group
- **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.
- **COMER -GO29436** : A Phase III, Open-Label, Randomized Study of MPDL3280A (Anti-PD-L1 Antibody) In Combination with Carboplatin + Paclitaxel With Or Without Bevacizumab Compared with Carboplatin + Paclitaxel + Bevacizumab In Chemotherapy-Naïve Patients with Stage IV Non-Squamous NSCL Cancer.
- **COMER -GO29437** : A Phase III, Open-Label, Study Evaluating the Efficacy AndSafety of MPDL3280A (Anti-PD-L1 Antibody) In Combination With Carboplatin +Paclitaxel or MPDL3280A In Combination with Carboplatin + Nab-Pacilitaxel Versus Carboplatin + Paclitaxel in Chemotherapy-Naïve Patients with Stage IV Squamous NSCLC

- **SOLAR/ASP8273** : Astellas, 8273-CL-0302, An Open-label, Randomized Phase 3 Efficacy Study of ASP8273 vs. Erlotinib or Gefitinib in First-line treatment of Patients with Stage IIIB/IV Non-small Cell Lung Cancer Tumors with EGFR activating mutations.

## OVAIRE - ENDOMETRE

- **ENGOT-cx1/BGOG-cx1**: Double-blind Phase II study comparing 3-weekly carboplatin (AUC 5 or 6) + paclitaxel 175 mg/m<sup>2</sup> with or without concomitant and maintenance Nintedanib (BIBF 1120) in advanced or recurrent cervical carcinoma.
- **BGOG-ov8/Inovatyon**: 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  $\geq$  70 years.
- **BGOG-OV19 -PAOLA-1** : randomized, double-blind, phase III trial of Olaprib vs placebo in patients with FIGO IIIb-IV high grade serous of endometrioid, fallopian tube, or peritoneal cancer treated with 1st line platinum-taxane and Bevacizumab.
- **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.
- **B9991009/BGOG** : A Phase 3, Randomized, Open-label study of Avelumab alone or with Pegylated Liposomal Doxorubicin versus Pegylated Liposomal Doxorubicin alone in patients with Platinum-Resistant/Refractory Ovarian 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

- **REASSURE** : Radium-223 alpha Emitter Agent in Safety Study in mCRPC population for long-term Evaluation
- **ATLAS/PCR3003** : A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ-56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy.

## THYROIDE

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

## 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.