

## Etudes (Clinique du sein)

### 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