

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 Oleclumab (MEDI9447) for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple-negative Breast Cancer.

*New study