ETUDES
Service d’Oncologie - Radiothérapie
Février 2012

SEIN-NEO ADJUVANT

**WT1-AS15-BRS-001**: a double blind, placebo-controlled phase I/II study of neo-adjuvant and adjuvant treatment with WT1-A10 + AS15 antigen specific cancer immunotherapeutic in combination with standard therapy in women with WT1-positive stage II or III breast cancer.

**EORTC 10054 (Lapatax)**: Trial phase I-II study of Lapatinib and Docetaxel as neoajuvant treatment for HER-2 positive locally advanced/inflammatory or large operable breast cancer.

**ONCO-RD-017**: A prospective, exploratory observational study evaluating specific biomarkers in primary invasive breast cancer and their modulation by standard neoadjuvant therapy.

SEIN ADJUVANT

**SNP Radiothérapie GAND**: modèle prédictif pour les effets secondaires au niveau de la peau à la suite d’une radiothérapie.

**PROCUBITUS**: étude prospective non interventionnelle d’évaluation de l’irradiation mammaire en inspiration bloquée et en position de décubitus ventral chez des patientes porteuses d’une néoplasie mammaire.

**D-Care**: Amgen 20060359: A randomized, double-blind, placebo-controlled, multi-center phase 3 study of Denosumab as adjuvant treatment for women with early stage breast cancer at high risk of recurrence.

**Amgen Denosumab 20110113**: To facilitate the access of denosumab for subjects with advanced cancer who have participated in a denosumab phase 3 study until denosumab is approved and available for sale.

**SOLD**: phase III study comparing trastuzumab plus docetaxel followed by FEC to the same regimen followed by single-agent trastuzumab as adjuvant treatments for early breast cancer.

**CYP-TAMBRUT 2**: An observational study to assess response to tamoxifen with measurable but inoperable or M+ ER+ BC by the the ‘tamoxifen activity score’ based on drug interaction and polymorphisms in genes coding for tamoxifen metabolising enzymes.

**SOLE**: Cont letrozole vs intermittant letrozole following 4 to 6 years of prior adjuvant endocrine therapy for postmenopausal women with hormone-receptor +, node positive early stage BC.

**MK-8669**: a two-part, adaptive, randomized trial of Ridaforolimus in combination with Dalotuzumab compared to Exemestane or compared to Ridaforolimus or Dalotuzumab monotherapy in Estrogen Receptor positive breast cancer patients.

**IBIS II DCIS**: An international multi-centre study of tamoxifen vs anastrozole in postmenopausal women with Ductal Carcinoma in Situ (DCIS).

**IBIS II Prevention**: An international multi-centre study of anastrozole vs placebo in postmenopausal women at increased risk of breast cancer.

**Late cardiac protocol**: Evaluation of the Three Arm Belgian Trial – a Phase III randomized trial involving node-positive early BC patients with a long median follow-up.

SEIN METASTASE

**BOLERO-3**: Herceptine and Vinorelbine +/- Everolimus in 2nd or 3rd line MBC pre-treated with a taxane and resistant to trastuzumab.
PHEREXA : PAREXEL : 2° line Herc + Xeloda +/- pertuzumab in MBC HER2+ that have progressed after one line trastuzumab-based therapy in the metastating setting

EGF114299 : Safety and efficacy of lapatinib + trastuzumab + Al vs trastuzumab + Al vs lapatinib + Al as 1st line in postmenop with hormone receptor +, HER2+ MBC who have received trastuzumab and endocrine therapy in neoadjuvant and/or adjuvant setting.

Marianne - Bo22589 : phase III study of T-DM1 combined with pertuzumab vs placebo (blinded for pertuzumab), versus the combination of trastuzumab plus taxane, as first line treatment in HER2+ progressive or recurrent locally advanced or MBC

NSCLC

PROCLAIM (H3E-MC-JMIG) : Phase III ALIMTA Cisplatine and RT followed by consolidation ALIMTA versus Etoposide, cisplatine + RT followed by consolidation CT of choice in patients with NSCLC other than squamous cell

AMGEN 20070782 : Aranesp en double aveugle chez les patients anémiques (Hb < = 11 g/dl) dans le NSCLC

SQUIRE (IMCLONE 0806): PPD : Global phase III study in 1st line treatment of patients with squamous stage IIIb or IV NSCLC

EORTC 08092 (Mapping) : Pazopanib vs placebo in NSCLC patients non progressive after first line chemotherapy.

TIME : An observational study of Tarceva as second-line treatment of patients with advanced NSCLC, after failure of first-line with Pemetrexed-containing regimen

SCLC

EORTC 08072 CONVERT : A 2-arm randomized controlled trial of concurrent CT RT twice daily RT in patients with limited SCLC+ centre satellite

PROSTATE

EORTC 22043-30041 : postoperative RXT with adjuvant HT vs postoperative RXT alone in prostate cancer (pT3-pT2 N0M0).

Millenium C21004 : A phase 3, randomized, double-blind, multicenter trial comparing Orteronel (Tak-700) plus prednisone with placebo plus prednisone in patients with chemotherapy-naive metastatic castration-resistant prostate cancer.

Millenium C21005 : A phase 3, Randomized, Double-Blind, Comparing TAK-700 +Prednisone With Placebo + Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer that has Progressed Following Taxane-based Therapy.

CERVEAU

EORTC 26081-22086 : Radiotherapy vs Temozolomide alone vs radiotherapy and Temozolomide for patients with 1p/19q codeleted anaplastic glioma.

COLON – RECTUM - ESTOMAC

DOGE : Randomised Phase II study of biweekly versus fractionated triweekly combination Taxotere-Cisplatin-5FU in advanced gastric and gastro-esophageal junction.

Axe-BEAM : A randomized phase II of bevacizumab, capecitabine and radiation therapy +/- oxaliplatin in the preoperative treatment of locally advanced rectal disease

AVAPLUS : Observational study on the use of chemotherapeutic regimens and avastin for the treatment of previously untreated mCRC in patients ≥ 70 Years Old.

Erbitwos: Observational study on the safety and efficacy of Erbitux® in daily clinical practice in Belgium in 2nd line treat of mCRC patients with KRAS wild-type tumor

Ce Registre du cancer DNET: An epidemiological and medical data collection of patients suffering from Digestive NeuroEndocrine Tumors via an electronic registry

REIN
IPSOC : Etude observationnelle ayant pour objectif d’analyser l’accompagnement pharmacothérapeutique des patients cancéreux atteints de carcinome métastasique à cellules rénales, traités par des médicaments anticancéreux oraux.

PROTECT (VEG113387) : A randomized, double-blind, placebo-controlled phase III study to evaluate the efficacy and safety of pazopanib as adjuvant therapy for subjects with localized or locally advanced RCC following nephrectomy.

TUMEURS SOLIDES

TRC112765 : GSK study with eltrombopag Administered to Patients with Solid Tumors Receiving Gemcitabine monotherapy or Gemcitabine Plus Carbo or Cisplatin

THYROIDE

Eisai E7080-G000-303: a placebo-controlled phase 3 trial of E7080 in 131I refractory differenciated thyroid cancer

URO GENITAL

MITO-8 : Second line in ovarian primary : randomisation between carbo-taxol and Caelyx

OVHPEC : Phase III randomised clinical trial for stage III ovarian randomising between secondary debulking surgery +/- hyperthermic intraperitoneal chemotherapy.

National Plan cancer for gynecologic cancer for single polymorphism analysis

XL147-201 : A phase 2 study of xl147 in subjects with advanced or recurrent endometrial carcinoma.

TRINOVA-2: Phase 3 avec le Caelyx + l’Amen 386 vs placebo dans le cancer de l’ovaire récurrent, partiellement sensible ou résistant aux sels de platine.

EFC 10260 Ombrabulin : A Phase 2, Double-Blind, placebo controlled, Randomized Study of Ombrabulin in Patients with Platinum-Sensitive Recurrent Ovarian Cancer treated with Carboplatin/Paclitaxel

ORL

GETTEC 2008-01: Assessment of regional response with PET-FDG in advanced head and neck squamous cell carcinoma

ETUDES EN PROJET

AZD4547 (D2610C00003) : Phase II Study of AZD4547 vs placebo in Combination with Exemestane in Patients with ER+ and FGFR1 Amplified (FISH ≥ 4) Breast Cancer who Have Progressed Following Treatment with One Prior Endocrine Therapy (Adjuvant or First-line Metastatic)

MYCARD: Screening and management of cardiovascular risk in Belgian women aged ≥ 65 years with metastatic breast cancer and anthracycline treatment.

APHINITY - Roche BO25126: placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo vs chemotherapy plus trastuzumab and pertuzumab as adjuvant therapy in patients with operable HER2-positive primary BC.

TRIO-020 : A randomized open-label phase II study of letrozole plus afinitib (BIBW2992) vs letrozole alone in first-line treatment of advanced ER+, HER2- postmenopausal breast cancer with low ER expression

Lung Art (EORTC 22055) : : Phase III study comparing post-operative conformal radiotherapy to no post-operative radiotherapy in pts with completely resected NSCLC and mediastinal N2 involvement

Met Mab OAM4971g (PPD): phase III study of Metmab in combination with Tarceva in patient with MET+ incurable stage IIIb/IV NSCLC who have failed standard therapy for advanced or M+disease.

CREST: Randomized trial on chest irradiation in extensive disease small cell lung cancer

TOP GEAR: A randomized phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer

ERBIFIRST: Observational study with cetuximab in combination with standard chemotherapy in daily clinical practice in first line treatment of mCRC patients with KRAS wild-type tumor

EC-FV-06 ENDOCYTE: phase 3 trial comparing EC145 and PLD in combination vs PLL alone in patients with platinum-resistant ovarian cancer
**MANGO – INOVATYON**: phase III study of Trabectedin plus PLD vs Carboplatin plus PLD in patients with ovarian cancer progressing within 6-12 months of last platinum.

**MEK115306**: A Phase III study comparing the combination of the BRAF inhibitor, GSK2118436 and the MEK inhibitor, GSK1120212 to each single agent combined with placebo in subjects with advanced (IIIc) or M+ (IV) BRAF V600E/K mutation-positive melanoma.

**UCL ONCO2011-01 RACATREX**: Randomized phase II study of Cabazitaxel vs Methotrexate in pts with recurrent or M+ SCC of the H&N previously treated with platinum-based therapy.

**TRINOVA III**: Phase III with AMG386 in ovarian cancer.