Overview of trials running in the Benelux

(Belg J Med Oncol 2011;5:166-73)

Randomized, double-blind, placebo-controlled phase III study of regorafenib plus best supportive care versus placebo plus best supportive care in patients with metastatic and/or unresectable gastrointestinal stromal tumours (GIST) which progressed despite prior treatment with at least imatinib and sunitinib

GIST - regorafinib - tyrosine kinase inhibtor - progression - imatinib - sunitinib

This is a **phase III** trial of the experimental compound **regorafenib** (160mg, 3 weeks on, 1 week off) as a 3rd line or greater treatment for **GIST**. The primary objective of this study in subjects with metastatic and/or unresectable GIST with progression after therapy with at least imatinib and sunitinib is to compare the treatment groups in terms of progression free survival per blinded central radiology review according to RECIST v1.1. The secondary objectives are to compare the groups in terms of overall survival, time to progression, disease control rate, tumour response rate, duration of response and safety of regorafenib. In addition, health-related quality of life, pharmacokinetics and biomarker studies will be measured. The **main inclusion criteria** of this study are: 18 years or older, histologically confirmed metastatic or unresectable GIST, disease progression on imatinib and sunitinib, measurable lesions and adequate bone marrow, liver and renal function. The **main exclusion criteria** are: prior treatment with regorafenib or other VEGFR targeting drugs (except sunitinib), diagnosed with another type of cancer in the previous 5 years, major surgery, open biopsy or significant traumatic injury in previous 28 days and pregnancy and breast-feeding. For more detailed information on **inclusion- and exclusion criteria** please contact the study coordinator. Potential trial candidates can be transferred to the Department of General Medical Oncology at the University Hospital Leuven. They will then be asked for informed consent, have a tumour assessment with CT or MRI, a bone scan in case of bone metastasis, a 12-lead ECG and an echocardiography or a MUGA scan. Patients should bring archived tumour material. Fresh biopsies will be collected of patients consenting to the collection of the material. Imaging will be performed every 4 weeks during the early stages of the trial, every 6 weeks in later stages and every 8 weeks thereafter. Treatment will be continued until disease progression, intolerance, or withdrawal of consent occurs.

For more information, please contact:
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The PASCE trial

cutaneous squamous cell carcinoma - phase II - EGFR - antibody - overall response rate

The PASCE trial is an open label multicentre phase II study of panitumumab in cutaneous squamous cell carcinoma (SCC). This study will evaluate the efficacy of panitumumab, an antibody against epidermal growth factor receptor (EGFR) in patients with a cutaneous SCC.
Activation of *EGFR* and *RAS* signalling pathways has been reported to play an important role in disease progression, possibly through downregulation of the immune system. Therefore, the study comprises a translational component (blood sample, tumour- and skin biopsies) for analysing the modification of some *EGFR* signalling pathway key protein expression profiles and in the regulation of the

immune system.
The primary aim consists of measuring the efficacy of panitumumab for SCC in terms of overall response rate. Secondary objectives include the safety profile, the time to treatment failure, the time to treatment progression and duration of response.

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Phase I/II study of peptide vaccination associated with tumour immunomodulation with pro-inflammatory cytokines and imiquimod in patients with advanced metastatic melanoma

metastatic melanoma - phase I/II - vaccination - cytokines - tumour response rate

The study will determine whether peptide vaccination associated with local peritumour treatment with a combination of interleukin-2, interferon-alpha, granulocyte-macrophage colony stimulating factors, and imiquimod, induces tumour responses. Patients with regional disease or with distant metastatic disease, and with at least 2 cutaneous metastases will be included. Moreover, the tumour of the patient should express either the antigen MAGE3-A1 or NA17.A2.
The tumour response will be reported according to the RECIST 1.1 guideline. We will also document the toxicity of treatment, and induction of T lymphocyte responses to the vaccine.

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Phase I/II study of therapeutic vaccination with escalating doses of CyaA-Tyr, a proteinic vector targeting dendritic cells, coupled to a melanoma antigen, in patients with advanced metastatic melanoma

metastatic melanoma - phase I/II - vaccination - proteinic vector - tyrosinase

This **phase I/II** study will test doses of a novel vaccine CyaA-Tyr in patients with advanced metastatic melanoma. Patients with ocular, mucosal or cutaneous melanoma will be included.
Previous tests on mice demonstrated that this vaccine CyaA-Tyr can induce strong and longlasting tyrosinase specific CTL responses. The safety and the toxicity of increasing doses of CyaA-Tyr will be monitored, as well as induction of immune response and clinical response.

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Multinational phase III, randomized, double-blind, placebo-controlled efficacy and safety study of oral MDV3100 in patients with progressive castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy

after docetaxel - castration - phase III - resistant prostate cancer - small molecule androgen receptor antagonist

In clinical practice, treatment of advanced prostate cancer is limited by the development of resistance to anti-androgen therapies. Most patients receive 2 or more hormonal manipulations before offered docetaxel. Once patients progress on docetaxel, no approved second-line therapy is available. Because many of these resistant tumours continue to over-express androgen receptors, second generation anti-androgens that are more potent and pure antagonists, like MDV3100, may be effective in these patients. The primary objective of this study is to determine the benefit of MDV3100 (160 g/d orally) compared to placebo as assessed by overall survival.

For more information please contact:
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A phase I trial of sutent, a tyrosine kinase inhibitor combined with ionizing irradiation in rectal cancer: protocol KIRC 08-01

phase I - radiotherapy - rectal cancer - sunitinib - tyrosine kinase inhibitor

The standard treatment for locally advanced rectal cancer combines radiotherapy with surgery and chemotherapy. It has been demonstrated that neo-adjuvant radiotherapy provides superior results compared to the postoperative setting. Sunitinib is a tyrosine kinase inhibitor (TKI) with anti-angiogenic properties. In murine models, the combination of sunitinib and fractionated radiotherapy inhibits tumour regrowth. This **phase I trial** is therefore designed to combine conventional radiotherapy with concomitant sunitinib in a preoperative approach for locally advanced rectal cancer.

Eligibility criteria include a cT3 or N+ (confined to mesorectum) rectal adenocarcinoma considered amenable to a R0 low anterior resection.

Three different doses of sunitinib (25, 37.5, and 50 mg) will be tested. The primary objective is to establish a recommended dose of sunitinib in these conditions. Secondary endpoints include overall survival, progression-free survival, downstaging and R0 resection rate, gene expression and proteomics. These results will pave the way for the design of a phase II trial that can potentially combine radio-therapy, chemotherapy, and sunitinib in the neo-adjuvant setting.

For more information please contact:
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A dosimetric study comparing breast radiotherapy planned in prone versus supine position and via conformal 3D versus IMRT techniques: protocol B-POS

breast - dosimetry - gating - IMRT - prone - radiotherapy - supine

Breast cancer is the most frequently diagnosed cancer in women. Radiotherapy is an essential component of the curative treatment algorithm. The current standard of care is radiotherapy, in the supine position, to the whole breast by 3D conformal planning. However, several questions remain regarding dose delivery and technique optimization. Can patient positioning improve dose homogeneity? Can the prone position reduce error associated with patient breathing or decrease the dose to healthy organs and tissues? This study is designed to compare prone versus (conventional) supine treatment and the impact of respiratory motion in each position. The benefits of IMRT versus conventional 3D conformal planning (in each position) will be compared with regard to dose delivery to the breast, dose to healthy organs and tissues and cost-efficiency regarding departmental resources. The results of this study will serve for the standardization of breast radiotherapy techniques within the Liège University Hospital.

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SORCE trial: a phase III randomized double-blind study comparing sorafenib with placebo in patients with resected primary renal cell carcinoma at high or intermediate risk of relapse

accrual ongoing - phase III - renal cell carcinoma - sorafenib

This **multicentre phase III trial** aims to assess the efficacy and tolerability of sorafenib in patients with resected renal cell carcinoma (RCC). Patients will be randomized to 3 treatment arms: 3 years placebo, 1 year sorafenib + 2 years placebo, or 3 years sorafenib. The main endpoints of the study are disease-free survival, RCC-specific survival, overall survival, and toxicity.

For more information please contact:
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EORTC 22043-30041 trial: postoperative external radiotherapy combined with concomitant and adjuvant hormonal treatment versus

postoperative external radiotherapy alone in pathological stage pT3a-b R0-1 N0M0, Gleason score 5-10 prostate carcinoma

accrual start: May-June 2009 - hormonotherapy - phase III - prostate cancer - radiotherapy

This **multicentre phase III trial** aims to investigate the potential benefit of a combined adjuvant treatment (short-term androgen suppression and postoperative radiotherapy) for improving the biochemical progression-free survival of patients who have undergone radical prostatectomy for cT1-2-3a N0M0 prostate cancer with baseline prostate-specific antigen (PSA) level ≤5x upper limit of normal range, and who present postoperatively with pathologic stage pT2 R1 / pT3-b R0-1 N0M0, Gleason score 5-10, and an undetectable postoperative PSA level.

Patients will be randomized between postoperative irradiation alone or postoperative irradiation and short-term adjuvant androgen deprivation.

The main endpoints of the study are biochemical and clinical progression-free survival, distant metastasis-free survival, overall survival, and toxicity.

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Two trials with intra-arterial chemotherapy for unresectable isolated liver metastases from colorectal cancer

cetuximab - colorectal cancer - liver metastases - oxaliplatin - phase II

CHOICE study

The CHOICE study is a multicentre phase II study (promoter: Institute Gustave-Roussy (IGR), Villejuif, France) including 45 colorectal cancer patients with isolated liver metastases in whom the primary tumour has been removed (first-line treatment). Patients with K-RAS mutant tumours are excluded from this study.

Patients will be treated as follows:

- intravenous chemotherapy: leukovorin (LV) + 5-fluorouracil (FU)2 + weekly cetuximab (provided by Merck);
- Intra-arterial chemotherapy: oxaliplatin (q 2 weeks).

OPTILIV study

The OPTILIV study is a muliticentre phase II study (promoter: 'Association pour la Recherche sur le temps Biologique et la Chronotherapie (ARTBC) internationale-Hopital P. Brousse', Villejuif, France) in which 60 colorectal cancer patients with isolated liver metastases are recruited in whom the primary tumour was removed (x^{th} treatment line).

Patients with K-RAS mutant tumours are excluded from this study. Patients will be treated as follows:

- IV: bi-weekly cetuximab (provided by Merck)
- IA: 5FU + irinotecan + oxaliplatin (q 2 weeks); chronomodulated schedule optional.

For more information please contact:
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A phase I trial on LBH589 (panobinostat), a histone deacetylase inhibitor in combination with external radiotherapy for the treatment of prostate cancer, oesophageal cancer and head and neck cancer: protocol CLBH589CBE01

deacytase inhibitor - histones - phase I trial - radiotherapy

Radiotherapy is a keystone in the treatment of prostate cancer (PC), oesophageal cancer (EC) and head and neck cancer (HNC). In PC, LBH589 degrades androgen receptors, a key regulator for cancer cell survival and proliferation. In squamous cell cancer, LBH589 is synergistic with radiation in preclinical models. Generally, there is a strong rationale to use pan-histone deacytelase inhibitor (HDACi) in HNC and gastrointestinal cancer. A **phase I trial** designed to assess the feasibility of combined administration of different oral LBH589 dosages in combination with ionizing irradiation in a selection of patients with PC, HNC and EC is currently starting at CHU-Liège. This will allow the optimal dose-establishment for further studies.

For more information please contact:
Philippe A. Coucke, study coordinator
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Assessing the efficacy of the combination of gemcitabine and cetuximab (ECHO) in advanced cholangiocarcinoma

BGDO - cetuximab - cholangiocarcinoma - gemcitabine - phase II

The Belgian Group of Digestive Oncology (BGDO) is launching a **phase II trial** assessing the efficacy of the combination of gemcitabine and cetuximab in advanced cholangiocarcinoma: the **ECHO trial**. These rare tumours represent an orphan disease, with no standard treatment and only phase II trials in the literature. If efficacy is shown after the first 13 patients, this study will hopefully include 45 patients. The aim of the study is to assess progression-free survival at 6 months, hoping to improve it from 20% (as estimated from the trials using gemcitabine) to 40% with the combined regimen. As biliary tract tumours express K-RAS in 50% of the cases, translational research will also be performed to see if mutated K-RAS can be predictive of response.

For more information please contact:
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Single-arm trial of BIBW2992 in demographically and genotypically selected non-small cell lung cancer patients

BIBW2992 - EGFR inhibitor - HER2-neu inhibitor - NSCLC - phase II

The primary objective of this **phase II trial** is to explore the efficacy of **BIBW2992**, a dual inhibitor of EGFR and HER2-neu, in patients with advanced non-small cell lung cancer (NSCLC) stage IIIB or IV whose tumours:

1. harbour activating **mutations** within exon 18 to exon 21 of the **EGFR receptor** and who have become **resistant to treatment with gefitinib or erlotinib**;
2. are **EGFR FISH-positive** and who have become resistant to treatment with **gefitinib or erlotinib**;
3. harbour **activating mutations in the HER2-neu receptor.**

The HER2 mutation screens are routinely performed in patients who were screened in the Laboratory of Molecular Oncology, Oncology Centre, University Hospital Brussels, and who were EGFR mutation negative.
The laboratory can also perform **HER2 mutation screens in phenotypically selected lung adenocarcinomas in never or past smokers** who have failed prior chemotherapy and were not previously considered for the FIELT study.
These mutation screens are performed on paraffin-embedded, formalin-fixed tissues.

For more information please contact:
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Activity of sunitinib in oesophageal cancer, melanoma and sarcoma (SEMS)

melanoma - oesophageal cancer - phase II - sarcoma - sunitinib

The melanoma and sarcoma cancer cohorts have been completed. Accrual continues in oesophageal cancer.
Therapeutic options in patients with advanced oesophageal cancer, melanoma and sarcoma are limited after failure of standard first-line chemotherapy. In the present, **multicentre 2-stage phase II trial** the activity of the single agent sunitinib malate (Sutent®) administered orally at 50 mg/day, 4 weeks on followed by 2 weeks off, will be examined.

Inclusion criteria:

- advanced cancer, locally or metastatic;
- presence of plasma and tissue sample;
- life expectancy of >3 months;
- measurable disease or disease evaluable with non-measurable lesions or tumour marker;
- disease progression on prior treatment and anti-cancer therapy-free period of >4 weeks before baseline examination for current study;
- Tumour-specific inclusion criteria:
  - **sarcoma and melanoma cohorts are closed (recruitment completed)**;
  - **oesophageal cancer**: second line after cisplatinum based chemotherapy.

The study comprises a translational component

including
- baseline plasma levels of VEGF-A, sVEGFR-2, sVEGFR-3 and placenta growth factor (PlGF);
- tumour gene copy number of VEGFR-2;
- evolution during treatment of circulating endothelial and tumour cells. Perfusion imaging with dynamic contrast enhanced MRI.

For more information please contact:
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The PATSGO trial

chemotherapy - glioblastoma - phase II - progression-free survival - temozolomide

The PATSGO trial is a randomized phase II trial evaluating the benefit of a prolonged adjuvant treatment in glioblastoma patients. Some patients present at the end of the 6 months adjuvant treatment with residual tumours that are still regressing. These patients could benefit from prolonged treatment. This study will also evaluate the efficacy of rechallenging patients with temozolomide when their tumour progresses. As temozolomide is thought to be inactive at relapse most relapsing patients do not receive it. However, some responses have been reported. The major enpoints of this trial are (1) progression-free and overall survival at 6 months; (2) safety and adverse event profile of prolonged adjuvant temozolomide; (3) comparison of the health-related quality of life of the patients randomized in the 2 arms; (4) overall tumour response in patients when they are rechallenged with temozolomide.

For more information please contact:
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The SOLE trial

disease free survival - early stage breast cancer - endocrine therapy - letrozole - phase III trial

The SOLE trial is a phase III trial evaluating the role of continuous letrozole versus intermittent letrozole following 4 to 6 years of prior adjuvant endocrine therapy in postmenopausal women with hormone receptor-positive, node-positive, early stage breast cancer (SOLE / IBCSG 35-07 / BIG 1-07).

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Open label phase Ia/Ib study of two dosing schedules of BI 847325, orally administered once a day in patients with advanced solid tumors, with repeated cyclic administration in patients with clinical benefit

MEK inhibitor – Phase Ia/Ib – solid tumors

BI 847325 is an orally available dual inhibitor of MEK and aurora kinase. In this ongoing dose escalation phase Ia/Ib study, BI 847325 is investigated as monotherapy in patients with advanced/metastatic solid tumors. The aim of the ongoing phase Ia (dose escalation) part of this study is to assess the maximum tolerated dose and safety of BI 847325 administered at escalating doses in 2 treatment arms using different schedules. In the phase Ib expansion part of the trial, that will start soon, the aim is to further evaluate the safety profile of BI 847325 at the recommended dose and schedule and to assess target modulation and the potential antitumor efficacy in patients with selected tumor types.
The main inclusion criteria are: Patients with a histologically or cytologically confirmed diagnosis of an advanced unresectable and/or metastatic solid tumor, and who have failed conventional treatment or for whom no therapy of proven efficacy exists or who are not amenable to standard therapies, age 18 years and older, written informed consent consistent with ICH-GCP and local legislation, ECOG 0 or 1, recovery of therapy-related toxicities from previous anti-tumor therapies to CTCAE grade 1 (with the exception of alopecia), written informed consent to the use of archival tumor sample for determination of the BRAF/RAS mutational status and a life expectancy of at least 12 weeks.
In addition, all patients included in the expansion

cohort phase (part Ib) must have been diagnosed with one of the following tumors: melanoma, colorectal carcinoma, non small cell lung cancer (NSCLC) or exocrine pancreas adenocarcinoma, and have been shown on their archival tumor sample to have KRAS or BRAF mutation. Furthermore they should have measurable disease, documented/proven progressive disease within the last 6 months, according to Response Evaluation Criteria In Solid Tumors (RECIST) criteria and a tumor lesion accessible for biopsies (pre- and post-treatment): this is mandatory for patients with colorectal carcinoma or melanoma, optional for patients with NSCLC or exocrine pancreas adenocarcinoma.

Main exclusion criteria are inability to swallow tablets, additional other serious illness, concomitant non-oncological disease (e.g. active infectious disease or known chronic Hepatitis B/Hepatitis C infection and HIV), or ongoing toxicity from prior therapies considered by the investigator to potentially compromise patient's safety in this trial, clinical evidence of symptomatic progressive brain or leptomeningeal disease during the last 28 days, second malignancy currently requiring another anti-cancer therapy, absolute neutrophil count less than 1,500/mm^3, platelet count less than 100,000/mm^3, bilirubin greater than 1.5 mg/dL (>26 μmol/L, SI unit equivalent) (except known Gilbert's syndrome), aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) greater than 2.5 times the upper limit of normal (if related to liver metastases, greater than five times the upper limit of normal), serum creatinine greater than 1.5 mg/dL (>132 μmol/L, SI unit equivalent), previous episode of QT prolongation due to a medication which, as a result of it, had to be discontinued; or long QT syndrome; or QTc with Fridericia's correction >480 msec on screening ECG, treatment with other investigational drugs or participation in another clinical interventional trial within the past four weeks before start of therapy or concomitant with this trial, and systemic anti-cancer therapy or radiotherapy within the past four weeks before start of therapy or concomitantly with this trial. This restriction does not apply to LHRH agonists, steroids and bisphosphonates.

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- A prospective, randomized study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0-3 positive nodes (MINDACT).
  Setting: breast cancer, adjuvant therapy
  Status: ongoing
  For more information please contact Joke Dyck,
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- A multicentre, open-label, phase II study to evaluate the safety of NKTR-102 (PEG-irinotecan) when given on a q14 day or q21 day schedule in patients with metastatic or locally advanced breast cancer whose disease has failed prior taxane-based treatment.
  Setting: breast cancer, second- and third-line treatment
  Status: ongoing
  For more information please contact Joke Dyck,
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- A randomized phase III trial of neoadjuvant chemotherapy followed by surgery versus concomitant radiotherapy and chemotherapy in FIGO Ib2, Iia, >4 cm or IIb cervical cancer (EORTC 55994).
  Setting: gynecological cancer, preoperative
  Status: ongoing
  For more information please contact Joke Dyck,
  email: joke.dyck@uza.be

- Preoperative chemosensitivity testing as predictor of treatment benefit in adjuvant stage III colon cancer (PePiTA trial).
  Setting: colon cancer, adjuvant setting
  Status: ongoing
  For more information please contact Peggy De Clercq,
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- An open-label, randomized phase III study on the efficacy and tolerability of linifanib (ABT-869) versus sorafenib in subjects with advanced hepatocellular carcinoma (protoc M10-963).
  Setting: hepatocellular cancer, first-line treatment
  Status: ongoing
  For more information please contact Véronique Derwael,
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- Intravenous versus intra-arterial fotemustine chemotherapy in patients with liver metastases from uveal melanoma: a randomized phase III study (EORTC 18021).
  Setting: melanoma, second-line treatment
  Status: ongoing
  For more information please contact Joke Dyck,
  e-mail: joke.dyck@uza.be

- Study of bevacizumab, temozolomide, and radiotherapy in patients with newly diagnosed glioblastoma (AVAGLIO).
  Setting: glioblastoma, first-line treatment
  Status: ongoing
  For more information please contact Ingrid Aelbrecht,
  e-mail: ingrid.aelbrecht@uza.be

- A randomized trial of single agent doxorubicin versus doxorubicin plus ifosfamide in the first-line treatment of advanced or metastatic soft tissue sarcoma (EORTC 62012).
  Setting: soft tissue sarcoma, first-line treatment
  Status: ongoing
  For more information please contact Joke Dyck,
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- A randomized phase II feasibility study of cetuximab combined with 4 cycles of docetaxel, cisplatin, and 5-FU (TPF) followed by platinum-based chemoradiation strategies (EORTC 24061).
  Setting: head and neck cancer, first-line treatment
  Status: on hold
  For more information please contact Ingrid Aelbrecht,
  e-mail: ingrid.aelbrecht@uza.be

- Phase II study of pemetrexed in combination with cisplatin and cetuximab in recurrent and metastatic squamous cell carcinoma of the head and neck (Eli Lilly).
  Setting: head and neck cancer, recurrent and metastatic
  Status: ongoing
  For more information please contact Ingrid Aelbrecht,
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- A phase I/II open-label study of bosutinib (SKI-606) administered in combination with capecitabine in subjects with solid tumor (colorectal, pancreatic, cholangio, glioblastoma) andErbB2-negative locally advanced or metastatic breast cancer.
  Setting: phase I
  Status: ongoing
  For more information please contact Joke Dyck, e-mail:
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- A single-arm, open-label phase II study: treatment beyond progression by adding bevacizumab to capecitabine plus oxaiplatin (XELOX) chemotherapy in patients with metastatic colorectal cancer and disease progression under first-line leucovorin, 5-FU, and irinotecan (FOLFIRI) + bevacizumab combination (AVASTAY).
  Setting: colorectal cancer, second-line treatment
  Status: expected
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

- A phase II, open-label study to assess the efficacy and safety of lenalidomide in combination with cetuximab in pretreated subjects with KRAS mutant metastatic colorectal cancer (Celgene).
  Setting: colorectal cancer, third-line treatment
  Status: expected
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

- Asymptomatic colon cancer with synchronous resectable liver metastases: a pilot phase II multicentre study.
  Setting: colon cancer
  Status: expected
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

- Evaluation of preoperative induction chemo-therapy and chemoradiation using cisplatin, infusional 5-FU and panitumumab in locally advanced oesogastric adenocarcinomas: a phase IIa study.
  Setting: gastric cancer, neoadjuvant treatment
  Status: ongoing
  For more information please contact Peggy De Clercq,
  e-mail: peggy.de.clercq@uza.be

Institutional websites with information on recruiting trials

Medische Oncologie UZ Leuven *http://www.uzleuven.be/nl/ig-algemeen-medische-oncologie/klinische-studies*
Medische Oncologie UZ Brussel *http://www.uzbrussel.be/u/view/nl/2555295-Medische+oncologie.html*
Password needed for access to in/exclusion criteria can be requested at *datamanagement.oncologischcentrum@uzbrussel.be*