

Adis Clinical Trials Insight: Presented at Meetings - Oncology

The table below highlights some of the randomised phase III only trials presented during sessions at the meetings described.

Annual San Antonio Breast Cancer Symposium (32nd : December 2009 : San Antonio, Texas, USA)

Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
1 803004486	Cyclophosphamide Doxorubicin Fluorouracil Paclitaxel	This study investigated the performance of a 30-gene predictor of pathological complete response (pCR) in patients who received either neoadjuvant paclitaxel then fluorouracil + doxorubicin + cyclophosphamide (FAC) or FAC alone in women with stage I-III breast cancer.	A 30-gene predictor of pathological complete response (pCR) successfully predicted the treatment response to neoadjuvant paclitaxel then fluorouracil + doxorubicin + cyclophosphamide (FAC) in women with stage I-III breast cancer. Patients who were predicted to achieve a pCR had a significantly higher pCR rate (38%) than unselected patients (19%). Paclitaxel + FAC resulted in a higher pCR rate than FAC alone (19% vs 9%; p<0.05).	
2 803005047	Capecitabine Docetaxel Epirubicin Trastuzumab	This study investigated the safety and efficacy of neoadjuvant epirubicin + docetaxel + capecitabine, compared with epirubicin and docetaxel alone, in patients with operable early breast cancer. Also, the efficacy of the addition of trastuzumab to the above regimens was investigated in patients with HER-2 positive early breast cancer. The primary endpoint was the complete pathological response rate (pCR) at the time of surgery.	Neoadjuvant epirubicin + docetaxel + capecitabine was associated with a similar incidence of adverse events to epirubicin + docetaxel alone, in patients with operable early breast cancer (26% vs 21%); Neoadjuvant epirubicin + docetaxel + capecitabine was associated with significantly higher rates of complete pathological response than epirubicin + docetaxel alone (primary endpoint; 24% vs 15%; p	
3 803004897	Cyclophosphamide Docetaxel Epirubicin Lapatinib Trastuzumab	This interim safety analysis of the GeparQuinto trial investigated the tolerability associated with lapatinib (L) compared to trastuzumab when administered with epirubicin, cyclophosphamide and docetaxel as neoadjuvant treatment of HER2-positive breast cancer.	Lapatinib and trastuzumab were both well tolerated when administered with epirubicin, cyclophosphamide and docetaxel as neoadjuvant treatment of HER2-positive breast cancer. Lapatinib was associated with more grade 1/2 skin rash (28% vs 7%), and less grade 1/2 anaemia (28% vs 52%).	
4 803005065	Bevacizumab Cyclophosphamide Docetaxel Epirubicin Everolimus Paclitaxel	The internal pilot phase for safety of this study investigated the tolerability of epirubicin + cyclophosphamide +/- bevacizumab, followed by paclitaxel + everolimus in non-responders (less than 50% decrease in tumour size), in patients with untreated breast	Bevacizumab in combination with epirubicin + cyclophosphamide was associated with more grade 3-4 neutropenia (70% vs 41%; p	

cancer. This reports on a planned safety analysis of 60 patients with HER-2 negative disease.				
Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
5 803004501	Exemestane Tamoxifen	The TEAM study compared the efficacy and tolerability of adjuvant exemestane versus tamoxifen for the treatment of postmenopausal women with hormone receptor-positive early breast cancer. This analysis focused on the second primary endpoint of DFS at 5 years for exemestane versus tamoxifen then exemestane.	This study compared the efficacy of exemestane with tamoxifen followed by a switch to exemestane for the treatment of postmenopausal women with hormone receptor-positive early breast cancer. The primary endpoint of focus was the disease-free survival at 5 years. Results data were not presented.	Pfizer
6 803004490	Exemestane Tamoxifen	This study compared the efficacy and tolerability of switching to exemestane versus continuing tamoxifen in women with early breast cancer who had already received 2-3 years of adjuvant tamoxifen treatment. Here, long-term follow-up efficacy data were reported, with respect to disease-free and overall survival outcomes.	After a median of 91 months follow-up, switching to exemestane was associated with significantly improved long-term disease-free survival outcomes, compared with continuing tamoxifen (hazard ratio [HR] 0.81; 95% CI 0.71, 0.92; p=0.001), as well as improved overall survival outcomes (HR 0.86; 95% CI 0.75, 0.99; p	Pfizer, Pharmacia
7 803004575	Anastrozole Exemestane	This study investigated the effects of new vasomotor or joint symptoms on relapse-free survival (RFS) in postmenopausal women with hormone-receptor-positive early breast cancer (with no relapse in the first 3 months) receiving either adjuvant anastrozole or exemestane.	There was no correlation between the emergence of the emergence of new vasomotor or joint symptoms and an improvement in the relapse-free survival (RFS) in postmenopausal women with hormone-receptor-positive early breast cancer (with no relapse in the first 3 months of treatment) receiving either adjuvant anastrozole or exemestane. RFS was not statistically significant between the women with or without new symptoms (hazard ratio 1.129; 95% CI, 0.708, 1.800).	
8 803005121	Cyclophosphamide Docetaxel Epirubicin Fluorouracil	This study compared the efficacy and tolerability of adjuvant fluorouracil + docetaxel versus no adjuvant therapy in women with inflammatory breast cancer who had received neoadjuvant epirubicin + cyclophosphamide then surgery then radiotherapy. The primary endpoint was disease-free survival.	Adjuvant fluorouracil + docetaxel was associated with a similar three-year disease-free survival rate to no adjuvant therapy (63% vs 60% of patients; primary endpoint) as well as a similarly high five-year survival rate (70% vs 70% of patients) in women with inflammatory breast cancer who had undergone neoadjuvant epirubicin + cyclophosphamide therapy then surgery then radiotherapy.; Neoadjuvant epirubicin + cyclophosphamide was associated with increased	

				grade 3/4 vomiting, infection, fever and nausea (53%, 13%, 9% and [CONT.]
Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
9 803005061	Cyclophosphamide Docetaxel Doxorubicin Paclitaxel	This trial investigated the incidence of oedema and weight gain and the effects on patient quality-of-life associated with four taxane-containing regimens in women with node-positive breast cancer who have undergone surgery. Patients were randomised to doxorubicin + cyclophosphamide followed by paclitaxel (regimen 1), doxorubicin + cyclophosphamide followed by docetaxel (regimen 2), paclitaxel alone (regimen 3) or docetaxel alone (regimen 4).	Adjuvant docetaxel, alone or in combination with cyclophosphamide + doxorubicin, was associated with greater weight gain from baseline than paclitaxel and cyclophosphamide + doxorubicin + paclitaxel (p	
10 803005126	Capecitabine Docetaxel Epirubicin	This trial compared the efficacy and tolerability of docetaxel + capecitabine and docetaxel + epirubicin as first-line adjuvant therapy in patients with metastatic breast cancer (MBC). The primary endpoint was the progression-free rate 6 months after randomisation, however, slow accrual to the trial led to its early termination.	Docetaxel + capecitabine appeared to be slightly more effective than docetaxel + epirubicin for the first-line adjuvant treatment of women with metastatic breast cancer. The proportion of patients who were progression free at 6 months (primary endpoint) were 76% and 66% in the capecitabine and epirubicin groups, respectively. The median progression-free survival duration was longer in the capecitabine group compared with the epirubicin group (12 vs 7 months; p<0.01).	Roche
11 803004577	Denosumab Zoledronic-acid	This pivotal phase III trial compared the efficacy and tolerability of denosumab and zoledronic acid for the treatment of bone metastases in women with advanced breast cancer. The primary endpoint was the noninferiority of denosumab versus zoledronic acid with respect to time to first on-study skeletal-related event (including fractures, spinal cord compression, or need for radiotherapy or surgery on the bone). However, this analysis focused on the secondary endpoints.	Denosumab was more effective than zoledronic acid in delaying time to first radiation to bone (hazard ratio [HR] 0.74; 95% CI 0.59, 0.94; p=0.01) and first on-study skeletal-related event (SRE) or hypercalcaemia of malignancy (HR 0.82; 95% CI 0.70, 0.95; p	Amgen, Daiichi Sankyo Inc

Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
12 803004435	Anastrozole Fulvestrant	This study compared the efficacy and tolerability of fulvestrant + anastrozole and anastrozole alone for the treatment of women with estrogen or progesterone receptor-positive advanced breast cancer after first relapse following primary treatment. The primary study endpoint was the time to progression.	Anastrozole + fulvestrant did not appear to be more effective than anastrozole alone for the treatment of women with estrogen or progesterone receptor-positive advanced breast cancer after first relapse following primary treatment. The disease progression rate was similar in the anastrozole + fulvestrant and anastrozole groups (both 78%).	AstraZeneca
13 803004431	Fulvestrant	This study compared the efficacy and tolerability of fulvestrant [Faslodex] 250 and 500mg for the treatment of postmenopausal women with estrogen receptor-positive advanced breast cancer progressing or relapsing after prior endocrine therapy. The primary study endpoint was the time to progression (TTP).	Fulvestrant 500 mg/month appeared to be more effective than fulvestrant 250 mg/month for the treatment of postmenopausal women with estrogen receptor-positive advanced breast cancer progressing or relapsing after prior endocrine therapy. The time to disease progression (primary endpoint) was longer in the 500 mg/month group than in the 250 mg/month group (hazard ratio 0.80; 95% CI 0.68, 0.94; p<0.01).	AstraZeneca
14 803004130	Octreotide Tamoxifen	This trial evaluated the efficacy of adjuvant tamoxifen +/- octreotide and its association with tissue inhibitor of metalloproteinase-1 (TIMP-1) in postmenopausal women with breast cancer. Patients were stratified according to receiving no, concurrent or sequential chemotherapy. This analysis focused on relapse-free survival, divided into four types: all types, bone only, all types of bone and nonbone.	Adjuvant tamoxifen +/- octreotide increased nonbone and bone only relapse-free survival in patients who had prior chemotherapy (p	
15 803004574	Tamoxifen	This trial evaluated the efficacy of adjuvant tamoxifen and radiotherapy, either alone or in combination, in women with ductal carcinoma in situ (DCIS).	Adjuvant radiotherapy improved the overall recurrence rate of breast cancer compared with tamoxifen (59% vs 29%, respectively), although tamoxifen improved the rate of contralateral tumours compared with radiotherapy (hazard ratios=0.44 vs 0.84, respectively), in women with ductal carcinoma in situ.	
16 803005063	Anastrozole Exemestane Letrozole	This trial evaluated the effects of adjuvant anastrozole vs letrozole vs exemestane on lipid metabolism, in postmenopausal women with invasive, estrogen receptor positive	Adjuvant anastrozole and letrozole had similar effects on lipid metabolism, whereas exemestane significantly (p	Novartis

breast cancer. Following four months of treatment patients were switched to tamoxifen for 12 months.				
Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
17 803004865	Bevacizumab Docetaxel	The AVADO study investigated the efficacy and tolerability of adding two dosages of bevacizumab to first-line therapy with docetaxel in patients with HER2-negative, locally recurrent or metastatic breast cancer. The primary endpoint was progression-free survival (PFS). Final overall survival (OS) and updated PFS results were presented.	Docetaxel + bevacizumab 7.5 and 15 mg/kg/day had an acceptable toxicity profile compared with docetaxel alone as first-line therapy in patients with HER2-negative, locally-recurrent or metastatic breast cancer. Grade V adverse events were reported in 1.6% and 1.6% versus 2.6% of patients, respectively.; Docetaxel + bevacizumab was more effective than docetaxel alone as first-line therapy in patients with HER2-negative, locally-recurrent or metastatic breast cancer. [CONT.]	Roche
18 803004580	Capecitabine Sunitinib	This study compared the efficacy and tolerability of sunitinib and capecitabine for the treatment of women with HER2-negative advanced breast cancer (ABC) who had previously failed taxane- and anthracycline-based therapy. The primary study endpoint was the progression-free survival (PFS) duration.	Sunitinib was not as effective as capecitabine for the treatment of women with HER2-negative advanced breast cancer who had previously failed taxane- and anthracycline-based therapy. The median progression-free survival (PFS; primary endpoint) was 2.8 months (95% CI 2.4, 3.9; 162 PFS events) compared with 4.2 months (95% CI 3.4, 5.0; 135 PFS events) for sunitinib and capecitabine, respectively (hazard ratio 1.473; 95% CI 1.167, 1.858; p<0.001).	Pfizer
19 803004212	Cyclophosphamide Doxorubicin Fluorouracil Methotrexate	This study compared the quality of life (QOL) effects of standard chemotherapy (doxorubicin + cyclophosphamide [AC] or cyclophosphamide + methotrexate + fluorouracil [CMF]) with capecitabine when administered for the adjuvant treatment of elderly women with early breast cancer.	Capecitabine resulted in better quality of life than standard chemotherapy (doxorubicin + cyclophosphamide or cyclophosphamide + methotrexate + fluorouracil) when administered as adjuvant therapy in women with early breast cancer. The overall European Organisation for Research and Treatment of Cancer scores were better in the capecitabine group than in the standard chemotherapy group (p<0.001).	
20 803004870	Anastrozole Exemestane Tamoxifen	This analysis of the N-SAS-BC04 study (substudy of TEAM) compared with effects of exemestane, tamoxifen and anastrozole on health-related quality of life (HRQOL) and psychological distress in Japanese postmenopausal women receiving adjuvant therapy for the treatment of hormone responsive early breast cancer.	Tamoxifen resulted in better quality of life scores than exemestane or anastrozole when administered for the adjuvant treatment of postmenopausal Japanese women with hormone responsive breast cancer. The Functional Assessment of Cancer Therapy (FACT) -G, -B and -ES scores were increased from baseline at 3 and 12 months in tamoxifen-treated women, but not in women treated with anastrozole or exemestane. There were no significant differences between groups in the Centre for Epidemiological	

			Studies Depression scores.		
Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor	
21 803004495	Arzoxifene	This study investigated the efficacy and tolerability of arzoxifene when administered for the prevention of breast cancer and vertebral fractures in women with postmenopausal osteoporosis or low bone mass. The primary study endpoints were the incidence of radiographical vertebral fractures at 3 years in osteoporotic patients, and the incidence of invasive breast cancer in the entire population at 4 years.	Arzoxifene was effective for the prevention of invasive breast cancer and vertebral fractures in women with postmenopausal osteoporosis or low bone mass. [CONT.]	Eli Lilly	
22 803004004	Cyclophosphamide Docetaxel Epirubicin Fluorouracil	This phase III trial examined the efficacy and tolerability of adjuvant epirubicin + cyclophosphamide with sequential docetaxel (E90C-D) compared with fluorouracil + epirubicin + cyclophosphamide (FE120C) in patients with advanced breast cancer with extensive lymph node metastases.	Epirubicin + cyclophosphamide + docetaxel appeared to be slightly better tolerated than fluorouracil + epirubicin + cyclophosphamide in patients with advanced breast cancer with extensive lymph node involvement. [CONT.]		
23 803005048	Anthracyclines Bevacizumab Capecitabine Cyclophosphamide Docetaxel Doxorubicin Epirubicin Fluorouracil Paclitaxel	The RIBBON-1 study investigated the efficacy of adding bevacizumab to commonly used chemotherapy regimens as first-line therapy in women with HER2-negative metastatic or locally-recurrent breast cancer. The study comprised two independently powered study groups: in group one, bevacizumab + capecitabine was compared with capecitabine alone; and in the second group, bevacizumab in combination with either a taxane (paclitaxel or docetaxel) or anthracyclines was compared with taxanes or anthracyclines alone. [CONT.]	The addition of bevacizumab to first-line chemotherapy with either capecitabine, or taxanes or anthracycline-based therapy, significantly improved progression-free survival (primary endpoint), compared with capecitabine alone (hazard ratio 0.69; p	Genentech, Roche	
24 803005062	Bevacizumab Docetaxel	The AVADO study investigated the efficacy of adding two dosages of bevacizumab [Avastatin] to first-line therapy with docetaxel in patients with human epidermal growth factor receptor-2 (HER2)-negative, locally	Docetaxel + bevacizumab 7.5 and 15 mg/kg/day were associated with significantly improved progression-free survival (primary endpoint) compared with docetaxel alone, as first-line therapy in patients with human epidermal growth factor receptor-2-negative, locally recurrent or metastatic	Roche	

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Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
25 803004437	Lapatinib Trastuzumab	recurrent or metastatic breast cancer. The primary endpoint was progression-free survival (PFS). This study compared the efficacy and tolerability of lapatinib + trastuzumab and lapatinib alone for the treatment of women with trastuzumab-refractory, HER2-positive, metastatic breast cancer (MBC).	breast cancer. The spread of metastatic lesions at disease progression was lower in patients receiving bevacizumab compared to placebo. Lapatinib + trastuzumab appeared to be more effective and lapatinib alone for the treatment of women with trastuzumab-refractory, HER2-positive metastatic breast cancer. The overall survival durations were 61 and 41 weeks in the lapatinib + trastuzumab and lapatinib groups, respectively (hazard ratio 0.74; 95% CI 0.57, 0.97; p<0.05).	GlaxoSmithKline
26 803004444	Carboplatin Cyclophosphamide Docetaxel Doxorubicin Trastuzumab	This third, planned interim analysis (after 650 disease-related events) of the Breast Cancer International Research Group 006 (BCIRG 006) trial compared the efficacy and tolerability of adjuvant docetaxel [Taxotere] + carboplatin + trastuzumab [Herceptin] or doxorubicin + cyclophosphamide then docetaxel with or without trastuzumab in women with HER2-positive early breast cancer. The primary endpoint was disease-free survival.	Results data not available.	sanofi-aventis
27 803004815	Cyclophosphamide Doxorubicin Paclitaxel Trastuzumab	This study compared the efficacy and tolerability of adjuvant doxorubicin + cyclophosphamide then paclitaxel versus doxorubicin + cyclophosphamide then paclitaxel then trastuzumab versus doxorubicin + cyclophosphamide then paclitaxel + trastuzumab then trastuzumab alone in women with stage I-III human epidermal receptor-2 (HER2) positive breast cancer. The primary endpoint was disease-free survival (DFS). Here, the results of an interim analysis are presented.	Adjuvant doxorubicin + cyclophosphamide then paclitaxel then trastuzumab was associated with significantly improved disease-free survival (primary endpoint) outcomes, compared with doxorubicin + cyclophosphamide then paclitaxel alone (hazard ratio [HR] 0.70; 95% CI 0.57, 0.86; p	Genentech

Annual Meeting and Exposition of the American Society of Hematology (51st : December 2009 : New Orleans, Louisiana, USA)

Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
28 803004178	Cyclophosphamide Fludarabine Rituximab	This study compared the efficacy and tolerability of rituximab + fludarabine + cyclophosphamide versus fludarabine + cyclophosphamide alone in patients with relapsed/refractory chronic lymphocytic leukaemia (CLL). Here, the results from a pharmacokinetic substudy are reported in which rituximab clearance was evaluated and compared with clearance rates found in patients with non-Hodgkin's disease.	Rituximab was associated with increased specific clearance (mediated by the CD20 receptor) during early courses in patients with relapsed/refractory chronic lymphocytic leukaemia also receiving fludarabine + cyclophosphamide, compared with specific clearance in patients with non-Hodgkin's disease (1280 vs 577 mL/day). Furthermore, the rate of change from specific to non-specific clearance (mediated by immunoglobulin-G1) was lower in patients with chronic lymphocytic leukaemia, compared to patients with non-Hodgkin's disease (0.024 vs 0.046/day).	Biogen Idec, Genentech, Roche
29 803004227	Melphalan Prednisolone Thalidomide	This phase III study assessed the efficacy and tolerability of melphalan + prednisolone with or without thalidomide as first-line therapy in elderly patients with multiple myeloma. Interim results are presented.	According to per-protocol analysis, overall clinical response rates were significantly higher in melphalan + prednisolone + thalidomide + dexamethasone recipients, compared with melphalan + prednisolone recipients (p	Erkim
30 803004133	Bendamustine Cyclophosphamide Doxorubicin Prednisone Rituximab Vincristine	This study investigated the efficacy and tolerability of rituximab + bendamustine versus rituximab + cyclophosphamide + doxorubicin + prednisone + vincristine (CHOP-R) in patients with indolent follicular and mantle-cell lymphomas. This analysis reported on the secondary endpoint - the ability of these treatments to mobilise a sufficient number (at least 2.0×10^6 CD 34+ cells/kg) of peripheral blood stem cells (PBSC) and progenitor cells.	First-line rituximab + bendamustine has similar efficacy in mobilising CD34+ cells of peripheral blood stem cells and progenitor cells to rituximab + cyclophosphamide + doxorubicin + prednisone + vincristine, in patients with indolent follicular and mantle-cell lymphomas. The median CD34+ cell count/kg was 4.55×10^6 and 6.17×10^6 cells/kg, respectively.	Roche
31 803003699	Antineoplastics Cytarabine Dexamethasone Pegaspargase Vincristine	This study assessed the efficacy of antineoplastics treatment, including induction cytarabine + vincristine + dexamethasone + pegaspargase, in children with non T-cell acute lymphoblastic leukaemia (ALL). Here, efficacy, with respect to effects of cytogenetics on response to treatment, are reported.	Induction cytarabine + vincristine + dexamethasone + pegaspargase was associated with a significantly higher six-year overall survival rate in patients with standard-risk non T-cell acute lymphoblastic leukaemia carrying trisomy 4 and trisomy 10 aneuploidies, compared with those patients that were not (99% vs 95% of patients; $p < 0.01$).	
32 803004003	Chlorambucil	This trial compared the efficacy and	Chlorambucil appeared to be effective as first-line therapy in	

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Rituximab	tolerability of first-line chlorambucil and rituximab, both alone and in combination, in patients with CD20-positive MALT lymphoma. Interim results in the first 320 patients randomised are reported here.	patients with CD20-positive MALT lymphoma. At a median follow-up of 40 months, event-free survival, progression-free survival and overall survival was observed in 62%, 88% and 96% of patients, respectively.
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Adis Clinical Trials Insight: Ongoing Trials Status Tracking – January 2010

The table below outlines the clinical trial activity of large (n>100), phase III & IV, randomised clinical trials identified whose status has changed during January 2010.

Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
1 700030319	Bevacizumab Capecitabine Erlotinib Fluorouracil Folinic-acid Irinotecan Oxaliplatin	Active, no longer recruiting	III	XELOX, XELIRI, FOLFOX, FOLFIRI: therapeutic use Colorectal cancer Phase III trial in combination with bevacizumab followed by maintenance therapy with bevacizumab +/- erlotinib in patients with metastatic disease	Roche
2 700041704	Cisplatin Gemcitabine	Recruiting	III	Cisplatin +/- gemcitabine: therapeutic use Cervical cancer Phase III trial in combination with radiotherapy in patients with positron emission tomography/computed tomography defined poor-prognostic advanced disease	Eli Lilly
3 700003351	Bleomycin Cyclophosphamide Dacarbazine Doxorubicin Etoposide Prednisone Procarbazine Vinblastine Vincristine	Active, no longer recruiting	III	BEACOPP vs ABVD: therapeutic use Hodgkin's disease Phase III trial in patients with stage III or IV disease	

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Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
4 700001380	Cytarabine Daunorubicin Oblimersen	Completed	III	Daunorubicin + cytarabine +/- oblimersen: therapeutic use Acute myeloid leukaemia Phase III trial of first-line therapy in older patients	Genta
5 700017013	Carboplatin DHA-paclitaxel Paclitaxel	Completed	III	DHA paclitaxel + carboplatin vs paclitaxel + carboplatin: therapeutic use Non-small cell lung cancer Phase III trial of first-line therapy in patients with advanced disease	Luitpold Pharmaceuticals
6 700018277	Vinflunine	Completed	III	Vinflunine: therapeutic use Bladder cancer In combination with best supportive care vs best supportive care alone in platinum-pretreated patients with advanced disease	Bristol-Myers Squibb, Pierre Fabre
7 700000261	Chlorambucil Fludarabine	Active, no longer recruiting	III	Chlorambucil vs fludarabine: therapeutic use Waldenstrom's macroglobulinaemia, lymphoma Phase III trial of first-line therapy in patients with advanced disease	Schering Health Care
8 700052326	Cisplatin Docetaxel	Recruiting	IV	Docetaxel + cisplatin: therapeutic use Non-small cell lung cancer Phase IV trial of first-line therapy in patients with advanced disease	sanofi-aventis
9 700036988	Capecitabine	Active, no longer recruiting	III	Capecitabine: therapeutic use Colon cancer 6 vs 12 months as adjuvant chemotherapy for stage 3 (Dukes C) disease	
10 700001314	Cisplatin Doxorubicin Etoposide Mitotane Streptozocin	Active, no longer recruiting	III	Antineoplastics: therapeutic use Adrenal cancer Phase III trial in patients with advanced disease	
11 700033345	Calcium-folate S-1 Tegafur/uracil	Active, no longer recruiting	III	Calcium folinate + tegafur/uracil vs S-1: therapeutic use Colorectal cancer Phase III cost analysis trial in patients with advanced disease	
12 700017143	Imatinib	Completed	III	Imatinib: therapeutic use Chronic myeloid leukaemia Phase III efficacy, tolerability and quality of life trial of first-line therapy	Novartis
13 700009670	Interferon-alpha-2b Peginterferon-alfa-2b	Active, no longer recruiting	III	Peginterferon alpha-2b vs interferon alpha-2b: therapeutic use Malignant melanoma Phase III trial in patients with stage II disease	Schering-Plough

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Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
14 700023253	Apaziquone	Active, no longer recruiting	III	Apaziquone: therapeutic use Bladder cancer Second pivotal phase III trial of adjuvant therapy in patients with non-invasive disease	Spectrum Pharmaceuticals
15 700030720	Bevacizumab Capecitabine Oxaliplatin	Active, no longer recruiting	III	Bevacizumab + capecitabine + oxaliplatin: therapeutic use Colorectal cancer Phase III trial as maintenance therapy in patients with metastatic disease	Roche
16 700037252	Fluorouracil Folinic-acid Oxaliplatin	Recruiting	III	Fluorouracil + folinic acid + oxaliplatin: therapeutic use Liver metastases Alone or in combination with radio-embolisation as first-line therapy in patients with unresectable metastatic colorectal cancer	
17 700022612	Lapatinib Paclitaxel Trastuzumab	Recruiting	III	Lapatinib, trastuzumab, paclitaxel: therapeutic use Early breast cancer Phase III trial as neoadjuvant therapy with paclitaxel in combination with trastuzumab, lapatinib or both	
18 700049419	Dacarbazine PLX-4032	Recruiting	III	PLX 4032 vs dacarbazine: therapeutic use Malignant melanoma Phase III as first-line therapy in patients with metastatic disease	Genentech, Plexikon, Roche
19 700047966	Cetuximab	Recruiting	III	Cetuximab: therapeutic use Head and neck cancer Phase III trial of radiotherapy alone or in combination with adjuvant chemotherapy in patients who have undergone surgery for locally advanced disease: Cost-utility trial	
20 700004711	Goserelin Leuprorelin Thalidomide	Completed	III	Leuprorelin, goserelin +/- thalidomide: therapeutic use Prostate cancer In patients with biochemically recurrent androgen dependent disease	

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