

Adis Clinical Trials Insight: Presented at Meetings - Oncology

The table below highlights some of trials presented during sessions at the meetings described.

2010 Gastrointestinal Cancers Symposium (January 2010 : Orlando, Florida, USA)

Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
1 803005742	Sunitinib	This study assessed the efficacy and tolerability of sunitinib in patients with progressive, well-differentiated pancreatic islet cell tumours. The primary endpoint was progression-free survival (PFS).	Sunitinib appeared generally well tolerated in patients with progressive, well-differentiated, advanced, pancreatic islet cell tumours. Serious adverse events were reported more frequently in the placebo arm than in the sunitinib arm (42% vs 27% of patients).; Sunitinib prolonged progression-free survival (primary endpoint) in patients with progressive, well-differentiated, advanced, pancreatic islet cell tumours. [CONT.]	Pfizer
2 803005944	Sorafenib	This study compared the cost effectiveness of sorafenib versus best supportive care (BSC) for the treatment of patients with unresectable hepatocellular carcinoma in Singapore.	Sorafenib appeared to be cost effective compared with best supportive care (BSC) for the treatment of patients with unresectable hepatocellular carcinoma in Singapore. Sorafenib had an incremental cost per life-year gained of S\$113,217 compared with BSC.	Bayer HealthCare Pharmaceuticals
3 803005979	Antineoplastics Gemcitabine	This study compared the cost effectiveness of neoadjuvant weekly gemcitabine + low- or high-dose radiotherapy, adjuvant chemotherapy + radiotherapy, and adjuvant gemcitabine for the treatment of patients with resectable pancreatic cancer in the USA.	Neoadjuvant chemotherapy + radiotherapy appeared to be cost effective compared with adjuvant gemcitabine for the treatment of patients with resectable pancreatic cancer in the USA. Compared with adjuvant gemcitabine, the neoadjuvant chemotherapy + high-dose radiotherapy and the neoadjuvant chemotherapy + low-dose radiotherapy strategies had incremental costs per life-year gained of \$US30,028 and \$US15,566, respectively.	
4 803005950	Doxorubicin Ethiodized-oil	This trial evaluated the safety and pharmacokinetics of doxorubicin-eluting microspheres [HepaSpheres; Biosphere Medical] vs doxorubicin + ethiodized oil, in patients with liver cancer.	Doxorubicin-eluting microspheres were associated with lower plasma levels of doxorubicin than doxorubicin + ethiodized oil, in patients with liver cancer.; Doxorubicin-eluting microspheres were better tolerated than doxorubicin + ethiodized oil, in patients with liver cancer.	
5 803005958	Gemcitabine GI-4000	This trial evaluated the safety of adjuvant GI 4000 + gemcitabine vs gemcitabine alone, in patients with pancreatic cancer.	Adjuvant GI 4000 + gemcitabine appeared to be similarly tolerated to gemcitabine alone, in patients with pancreatic cancer.	Globelimmune
6 803006052	Cisplatin Fluorouracil Interferon-alpha	This trial evaluated the efficacy and safety of hepatic arterial infusion (HAI) chemotherapy with cisplatin + fluorouracil (FP) vs interferon alpha + fluorouracil (IFN/5FU), in patients with unresectable liver cancer involving the	Hepatic arterial infusion with cisplatin + fluorouracil did not significantly improve overall survival (primary endpoint) compared with interferon alpha + fluorouracil, in patients with unresectable advanced liver cancer involving the main trunk or first branch of the portal vein or the inferior vena cava.; Hepatic arterial infusion	



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		main trunk or first branch of the portal vein or the inferior vena cava. The primary endpoint was overall survival (OS) duration.	with cisplatin + fluorouracil or interferon alpha + fluorouracil were similarly tolerated, in patients with unresectable advanced liver cancer involving than main trunk or first branch of portal [CONT.]	
7 803005751	Cetuximab Fluorouracil Folinic-acid Irinotecan	This study investigated the effects of KRAS status on treatment response in patients with metastatic colorectal cancer (mCRC) treated with first-line fluorouracil + folinic acid + irinotecan (FOLFIRI) +/- cetuximab [Erbix; ImClone Systems].	Fluorouracil + folinic acid + irinotecan (FOLFIRI) + cetuximab was more effective than FOLFIRI alone in patients with KRAS wild-type patients, but not in KRAS mutant-type patients, when administered as first-line therapy in patients with metastatic colorectal cancer. [CONT.]	EMD Pharmaceuticals, Merck KGaA, Merck Serono
8 803005535	Fluorouracil Folinic-acid Irinotecan Panitumumab	This trial investigated the efficacy and tolerability of the addition of panitumumab (pmab) [Vectibix; Amgen] to fluorouracil + folinic acid + irinotecan (FOLFIRI) in the second-line treatment of metastatic colorectal cancer (mCRC). The co-primary endpoints were the progression-free survival (PFS) and overall survival; these were analysed based on patient KRAS status.	Addition of panitumumab to fluorouracil, folinic acid and irinotecan (FOLFIRI) improved outcomes in the second-line treatment of metastatic colorectal cancer in patients with wild type KRAS. Progression-free survival in wild type KRAS patients was longer in those receiving panitumumab with FOLFIRI than FOLFIRI alone (co-primary endpoint; 6 vs 4 months; p	Amgen
9 803005929	Fluorouracil Folinic-acid Oxaliplatin Panitumumab	This pivotal phase III trial investigated the efficacy and tolerability of the addition of panitumumab [pmab; Vectibix; Amgen] to folinic-acid, fluorouracil and oxaliplatin (FOLFOX4) in the first-line treatment (tx) of metastatic colorectal cancer (mCRC). The primary endpoint was the progression-free survival (PFS) analysed based on patient KRAS status, wild-type (WT) versus mutant (MT).	Addition of panitumumab to fluorouracil, folinic acid and oxaliplatin (FOLFOX4) improved outcomes in the first-line treatment of metastatic colorectal cancer in patients with wild type KRAS. Progression-free survival in wild type KRAS patients was longer in those receiving panitumumab with FOLFOX4 than FOLFOX4 alone (primary endpoint; 10 vs 8 months; p	Amgen
10 803005744	Capecitabine Fluorouracil Folinic-acid Oxaliplatin	This trial compared the efficacy and tolerability of capecitabine + oxaliplatin (XELOX) with fluorouracil + folinic acid (5-FU/LV) as adjuvant therapy in patients with stage III colon cancer. The primary endpoint was disease-free survival (DFS). In this analysis, the DFS was compared in patients aged less than 70 and greater than or equal to 70 years.	Oral capecitabine + intravenous oxaliplatin was more effective than intravenous fluorouracil + folinic acid as adjuvant, first-line therapy in patients with stage III colon cancer. The 5-year disease-free survival (primary endpoint) rates were 66% and 60% in the capecitabine + oxaliplatin and fluorouracil + folinic acid groups, respectively. The efficacy of treatment appeared to be maintained in patients aged greater than 70 years.	Genentech, Roche

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11 803006005	Fluorouracil Folinic-acid Oxaliplatin Picoplatin	This trial investigated the tolerability and efficacy of picoplatin [Poniard Pharmaceuticals] + fluorouracil + folinic acid (FOLPI), compared with fluorouracil + folinic acid + oxaliplatin (FOLFOX 6) as a first-line treatment in patients with advanced colorectal cancer (CRC). The primary endpoint was the incidence of neurotoxicities.	Picoplatin + fluorouracil + folinic acid (FOLPI) was associated with a significantly reduced incidence of neurotoxicity compared to fluorouracil + folinic acid + oxaliplatin (FOLFOX 6) in the first-line treatment of patients with advanced colorectal cancer (primary endpoint; p	Poniard Pharmaceuticals
12 803005777	Celecoxib	This study investigated the effects of neoadjuvant celecoxib on gene expression and inflammatory markers in patients with colorectal neoplasia.	Neoadjuvant celecoxib targeted genes and pathways involved mainly in inflammation and malignant transformation in patients with colorectal cancer. There were 687 genes that were differentially expressed in at least two patients in celecoxib-treated group, and 142 of these showed no similar pattern in patients who did not receive celecoxib. There was a downregulation of interleukins, particularly the interleukin-8 gene.	
13 803005993	Fluorouracil Folinic-acid Oxaliplatin	This analysis of the NSABP-C07 study compared the 7-year efficacy of adjuvant fluorouracil + folinic acid +/- oxaliplatin in patients with stage II or III colon cancer. The primary study endpoint was the disease-free survival (DFS).	After 7 years of follow-up, adjuvant fluorouracil + folinic acid + oxaliplatin continued to show improved disease-free survival (DFS; primary endpoint) and time-to-recurrence compared with fluorouracil + folinic acid in patients with stage II or III colon cancer. Overall survival and colon cancer-specific mortality were similar in both groups, but the survival after recurrence was better in the fluorouracil + folinic acid group. [CONT.]	
14 803006036	Capecitabine Cetuximab Fluorouracil Oxaliplatin	This trial evaluated the efficacy of oxaliplatin (Ox) + fluoropyrimidine derivatives (either capecitabine or fluorouracil) + cetuximab (C) vs oxaliplatin + fluoropyrimidine derivatives alone, in patients with advanced colorectal cancer. The primary endpoint was overall survival (OS) in Kirsten rat sarcoma viral oncogene homolog (KRAS) wild-type (wt) patients.	Addition of cetuximab to oxaliplatin + fluoropyrimidine derivatives (capecitabine or fluorouracil) did not improve overall or progression-free survival, in KRAS wild-type patients with advanced colorectal cancer.	
15 803006046	Capecitabine Fluorouracil Oxaliplatin	This trial evaluated the efficacy of continuous chemotherapy (cOxFp) with oxaliplatin + fluoropyrimidine derivatives (capecitabine every 3 weeks or fluorouracil + folinic acid every 2 weeks) until treatment failure vs intermittent chemotherapy (iOxFp) with the	Oxaliplatin + fluoropyrimidine derivatives (capecitabine or fluorouracil + folinic acid) was associated with a small increase in overall survival duration when administered continuously compared with intermittently (for 12 weeks and then further 12 weeks courses on disease progression), in patients with advanced colorectal cancer.	

same regimens for 12 weeks, then further 12 week courses in the case of progression, in patients with advanced colorectal cancer.

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16 803005974	Cetuximab Fluorouracil Folinic-acid Irinotecan Oxaliplatin	This study investigated the cost effectiveness of the addition of cetuximab to either fluorouracil + folinic acid + oxaliplatin (FOLFOX) or fluorouracil + folinic acid + irinotecan (FOLFIRI) for the first-line treatment of patients with metastatic colorectal cancer (mCRC) following resection of liver metastases in the UK.	The addition of cetuximab to either fluorouracil + folinic acid + irinotecan (FOLFIRI) or fluorouracil + folinic acid + oxaliplatin (FOLFOX) appeared to be cost effective compared with FOLFIRI and FOLFOX alone for the first-line treatment of patients with metastatic colorectal cancer following resection of liver metastases in the UK. Compared with FOLFIRI and FOLFOX alone, the addition of cetuximab resulted in incremental costs per quality-adjusted life-year gained of GBP19,557 and GBP21,056, respectively.	Merck Serono
17 803006032	Capecitabine Perifosine	This study compared the efficacy and tolerability of capecitabine + perifosine and capecitabine monotherapy for the second- or third-line treatment of patients with metastatic colorectal cancer. The primary endpoints were the time to disease progression and the response rate.	Capecitabine + perifosine appeared to be generally well tolerated when administered for the second- or third-line treatment of patients with advanced colorectal cancer. [CONT.]	Keryx Biopharmaceuticals
18 803005941	Cisplatin Docetaxel Fluorouracil Granulocyte-colony-stimulating-factors	This trial evaluated the efficacy and safety of first-line therapy with modified docetaxel + cisplatin + fluorouracil (mDCF; designed to minimise toxicity without compromising efficacy) vs docetaxel + cisplatin + fluorouracil (DCF) + granulocyte colony stimulating factors (GCSF), in patients with metastatic gastric and oesophageal cancer. The primary endpoint was 6-month progression-free survival.	First-line therapy with modified docetaxel + cisplatin + fluorouracil improved 6-month progression-free survival (primary endpoint) compared with docetaxel + cisplatin + fluorouracil + granulocyte colony-stimulating factors (90% vs 78%, respectively), in patients with metastatic gastric and oesophageal cancer.; First-line therapy with modified docetaxel + cisplatin + fluorouracil was better tolerated than docetaxel + cisplatin + fluorouracil + granulocyte colony-stimulating factors, in patients with metastatic gastric and oesophageal cancer.	sanofi-aventis
19 803005963	Fluorouracil Folinic-acid Oxaliplatin	This trial investigated the efficacy and tolerability of fluorouracil + folinic acid + oxaliplatin (FOLFOX) compared to fluorouracil + folinic acid with intermittent oxaliplatin (modified OPTIMOX1) in the first-line treatment of advanced colorectal cancer. This trial evaluated progression-free survival and objective clinical response rate. The	Fluorouracil + folinic acid with intermittent oxaliplatin (modified OPTIMOX1) appeared to be more effective than fluorouracil + folinic acid + oxaliplatin (FOLFOX) in the first-line treatment of advanced colorectal cancer. [CONT.]	

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interim results are reported here.

Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
20 803005982	Capecitabine Cisplatin Epirubicin	This study compared the efficacy and tolerability of epirubicin + cisplatin + capecitabine (ECX) and cisplatin + capecitabine (CX) for the first-line treatment of patients with advanced gastric cancer (AGC). The primary study endpoint was the progression-free survival.	Epirubicin + cisplatin + capecitabine and cisplatin + capecitabine appeared to be similarly effective for the first line treatment of patients with advanced gastric cancer. The progression-free survival durations (primary endpoint) were 6.4 and 6.5 months in the cisplatin + capecitabine and epirubicin + cisplatin + capecitabine groups, respectively.	
21 803005715	Imatinib	This study investigated factors that predicted treatment response in patients with KIT-expressing gastrointestinal stromal tumours (GIST) receiving adjuvant imatinib therapy. Updated (after a median of 20 months follow-up) recurrence-free survival (RFS) rates (primary endpoint) were also reported.	Imatinib improved recurrence-free survival (RFS) when given as adjuvant therapy in patients with Kit-positive gastrointestinal stromal tumours. The pathological features of tumour size, location, and especially the mitotic rate correlated with RFS. The 2-year RFS rates (primary endpoint) were 91% and 74% in the imatinib and placebo groups, respectively. [CONT.]	Novartis
22 803005977	Retaspimycin	This study investigated the efficacy and tolerability of retaspimycin for the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumours (GIST) following failure of at least imatinib and sunitinib. The primary study endpoint was progression-free survival.	Retaspimycin was not well tolerated when administered for the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumours following failure of at least imatinib and sunitinib. The trial was terminated early due to the occurrence of four on-treatment related deaths (including renal failure, metabolic acidosis, liver failure and cardiopulmonary arrest) in the retaspimycin group. Grade III or IV aspartate aminotransferase or alanine aminotransferase abnormalities were present of three of the patients who died.	AstraZeneca, Infinity Pharmaceuticals, MedImmune
23 803005717	Capecitabine Cisplatin Fluorouracil Trastuzumab	This study compared the effects on quality of life (QOL) of fluorouracil or capecitabine + cisplatin +/- trastuzumab when administered for the first-line treatment of patients with HER2-positive advanced gastric or gastro-oesophageal junction cancer.	Capecitabine or fluorouracil + cisplatin +/- trastuzumab improved quality of life (QOL) from baseline when administered as first-line treatment in patients with HER2-positive advanced gastric or gastro-oesophageal junction cancer. QOL Questionnaire Core-30 Items (QLQ-C30) Global Health Status scores increased during treatment in both arms, and showed further improvement after completion of treatment (trastuzumab arm from 55 to 64 to 72 and non-trastuzumab arm from 55 to 61 to 71).	Roche

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Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
24 803005938	Capecitabine Epirubicin Oxaliplatin Panitumumab	This dose-finding study compared the efficacy and tolerability of epirubicin + oxaliplatin + capecitabine (EOC) + panitumumab and EOC alone for the first-line treatment of patients with advanced oesophagogastric cancer.	The recommended dose for epirubicin + oxaliplatin + capecitabine (EOC) + panitumumab was the dose level -2 (epirubicin 50 mg/m ² /day + oxaliplatin 100 mg/m ² /day + capecitabine 1000 mg/m ² /day + panitumumab 9 mg/kg/day) when administered for the first-line treatment of patients with advanced oesophagogastric adeno- and undifferentiated carcinoma. No patients reported any grade III/IV adverse events at these dosages.	Amgen
25 803005986	Fluorouracil Folinic-acid Irinotecan	This study compared the efficacy and tolerability of irinotecan + fluorouracil + folinic acid and irinotecan monotherapy as salvage treatment in patients with previously-treated advanced or metastatic gastric adenocarcinoma. The primary study endpoints were the response rate and the time to treatment failure.	Irinotecan monotherapy and irinotecan + fluorouracil + folinic acid appeared to be similarly effective as salvage therapy in patients with previously-treated advanced or metastatic gastric adenocarcinoma. The objective response rates (co-primary endpoint) were 12% and 21% in the irinotecan monotherapy and irinotecan + fluorouracil + folinic acid groups, respectively. However, the progression-free survival duration was longer in the combination group than in the irinotecan monotherapy group (4.1 vs 2.2 months; p<0.05).	
26 803005933	Fluorouracil Paclitaxel S-1	This phase II factorial selection designed study compared the efficacy and tolerability of sequential and concomitant paclitaxel + fluorouracil versus sequential and concomitant S 1 + paclitaxel for the treatment of patients with advanced gastric cancer. The primary study endpoint (not reported) was the 10-month survival rate.	Concomitant administration of S 1 + paclitaxel or fluorouracil + paclitaxel had slightly higher rates of serious adverse events than sequential administration of S 1 then paclitaxel and fluorouracil then paclitaxel when administered for the treatment of patients with advanced gastric cancer. [CONT.]	
27 803005522	Sorafenib	This trial investigated the efficacy and tolerability of sorafenib administered in the treatment of advanced hepatocellular carcinoma (HCC) after transarterial chemoembolisation (TACE) in Japanese and Korean patients. The primary efficacy endpoint was the time to cancer progression or recurrence (TTP) by central review.	Sorafenib was associated with no unexpected adverse events in the treatment advanced hepatocellular carcinoma after transarterial chemoembolisation in Japanese and Korean patients. Grade 3/4 treatment emergent adverse events in sorafenib versus placebo recipients included hand and foot skin reactions, hypertension, and diarrhoea (35% vs 0%, 16% vs 2% and 6% vs 2%, respectively). [CONT.]	Bayer Yakuhin
Annual San Antonio Breast Cancer Symposium (32nd : December 2009 : San Antonio, Texas, USA)				
28 803006008	Anastrozole Goserelin	This study compared the cost effectiveness of goserelin + anastrozole or tamoxifen +/-	Goserelin + anastrozole or tamoxifen + zoledronic acid appeared to be cost effective compared with goserelin + anastrozole or	Novartis Pharmaceuticals

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Adis CTI Record	Drug(s)	Purpose	Study Results	Sponsor
	Tamoxifen Zoledronic-acid	zoledronic acid for the treatment of premenopausal women with hormone-receptor-positive early breast cancer from the perspectives of the healthcare systems in Sweden, Norway, Denmark, and Finland.	tamoxifen for the treatment of premenopausal women with hormone receptor-positive early breast cancer in in Sweden, Norway, Denmark, and Finland. The addition of zoledronic acid resulted in incremental costs per quality-adjusted life-year gained of EUR1510, EUR2162, EUR3369 and EUR3494 for Norway, Sweden, Finland and Denmark, respectively.	Corporation
29 803003845	Cyclophosphamide Docetaxel Doxorubicin Fluorouracil Methotrexate	This study investigated the efficacy of docetaxel with or after doxorubicin-based adjuvant therapy followed by cyclophosphamide + methotrexate + fluorouracil (CMF), compared with docetaxel + CMF alone, in patients with lymph node-positive breast cancer. Results after a median 8 years follow-up are reported here.	Docetaxel with or after doxorubicin may provide additional benefits to cyclophosphamide + fluorouracil + methotrexate (CMF) at long-term follow-up in patients with lymph node-positive breast cancer. At median follow-up of 9 years, docetaxel with or after doxorubicin followed by CMF, compared with regimens with no docetaxel, appeared to increase disease free survival (hazard ratio 0.91; 95% 0.81, 1.05) and overall survival (hazard ratio 0.91; 95% 0.77, 1.08).	sanofi-aventis

Adis Clinical Trials Insight: Ongoing Trials – Status Tracking February 2010

The table below highlights the Large (>100), Randomised Phase III & IV ongoing trials whose status has changed during February 2010

Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
1 700026667	Aflibercept	Active, no longer recruiting	III	Aflibercept: therapeutic use Prostate cancer Phase III trial in patients with metastatic hormone-refractory disease receiving docetaxel + prednisone/prednisolone: The VENICE trial	Regeneron Pharmaceuticals, sanofi-aventis
2 700027298	Aflibercept Docetaxel	Active, no longer recruiting	III	Aflibercept + docetaxel vs docetaxel: therapeutic use Non-small cell lung cancer Second-line treatment in patients with locally advanced or metastatic disease: VITAL	Regeneron Pharmaceuticals, sanofi-aventis, Sanofi-Synthelabo
3 700028083	Amrubicin Topotecan	Active, no longer recruiting	III	Amrubicin vs topotecan: therapeutic use Small cell lung cancer Pivotal phase III second-line therapy in patients with sensitive or refractory disease	Celgene Corporation, Pharmion Corporation
4 700047016	Anastrozole	Active, no longer recruiting	III	Anastrozole: therapeutic use Early breast cancer	AstraZeneca

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Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
				Assessing the impact of educational material on the adherence to treatment with adjuvant therapy in postmenopausal women with hormone sensitive disease	
5 70001371	Anastrozole Trastuzumab	Completed	III	Anastrozole +/- trastuzumab: therapeutic use Advanced breast cancer In postmenopausal patients with hormone receptor-positive, HER2-positive metastatic disease: TANDEM trial	Roche
6 700039449	Antineoplastics	Recruiting	III	Antineoplastics: treatment Colorectal cancer Phase III trial alone or in combination with surgery in patients with asymptomatic metastatic disease: Cost-analysis	
7 700011596	Antineoplastics	Active, no longer recruiting	III	Antineoplastics: therapeutic use Breast cancer Phase III trial of adjuvant chemoradiotherapy versus adjuvant radiotherapy in patients with locoregional relapsed disease	
8 700044792	Antineoplastics Contusugene-ladenovec	Recruiting	IV	Contusugene ladenovec +/- antineoplastics: therapeutic use Orofacial cancer Intra-tumoural injection with or without concurrent chemotherapy or surgery in patients with advanced disease	Shenzhen SiBiono GeneTech
9 700016391	BCG Cyclophosphamide Interleukin-2 Melanoma-vaccine-DNP-VACC	Suspended	III	BCG + cyclophosphamide + interleukin-2 +/- melanoma vaccine DMP VACC: therapeutic use Malignant melanoma Pivotal phase III trial in patients with stage IV disease	AVAX Technologies
10 700043796	Bevacizumab Capecitabine Cisplatin	Active, no longer recruiting	III	Capecitabine + cisplatin +/- bevacizumab: therapeutic use Gastric cancer Phase III trial as first-line therapy in patients with advanced disease	Roche
11 700030720	Bevacizumab Capecitabine Oxaliplatin	Recruiting	III	Bevacizumab + capecitabine + oxaliplatin: therapeutic use Colorectal cancer Phase III trial as maintenance therapy in patients with metastatic disease	Roche
12 700017396	Bevacizumab Docetaxel Trastuzumab	Recruiting	III	Docetaxel + trastuzumab +/- bevacizumab: therapeutic use Advanced breast cancer Phase III trial in patients with HER2-positive locally recurrent or metastatic disease	Roche

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Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
13 700006175	Capecitabine Cyclophosphamide Epirubicin Fluorouracil Methotrexate	Active, no longer recruiting	III	Epirubicin + capecitabine vs epirubicin + CMF: therapeutic use Early breast cancer Phase III trial of conventional versus accelerated epirubicin followed by capecitabine or cyclophosphamide + methotrexate + fluorouracil	Amgen, Pfizer, Roche
14 700013572	Capecitabine Oxaliplatin	Recruiting	III	Capecitabine + oxaliplatin: therapeutic use Gastric cancer Phase III trial of adjuvant chemotherapy versus surgery alone in treatment naive patients with stage II-IIIb disease	Roche, Roche Korea
15 700049714	Carboplatin Paclitaxel Reovirus	Not yet recruiting	III	Paclitaxel + carboplatin +/- reovirus: therapeutic use Head and neck cancer Pivotal adaptive phase III trial in patients with metastatic or recurrent disease	Oncolytics Biotech
16 700014306	Cisplatin Doxifluridine Mitomycin	Completed	III	Mitomycin + doxifluridine +/- cisplatin: therapeutic use Gastric cancer Adjuvant therapy in patients with advanced disease	
17 700049188	Cisplatin Gemcitabine Necitumumab	Recruiting	III	Gemcitabine + cisplatin +/- necitumumab: therapeutic use Non-small cell lung cancer Phase III trial as first line treatment of patients with squamous stage IIIb or IV disease	ImClone Systems
18 700002600	Cisplatin Paclitaxel	Completed	III	Cisplatin + paclitaxel: therapeutic use Non-small cell lung cancer Comparison of two chemoradiotherapy regimens in patients with unresectable stage III disease	
19 700010609	Clodronic-acid Demeclocycline Ibandronic-acid Tetracycline Zoledronic-acid	Active, no longer recruiting	III	Zoledronic acid vs clodronic acid vs ibandronic acid: therapeutic use Prevention of bone metastases Phase III trial of adjuvant therapy in patients with stage I-III breast cancer	
20 700044399	Contusugene-ladenovec	Recruiting	IV	Contusugene ladenovec: therapeutic use Head and neck cancer With or without concurrent chemotherapy, radiotherapy or surgery in patients with advanced disease	Shenzhen SiBiono GeneTech
21 700044800	Contusugene-ladenovec	Recruiting	IV	Contusugene ladenovec: therapeutic use Thyroid cancer Intratumoural injection in combination with radiotherapy or surgery in patients	Shenzhen SiBiono GeneTech

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with advanced disease

Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
22 700003874	Cyclophosphamide Docetaxel Doxorubicin	Completed	III	Doxorubicin + cyclophosphamide +/- docetaxel: therapeutic use Breast cancer Phase III trial of neoadjuvant +/- adjuvant therapy in patients with operable disease	
23 700000294	Cyclophosphamide Docetaxel Doxorubicin	Completed	III	Doxorubicin + docetaxel vs doxorubicin + cyclophosphamide: therapeutic use Advanced breast cancer The Anglo-Celtic II trial, part A	
24 700006184	Cyclophosphamide Doxorubicin Prednisone Rituximab Vincristine	Active, no longer recruiting	III	Rituximab + CHOP: therapeutic use Diffuse large B cell lymphoma Phase III trial of first-line chemotherapy administered every 21 days versus every 14 days	Amgen, Chugai Pharma Europe
25 700013213	Cyclophosphamide Fludarabine Rituximab	Recruiting	III	Rituximab +/- fludarabine + cyclophosphamide: therapeutic use Chronic lymphocytic leukaemia Phase III trial in previously treated patients	Roche
26 700001819	Cytarabine Daunorubicin Etoposide Interleukin-2 Valspodar	Completed	III	Antineoplastics: therapeutic use Acute myeloid leukaemia Phase III trial of first-line therapy followed by stem-cell transplant	
27 700018624	Dacarbazine Temozolomide Velimogene-aliplasmid	Active, no longer recruiting	III	Velimogene aliplasmid vs dacarbazine, temozolomide: therapeutic use Malignant melanoma Pivotal phase III trial in patients with metastatic disease	AnGes MG, Vical
28 700018253	Docetaxel Sunitinib	Active, no longer recruiting	III	Docetaxel +/- sunitinib: therapeutic use Advanced breast cancer Phase III trial as first line therapy in patients with unresectable locally recurrent or metastatic disease	Pfizer
29 700020804	Fluorouracil Folinic-acid Irinotecan Oxaliplatin Talaporfin	Active, no longer recruiting	III	FOLFOX4, FOLFIRI +/- talaporfin: therapeutic use Liver metastases Phase III trial in patients with colorectal cancer	Light Sciences Oncology

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30 700020963	Fluorouracil Folinic-acid Levamisole	Completed	III	Fluorouracil, levamisole, folinic acid: therapeutic use Colorectal cancer Comparison of various combinations in patients with Dukes' B and C disease	
31 700025794	Gemcitabine S-1	Active, no longer recruiting	III	Gemcitabine, S-1: therapeutic use Pancreatic cancer Comparing monotherapy and combination therapy in patients with unresectable advanced disease	Taiho Pharmaceutical, TTY Biopharm
32 700009915	Human-papillomavirus-vaccine-MEDI-517	Active, no longer recruiting	III	Human papillomavirus vaccine MEDI-517: pharmacodynamics Immunogenicity and reactogenicity Phase III trial in females 15-24 years of age	GlaxoSmithKline
33 700040216	Human-papillomavirus-vaccine-recombinant-quadrivalent	Recruiting	III	Human papillomavirus vaccine recombinant quadrivalent: therapeutic use Prevention of human papillomavirus infections, cervical cancer Phase III trial in underserved African American adolescent females: Drug-utilisation trial	Merck & Co
34 700005522	Ibandronic-acid Zoledronic-acid	Completed	III	Ibandronic acid vs zoledronic acid: therapeutic use Bone metastases In patients with malignant and painful bone disease	Roche
35 700004142	Interferon-alpha-2b	Completed	III	Interferon alpha-2b: therapeutic use Malignant melanoma Phase III trial of adjuvant therapy with or without radiotherapy in patients with metastatic disease	
36 700038991	Mitomycin	Discontinued	IV	Mitomycin: therapeutic use Bladder cancer Phase IV trial in patients underwent transurethral resection	
37 700013209	Rituximab	Recruiting	IV	Rituximab: therapeutic use Diffuse large B cell lymphoma, follicular lymphoma Phase IV trial of maintenance therapy versus observation in patients with aggressive disease responsive to first-line therapy	Roche

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