

Adis Clinical Trials Insight: Presented at Meetings - PharmacoEconomics

The table below highlights some of the randomised 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 803005024	Anastrozole Tamoxifen	This study compared the cost effectiveness of anastrozole, tamoxifen and radiotherapy for the adjuvant treatment of elderly women with node-negative, estrogen receptor (ER)-positive, early breast cancer following lumpectomy in the USA.	Tamoxifen appeared to be cost effective compared with anastrozole and radiotherapy for the adjuvant (following lumpectomy) treatment of elderly women with node-negative, estrogen receptor-positive, early breast cancer in the USA. The treatment failure rates (recurrence of ipsilateral or contralateral breast cancer) were 5.32%, 3.41% and 5.25% in the radiotherapy, anastrozole and tamoxifen groups, respectively, and this resulted in total costs per patient of \$US12,252, \$US18,987, and \$US1,540, respectively.	
2 803004867	Zoledronic-acid	This study compared the cost effectiveness of delayed and up-front zoledronic acid and no zoledronic acid for the prevention of osteoporotic fractures in postmenopausal women with hormone receptor-positive early breast cancer (EBC) with a bone mineral density (BMD) T-score of greater than or equal to -2 at baseline receiving adjuvant letrozole in the UK.	Delayed and up-front zoledronic acid appeared to be cost effective compared with no zoledronic acid for the prevention of osteoporotic fractures in postmenopausal women with hormone receptor-positive early breast cancer with a baseline bone mineral density T-score of greater than or equal to -2 receiving adjuvant letrozole in the UK. Compared with no zoledronic acid, the up-front and delayed zoledronic acid strategies had incremental costs per quality-adjusted life-year (QALY) gained of GBP16,069 and GBP21,973, respectively. [CONT.]	Novartis Oncology
3 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	

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4 803005023	Cyclophosphamide Docetaxel Doxorubicin Fluorouracil	This study compared the cost effectiveness of docetaxel + doxorubicin + cyclophosphamide (TAC) and fluorouracil + doxorubicin + cyclophosphamide (FAC) for the adjuvant treatment of women with node-negative early breast cancer in the USA.	Docetaxel + doxorubicin + cyclophosphamide (TAC) appeared to be cost effective compared with fluorouracil + doxorubicin + cyclophosphamide (FAC) for the adjuvant treatment of women with node-negative early breast cancer in the USA. TAC had an incremental cost per quality-adjusted life-year gained of \$US26,654 compared with TAC.	sanofi-aventis
5 803004211		This study investigated the cost effectiveness of ultrasound following clinical examination (CE) and mammography for the diagnosis of breast cancer in women in Germany.	Ultrasound following clinical examination and mammography had similar cost effectiveness ratios in patients who were clinically and mammographically asymptomatic and in patients with abnormalities with either palpation or mammography, for the diagnosis of occult breast cancer malignancies in Germany. The costs per additional cancer detected were EUR4150 and EUR4410 in patients who were asymptomatic under the original examination, and in patients with abnormalities, respectively.	
6 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 ($p < 0.001$).	
7 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.	

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8 803004915	Antineoplastics	This study investigated the cost effectiveness and effects on quality of life (QOL) of the addition of neoadjuvant radiotherapy following adjuvant endocrine therapy and surgery in elderly women with low-risk breast cancer in the UK.	The addition of neoadjuvant radiotherapy following adjuvant endocrine therapy and surgery did not appear to improve quality of life, or be cost effective, compared with no neoadjuvant radiotherapy, for the treatment of elderly women with low risk breast cancer in the UK. Overall the quality of life and quality-adjusted life-years were similar in both groups, and neoadjuvant radiotherapy cost and additional GBP2128 per patient.	
Annual Meeting and Exposition of the American Society of Hematology (51st : December 2009 : New Orleans, Louisiana, USA)				
9 803004298	Bortezomib Melphalan Prednisone	This study compared the cost effectiveness of bortezomib [Velcade] + melphalan + prednisone (VMP) melphalan + prednisone (MP) and thalidomide plus MP (MPT) in patients with newly diagnosis multiple myeloma ineligible for autologous stem cell transplantation (ASCT).	Bortezomib + melphalan + prednisone was associated with an incremental cost of \$US56,109 per quality-adjusted life-year gained compared with melphalan + prednisone in patients with newly diagnosis multiple myeloma ineligible for autologous stem cell transplantation. Additionally, bortezomib + melphalan + prednisone was more effective and less costly (i.e dominant) versus thalidomide + melphalan + prednisone.	Johnson & Johnson, Millennium
10 803002937	Antithymocyte-globulin Busulfan Ciclosporin Fludarabine Mycophenolate-mofetil	This study compared the efficacy, cost effectiveness and quality of life outcomes of non-myeloablative (FLU-TBI) [fludarabine + total body irradiation] versus reduced intensity (FLU-BU-ATG) [fludarabine + busulfan + antithymocyte globulin] conditioning in allogenic stem cell transplantation for the prevention of graft versus host disease (GVHD) and treatment of myelodysplastic syndromes or acute myeloid leukaemia (AML) in France.	Allogeneic stem cell transplant + a reduced-intensity conditioning regimen [fludarabine + busulfan + antithymocyte globulin] (FLU-BU-ATG) and allogenic stem cell transplant + a non-myeloablative conditioning regimen [fludarabine + total body irradiation] (FLU-TBI) appeared to be similarly effective for the treatment of patients with chronic myeloid leukaemia or myelodysplastic syndromes, the 1 year overall survival rates (primary endpoint) were 0.75 and 0.74, respectively.; Allogeneic stem cell transplant + a reduced-intensity conditioning regimen [fludarabine + busulfan + [CONT.]	Amgen, Genzyme Corporation, Pierre Fabre
11 803003583		This study determined the cost effectiveness of screening for von Willebrand disease in adolescents with menorrhagia.	Screening for von Willebrand disease in adolescents with menorrhagia cost \$US45,061 per QALY gained compared with no testing.	
Annual Scientific Sessions of the American Heart Association (82nd : November 2009 : Orlando, Florida, USA)				
12 803003991	Cardiovascular-therapies	This study investigated the cost effectiveness of early revascularisation versus initial medical stabilisation with clinically selected delayed	Early revascularisation was associated with a discounted incremental cost of \$US30,857 per life-years saved compared with initial medical stabilisation with clinically	

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revascularisation in patients with acute myocardial infarction complicated by cardiogenic shock.				
selected delayed revascularisation in patients with acute myocardial infarction complicated by cardiogenic shock.				
GASTRO 2009 (Joint Meeting) (November 2009 : London, England)				
13 803002767	Pantoprazole	This study compared the efficacy and cost-utility ratios of an original version of pantoprazole [Controloc; Nycomed] versus two generic versions of pantoprazole (Nolpaza; Krka) and [Pantoprazol Ratiopharm; Ratiopharm]) in patients with gastro-oesophageal reflux.	At four weeks, pantoprazole (Pantoprazol Ratiopharm [generic]) and pantoprazole (Nolpaza [generic]) were associated with similar changes from baseline in symptom score to pantoprazole (Controloc; Nycomed [original]) (+2.63 and +3.22, respectively, vs +2.94) in patients with gastro-oesophageal reflux.; Pantoprazole (Pantoprazol Ratiopharm [generic]) and pantoprazole (Nolpaza [generic]) were associated with higher cost-utility ratios than pantoprazole (Controloc; Nycomed [original]) in patients with gastro-oesophageal reflux.	

Adis Clinical Trials Database: Ongoing

The table below highlights the ongoing trials whose status has changed during January 2010

Adis CTI Record	Drug(s)	Study Status	Study Phase	Headline	Sponsor
1 700028545	Carboplatin Docetaxel	Completed	II	Carboplatin + docetaxel: therapeutic use Ovarian cancer Phase II trial and quality-of-life analysis of neoadjuvant therapy in patients with advanced disease	sanofi-aventis
2 700025732	Paclitaxel Sorafenib	Active, no longer recruiting	II	Paclitaxel +/- sorafenib: therapeutic use Advanced breast cancer In patients with locally recurrent or metastatic disease	Bayer HealthCare Pharmaceuticals, Onyx Pharmaceuticals
3 700020133		Completed	III	Endometrial cancer: treatment Cost-effectiveness analysis of laparoscopy versus laparotomy in patients with early stage disease	
4 700020136		Completed		Intestinal obstruction: treatment Cost and quality-of-life analyses of colonic stenting as a bridge to surgery	

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				versus emergency surgery In patients with acute left-sided malignant colonic obstruction: the STENT-IN 2 trial	
5 700010486	Paclitaxel	Active, no longer recruiting	II	Paclitaxel: therapeutic use Endometrial cancer Phase II trial of efficacy and quality of life in patients with papillary serous carcinoma undergoing radiotherapy	
6 700021246		Completed		Type 2 diabetes mellitus: treatment Cost effectiveness and cost utility of an innovative shared diabetes care model	
7 700022650		Active, no longer recruiting	IV	Depressive disorders: treatment Assessing cost of cognitive behavioural therapy versus self examination therapy	
8 700024370	INCB-18424	Active, no longer recruiting	I/II	INCB 18424: therapeutic use Myelofibrosis Phase Ib/IIa trial in patients with primary and secondary disease	Incyte Corporation
9 700030507		Completed	IV	Barrett's oesophagus: diagnosis Cost-analysis Intermediate segment vs long segment in patients presenting for surveillance of upper chromoendoscopy	AstraZeneca
10 700034947		Active, no longer recruiting	IV	Goitre: treatment Comparing cost-effectiveness of classic thyroidectomy with or without drains	
11 700032575		Completed	IV	Heart failure: treatment Wait list vs psychoeducational program Cost-effectiveness	
12 700006410	Antiparkinsonians Catechol-O-methyltransferase-inhibitors Dopamine-receptor-agonists Levodopa Monoamine-oxidase-B-inhibitors	Active, no longer recruiting	IV	Antiparkinsonians: therapeutic use Parkinson's disease Phase IV trial of cost-effectiveness, cost-utility, cost-minimisation and quality-of-life effects: the PDMED study	

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13 700039514	Budesonide/formoterol	Completed	IV	Budesonide/formoterol: therapeutic use Asthma Evaluating the the incidence of misuse of the drug in patients with persistent disease	AstraZeneca
14 700007371	Fluorouracil Folinic-acid Irinotecan	Completed	II	Irinotecan + fluorouracil + folinic acid: therapeutic use Gastric cancer, pancreatic cancer Phase II trial in patients with relapsed or refractory advanced disease	sanofi-aventis
15 700012321	Chlorhexidine Mupirocin	Completed	IV	Mupirocin + chlorhexidine: therapeutic use Prevention of nosocomial infections Caused by Staphylococcus aureus	
16 700012994	Atomoxetine	Completed	III	Atomoxetine: therapeutic use Attention-deficit hyperactivity disorder Phase III trial of the quality-of-life effects in children and adolescents	Eli Lilly
17 700044734	Clonidine Midazolam	Recruiting	IV	Clonidine vs midazolam: therapeutic use Sedation Efficacy and cost effectiveness in paediatric intensive care	
18 700011302	Bevacizumab Capecitabine Erlotinib Gemcitabine	Active, no longer recruiting	I/II	Erlotinib + gemcitabine + bevacizumab + capecitabine: therapeutic use Pancreatic cancer Phase I/II trial in patients with locally advanced or metastatic disease: efficacy, tolerability and QOL analysis	Roche
19 700018174		Active, no longer recruiting	III	Post-traumatic stress disorder: treatment Cost analysis The RESPECT-P trial	
20 700000202	Esomeprazole	Completed	III	Esomeprazole: therapeutic use Gastro-oesophageal reflux Compared to laparoscopic anti-reflux surgery in patients with chronic disease	AstraZeneca
21 700040522		Completed	IV	Food allergy: treatment Costs and prevalence of disease in Europe The EUROPREVALL trial	
22 700032136		Active, no longer recruiting	IV	Fracture: treatment Comparing cost of vacuum assisted closure vs traditional gauze wound dressing In patients with pelvic and acetabular disease	

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23 700048104		Active, no longer recruiting	IV	Leg ulcer, varicose ulcer: treatment Comparing costs of Tiscover, an autologous tissue engineered skin substitute with present costs for caring/treatment In patients with chronic wounds due to venous ulcers, ulcers of mixed origin and arteriosclerotic ulcer	
24 700035909	Antiseptics Mupirocin	Discontinued	II	Mupirocin vs antiseptics: therapeutic use Meticillin-resistant Staphylococcus aureus infections	
25 700043774	Proton-pump-inhibitors	Completed	IV	Proton pump inhibitors: therapeutic use Gastro oesophageal reflux	AstraZeneca
26 700037847		Active, no longer recruiting	IV	Varicose ulcer, varicose veins: treatment Assessing cost effectiveness and quality of life	
27 700031417	Aripiprazole	Active, no longer recruiting	IV	Aripiprazole: therapeutic use Depression In patients with treatment-refractory disease: efficacy and quality-of-life effects	Bristol-Myers Squibb
28 700022661		Active, no longer recruiting	IV	Gram-positive infections: diagnosis Cost of F-18-fluorodeoxyglucose positron emission tomography for detection of metastatic infectious foci In patients with Gram-positive bacteraemia: MI-PET	
29 700029559	Diltiazem Landiolol	Completed	IV	Landiolol vs diltiazem: therapeutic use Atrial fibrillation, atrial flutter Efficacy, tolerability and costs following cardiovascular surgery: The JL-KNIGHT study	
30 700044905		Recruiting		Nausea and vomiting: treatment Cost-effectiveness analysis of gastric electrical stimulation In patients with refractory symptoms either idiopathic, postsurgical or due to diabetes mellitus	
31 700050515		Recruiting	IV	Peritonitis: treatment Cost-effectiveness trial comparing laparoscopic lavage with resection In patients with either purulent or faecal disease for perforated diverticulitis: The Ladies Trial	
32 700034875	Antipsychotics Quetiapine	Active, no longer recruiting	IV	Quetiapine + antipsychotics: therapeutic use Schizophrenia Efficacy and quality-of-life effects	AstraZeneca

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33 700046043		Recruiting	IV	Psychotic disorders: treatment Outcomes and costs of a stage-specific case management in Hong Kong	
34 700041113	Smoking-cessation-therapies	Completed	IV	Smoking cessation therapies: therapeutic use Smoking withdrawal Comparing proactive referral vs reactive referral and multi session counseling vs brief counseling: Efficacy and cost-analysis	
35 700021430		Completed	III	Appendicitis: treatment Early versus interval appendectomy Cost analysis study in paediatrics with ruptured appendicitis	
36 700036356		Active, no longer recruiting	I/II	Cognition disorders: treatment Cost-analysis of augmented standard care, resource nurse care at the same site vs after the site switches to advanced practice nurse care In elderly	
37 700028403		Active, no longer recruiting	III	Depression, cancer pain: treatment Cost and cost-effectiveness assessment of telemedicine and standard care in patients with cancer	
38 700019503	Enzastaurin Temozolomide	Completed	I/II	Enzastaurin + temozolomide: therapeutic use Glioblastoma Phase I/II trial of chemoradiotherapy in patients with newly diagnosed glioblastoma multiforme or gliosarcoma	Eli Lilly
39 700016938	Clomifene Infertility-therapies Urofollitropin	Active, no longer recruiting	IV	Infertility therapies: therapeutic use Female infertility Clomifene/IUI then IVF vs urofollitropin/IUI then IVF vs immediate IVF Efficacy and cost analysis in women aged 38-43 years: the FORT-T Trial	
40 700020619	Pertussis-vaccine	Completed	III	Pertussis vaccine: therapeutic use Prevention of pertussis Cost analysis in healthcare workers: the VPES trial	
41 700035689	Chloroquine Pyrimethamine/sulfadoxine	Discontinued	IV	Pyrimethamine/sulfadoxine + chloroquine: therapeutic use Malaria Cost-effectiveness of two drug distribution methods for home based management of fever in Uganda	
42 700039083	Argatroban Desirudin	Discontinued	IV	Argatroban vs desirudin: therapeutic use Thrombocytopenia Cost utility trial in patients with heparin-induced disease without clinically evident thrombosis	Canyon Pharmaceuticals

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43 700026497	Amitriptyline Baclofen Ketamine	Active, no longer recruiting	III	Baclofen + amitriptyline + ketamine: therapeutic use Neuropathic pain Quality-of-life effects in cancer patients with chemotherapy induced disease	
44 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	
45 700030603	Cetuximab Cisplatin Docetaxel Fluorouracil	Active, no longer recruiting	II	Cetuximab + cisplatin + docetaxel + fluorouracil: therapeutic use Laryngeal cancer Phase II trial of chemoradiotherapy in patients with advanced disease: efficacy and quality-of-life effects	
46 700017143	Imatinib	Completed	III	Imatinib: therapeutic use Chronic myeloid leukaemia Phase III efficacy, tolerability and quality of life trial of first-line therapy	Novartis
47 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
48 700050053	Tocilizumab	Active, no longer recruiting	IV	Tocilizumab + DMARDs: therapeutic use Rheumatoid arthritis Quality-of-life evaluation in patients with moderate to severe disease and an inadequate response to DMARDs	Roche
49 700043930		Recruiting	II	Vascular disorders: prevention Outcomes and costs of a rehabilitation and education programme for secondary prevention In patients with previous non-disability stroke or transient ischaemic attack	
50 700052706	Antidepressants	Recruiting	III	Antidepressants: therapeutic use Major depressive disorder, dysthymic disorder Evaluating the cost of a multi-component intervention versus usual care in women with antenatal depression	
51 700050889		Recruiting	IV	Appendicitis: treatment Cost and outcomes of single port versus conventional 3 port laparoscopic appendectomy	

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52 700034961		Discontinued	IV	Chronic wounds: treatment Comparing negative pressure wound therapy to standard wound care for the treatment of chronic pressure disease of the pelvic region Cost-utility and cost effectiveness trial	
53 700035128		Active, no longer recruiting		Colorectal cancer: diagnosis Comparison of 3 systems of support Cost-effectiveness analysis	
54 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	
55 700045702	Lactobacillus-acidophilus Lactobacillus-casei-cell-lysate	Completed	III	Lactobacillus acidophilus + lactobacillus casei cell lysate: therapeutic use Prevention of Traveller's diarrhoea Cost analysis trial	
56 700034816	Antihypertensives	Recruiting	IV	Antihypertensives: therapeutic use Hypertension, prevention of heart failure In combination with behavioural therapy in asymptomatic patients: Efficacy and cost-effectiveness	
57 700048303		Recruiting	II	Aphasia, stroke: treatment Cost-effectiveness of computer therapy compared with usual stimulation	
58 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	
59 700038130	Labetalol Nicardipine	Completed	IV	Nicardipine vs labetalol: therapeutic use Hypertension Cost analysis study in emergency department patients	EKR Therapeutics
60 700013772	Dexamethasone	Recruiting	III	Dexamethasone: treatment Prevention of chemotherapy-induced nausea and vomiting Effects on quality of life in patients undergoing moderately emetogenic chemotherapy	

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