

St. Vincent's Department of Oncology is committed to supporting and conducting clinical trials in collaboration with Australian and international clinical trials groups, to directly influence the treatment practice and management of cancer.

### About us

The Department of Oncology provides a multidisciplinary approach to patient management that emphasises the importance of optimising all aspects of the patient's wellbeing.

Medical Oncology, together with disciplines such as surgery, pathology, radiology, radiation oncology, allied health and supportive care services meet regularly at multidisciplinary meetings to discuss optimal treatment plans for patients. It is hoped that these meetings will improve outcomes for newly diagnosed patients and identify patients who are potentially eligible for clinical trials. Patients can also access clinical trials via satellite clinics at: Shepparton, Echuca, St Vincent's Private, Masada and Werribee Mercy Hospitals.

The department has been operating for 30 years and has taken part in over 100 clinical trials involving more than 1,800 patients.

We participate in trials that treat patients who have either early stage disease and/or advanced cancer. Our research involves investigating new drug treatments for various phases of cancer (including prevention) as well as studies of psychosocial support.

Trials are usually conducted in collaboration with Australian and international clinical trials groups. Patients who consent to take part receive either the best known treatment or a new treatment program building on the current standard of care. As a secondary benefit, doctors are able to gain first hand experience of these new agents in a controlled clinical setting before they are widely available.

The department is currently involved in clinical trials in tumours of the breast, colon, lung, lymph nodes, brain, pancreas, stomach, biliary tract, kidney and liver. These trials are usually Phase 2 and 3 randomised studies.

### Highlights

In 2008 we became members of Clinical Trials Australia, a collaborative group based in Victoria with the aim of increasing the range of trials available to our patients.

### The team

**Assoc Prof Snyder Raymond, Director;** Dr William Ivon Burns, Medical Clinician; Jan Chapple, Nurse; Dr Bianca Devitt, Registrar; Dr Anthony John Dowling, Medical Clinician; Dr Prudence Francis, Medical Clinician; Catherine

Johnston, Nurse; Dr Sue-Anne McLachlan, Medical Clinician; Dr Genni Newnham, Medical Clinician; Dr Andrew Wirth, Medical Clinician

### Highlights

#### *Jan Chapple*

- Nominated for State of Victoria Nurse Excellence Awards

### Higher degrees conferred in 2008

- Prudence Francis, Doctor of Medicine (MD), University of Melbourne

### Grants

*Burns WI, Dowling AJ, Francis PA, Newnham G, Snyder R, McLachlan S, Wirth A*

A randomised, multi-centre, phase II study to explore whether biomarkers correlate with treatment outcome in chemo-naïve patients with advanced or recurrent non-squamous cell lung cancer, who receive treatment with bevacizumab (at a dose of either 7.5 mg/kg or 15 mg/kg) in addition to carboplatin-based chemotherapy (gemcitabine or paclitaxel). International sponsor, (2008)

A multi-centre, randomised, double-blind, placebo-controlled, phase III study of single-agent Tarceva® (erlotinib) following complete tumour resection with or without adjuvant chemotherapy in patients with stage IB-IIIa non small-cell lung carcinoma who have EGFR-positive tumours. International sponsor

A multi-centre, open-label, randomised, phase III study to evaluate the efficacy of Tarceva™ or

comparator Alimta® (pemetrexed) or Taxotere® (docetaxel) in patients with histologically documented, advanced or recurrent (stage IIIB and not amenable for combined modality treatment) or metastatic (Stage IV) non small-cell lung cancer who have experienced disease progression during platinum-based chemotherapy. International sponsor

Multi-centre international study of capecitabine + or-bevacizumab as adjuvant treatment of colon cancer. Collaborative group

A multi-centre, randomised, double-blind, placebo-controlled Phase III study of the efficacy of xaliproden in preventing the neurotoxicity of oxaplatin in first line treatment of patients with metastatic colorectal cancer treated with Oxaplatin/5FU/LV. International sponsor

A phase III randomised study of Brivanib Alaninate (bms-582664) in combination with Cetuximab (Erbix®) versus placebo in combination with Cetuximab (Erbix®) in patients previously treated with combination chemotherapy for metastatic colorectal carcinoma. Collaborative group

A feasibility study of accelerated BEP as first-line chemotherapy for advanced germ cell tumours. Collaborative group

A phase III, randomised, double-blind, parallel-group, multi-centre study to assess the efficacy and safety of ZD6474 (ZACTIMA™) in combination with Pemetrexed (Alimta®) versus Pemetrexed alone in patients with

locally-advanced or metastatic (stage IIIB or IV) non small-cell lung cancer (NSCLC) after failure of 1st line anti-cancer therapy. International sponsor

A phase III, international, randomised, double-blind, parallel-group, multi-centre study to assess the efficacy of ZD6474 (ZACTIMA™) plus best supportive care versus placebo plus best supportive care in patients with locally advanced or metastatic (Stage IIIB-IV) non small-cell lung cancer (NSCLC) after prior therapy with an epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI). International sponsor

*Dowling AJ, Burns WI, Snyder R, Francis PA, McLachlan S, Newnham G, Wirth A*

A phase III open label, randomised, two-parallel-arm multi-centre study of E7389 versus Capecitabine in patients with locally advanced or metastatic breast cancer previously treated with Anthracyclines and Taxanes and Refractory to the most recent chemotherapy. International sponsor

Phase II trial of Temozolomide and Caelyx in the treatment of patients with Glioblastoma Multiforme following concurrent radiotherapy and chemotherapy. Investigator

*McLachlan S, Snyder R, Burns WI, Francis PA, Newnham G, Dowling AJ, Wirth A*

A randomised, phase II study comparing cisplatin and docetaxel with or without cetuximab given as neoadjuvant therapy in patients with stage II and IIIA resectable non small-cell lung cancer: Collaborative group, (2008)

MAGE-A3-positive non small-cell lung cancer – double-blind, randomised,

placebo-controlled Phase III study to assess the efficacy of recMAGE-A3 + AS15 antigen specific cancer immunotherapeutic as adjuvant therapy in patients with resectable MAGE-A3-positive non small-cell lung cancer. International sponsor

Preferences for adjuvant chemotherapy in non small-cell lung cancer: what makes it worthwhile to patients and their doctors? Collaborative group

*McLachlan S*

A randomised phase III trial of adding nitroglycerine to first-line chemotherapy in advanced non small-cell lung cancer. Multi-state Cancer Council, (2008-2009), \$254,000

*Snyder R, Burns WI, Dowling AJ, Francis P, McLachlan S, Wirth A, Newnham G*

An international multi-centre study of Anastrozole vs placebo in postmenopausal women at increased risk of breast cancer. Collaborative group

*Snyder R, Burns WI, Dowling AJ, Francis PA, McLachlan S, Newnham G, Wirth A*

An international multi-centre study of tamoxifen vs anastrozole in postmenopausal women with hormone sensitive Ductal Carcinoma In Situ. Collaborative group

A randomised, double-blind trial to assess the effects on bone mineral density and bone biomarkers of anastrozole when used to prevent breast cancer in postmenopausal women. Collaborative group

A phase II trial evaluating the efficacy and safety of epirubicin and cyclophosphamide (EC) followed by docetaxel with gemcitabine (DG)

(+ trastuzumab if HER2 positive) as neoadjuvant chemotherapy for women with large operable or locally advanced breast carcinoma. Collaborative group

Bisphosphonate and Anastrozole trial – bone maintenance algorithm assessment. Investigator

Phase III trial of LHRH Analog administration during chemotherapy to reduce ovarian failure following chemotherapy in early stage, hormone-receptor negative breast cancer. Collaborative group

A phase III trial evaluating the role of ovarian function suppression and the role of exemestane as adjuvant therapies for premenopausal women with endocrine responsive breast cancer. Collaborative group

A randomised, multi-centre, open-label, phase III study of adjuvant lapatinib, trastuzumab, their sequence and their combination in patients with HER2/ErbB2 positive primary breast cancer. International sponsor

An international multi-centre open-label 2-arm phase III trial of adjuvant bevacizumab in triple negative breast cancer. International sponsor

### Select international presentations

#### Chapple J

– Speaker, ‘Myelodysplastic syndrome the value of transfusion plans’, Haematology Society of Australia and New Zealand Annual Meeting, Perth, Australia, 2008

#### Dowling AJ

– Speaker, ‘A phase II trial of temozolomide in patients with untreated high grade oligodendroglial brain tumours’, American Society of Clinical Oncology Annual Meeting, Chicago, Illinois

#### McLachlan S

– ‘A comparison of quality of life in patients with rectal cancer receiving short course versus long course preoperative radiation. A Trans-Tasman Radiation Oncology Group Trial (TROG 01.04)’, and ‘Complementary and Alternative Medicine (CAM) use in high risk women in the Kathleen Cunningham Foundation Consortium for Research into Familial Breast Cancer (kConFab)’, American Society of Clinical Oncology, USA

### Publications

Dawson SJ, Price MA, Jenkins MA, McKinley JM, Butow PN, McLachlan SA, Lindeman GJ, Weideman P, Friedlander ML, Hopper JL, Phillips KA 2008, ‘Cancer risk management practices of noncarriers within BRCA1/2 mutation positive families in the Kathleen Cunningham Foundation Consortium for Research into Familial Breast Cancer’, *J Clin Oncol*, 26, 2, 225-32

Devitt B, McLachlan SA 2008, ‘Use of ibandronate in the prevention of skeletal events in metastatic breast cancer’, *Ther Clin Risk Manag*, 4, 2, 453-8

Francis P, Crown J, Di Leo A, Buyse M, Balil A, Andersson M, Nordenskjold B, Lang I, Jakesz R, Vorobiof D, Gutierrez J, van Hazel G, Dolci S, Jamin S, Bendahmane B, Gelber RD, Goldhirsch A, Castiglione-Gertsch M, Piccart-Gebhart M 2008, ‘Adjuvant chemotherapy with sequential or concurrent anthracycline and docetaxel: Breast International Group 02-98 randomised trial’, *J Natl Cancer Inst*, 100, 2, 121-33

Francis PA 2008, ‘Surprised by hope’, *J Clin Oncol*, 26, 36, 6001-2

Gianni L, Cole B, Panzini I, Snyder R, Holmberg S, Byrne M, Crivellari D, Colleoni M, Aebi S, Simoncini E 2008, ‘Anemia during adjuvant non-taxane chemotherapy for early breast cancer: incidence and risk factors from two trials of the International Breast Cancer Study Group’, *Supportive Care in Cancer*, 16, 1, 67-74

Kim PJ, Hicks RJ, Wirth A, Ryan G, Seymour JF, Prince HM, Mac Manus MP 2008, ‘Impact of (18)F-Fluorodeoxyglucose Positron Emission Tomography before and after definitive radiation therapy in patients with apparently solitary plasmacytoma’, *Int J Radiat Oncol Biol Phys*

Newnham GM, Thomas DM, McLachlan SA, Wright G, Conron M 2008, ‘Molecular profiling of non small-cell lung cancer: of what value in clinical practice?’, *Heart Lung Circ*, 17, 6, 451-62

Pestalozzi BC, Francis P, Quinaux E, Dolci S, E A, Gelber RD, Viale G, Balil A, M A 2008, ‘Is risk of central nervous system (CNS) relapse related to adjuvant taxane treatment in node-positive breast cancer? Results of the CNS-substudy in the intergroup phase III BIG 02-98 Trial’, *Annals of Oncology*, 19, 1837-1841

Pestalozzi B, Zahrieh D, Mallon E, Gusterson B, Price K, Gelber R, Holmberg S, Lindtner J, Snyder R, Thurlimann B 2008, ‘Distinct clinical and prognostic features of infiltrating lobular carcinoma of the breast: combined results of 15 international breast cancer study group clinical trials’, *Journal of Clinical Oncology*

Plumridge NM, Millward MJ, Rischin D, Macmanus MP, Wirth A, Michael M, Yuen K, Ball DL 2008, ‘Long-term survival following chemoradiation for inoperable non-small cell lung cancer’, *Med J Aust*, 189, 10, 557-9

Regan M, Pagani O, Walley B, Torrisi R, Perez E, Francis P 2008, ‘Premenopausal endocrine-responsive early breast cancer: who received chemotherapy’, *Annals of Oncology*, 19, 1231-1241

Wirth A, Foo M, Seymour JF, Macmanus MP, Hicks RJ 2008, ‘Impact of [18f] fluorodeoxyglucose positron emission tomography on staging and management of early-stage follicular non-hodgkin lymphoma’, *International Journal of Radiation Oncology Biology Physics*, 71, 1, 213-9