



Skin Cancer Update

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SORAFENIB

FOTEMUSTINE

TROG 02.01

SUNSMART REPORT

Produced by the Skin Cancer Committee
of the Victorian Cooperative Oncology Group
Centre for Clinical Research in Cancer



SKIN CANCER UPDATE

December 2005

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This newsletter is produced by The Cancer Council Victoria's Skin Cancer Committee and sent to health professionals interested in management of skin cancer(s). The Victorian Cooperative Oncology Group's advisory committees on breast, gastrointestinal, gynaecological, head & neck, lung and urological cancers also produce twice yearly cancer updates.

If you would like to have your name removed from the distribution list, or if you are interested in receiving any of the other updates please contact Mrs Noellyn Ngo, Ph: (03) 9635 5265.

***** Last Issue – No. 12 – July 2005 *****

The articles in the Skin Cancer Update have been published to contribute to professional debate and exchange. The opinions expressed are not necessarily those of The Cancer Council Victoria.

Editorial

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Welcome to the December 2005 edition of the Skin Cancer Update. In this edition we are focusing on four different modalities for management of melanoma. Andrew Haydon provides a summary of the information emerging for sorafenib, a small molecule oral tyrosine kinase inhibitor of cell signalling. Sorafenib has already shown considerable promise in treating metastatic melanoma and other malignancies. Grant McArthur discusses the use of a cytotoxic agent, fotemustine, recently approved by PBAC for treatment of metastatic melanoma. Medical oncologists can now choose between two drugs with similar mechanisms of action for first line treatment (DTIC is not PBS-listed), but there may be other issues consider that will affect the choices we make. Michael Henderson gives an update on the very important TROG 02.01 study examining the role of adjuvant radiotherapy to lymph node basins after resection of melanoma nodal metastases. We encourage you to consider referring patients for this study. At the other end of the diagnostic / prevention

spectrum, Kylie Strong from SunSmart presents some interesting data on The Cancer Council Australia National Sun Survey, and we include a media release from The Cancer Council Victoria about the role of the GP in cancer prevention.

In addition to this wealth of information we have our usual segments outlining the clinical trials that are currently open or about to open, with relevance to skin cancers. Again, please consider referring patients for these studies. We also provide pointers to some key published articles for your entertainment and edification.

This will be my final editorial for the Skin Cancer Update. Thanks to many of you for your helpful feedback during my tenure. The next edition will be edited with surgical precision by the dancing fingers of David Speakman. Many thanks to Noellyn Ngo and the rest of the team at The Cancer Council Victoria Centre for Clinical Research in Cancer for the wonderful work they do on this, and of course to all our contributors; your efforts make an editor's job easy.

Contributions Welcome

The Skin Cancer Update welcomes contributions – conference reports, review of an area of interest, reviews of recent journal articles, clinical trial updates.

	Deadline	Issue Date
Mid-year issue	1 June	1 July
Year-end issue	1 November	1 December

Contributions should be forwarded to:

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Sorafenib (BAY 43-9006)

Dr Andrew Haydon
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Sorafenib (known as BAY 43-9006 Nexavar® formerly) is a novel bi-aryl urea which has recently been shown to have activity in a number of tumours. Sorafenib has two major modes of action; it inhibits tumor cell proliferation by targeting the RAF/MEK/ERK signaling pathway in addition to inhibiting certain receptor tyrosine kinases (RTK's) and their associated signaling cascades.¹

The RAF/MEK/ERK Pathway

The RAF/MEK/ERK module is an important component of the mitogen-activated protein kinase (MAPK) pathway,² which itself is important in cellular proliferation and survival (Figure 1). RAF activation occurs immediately downstream of RAS.³

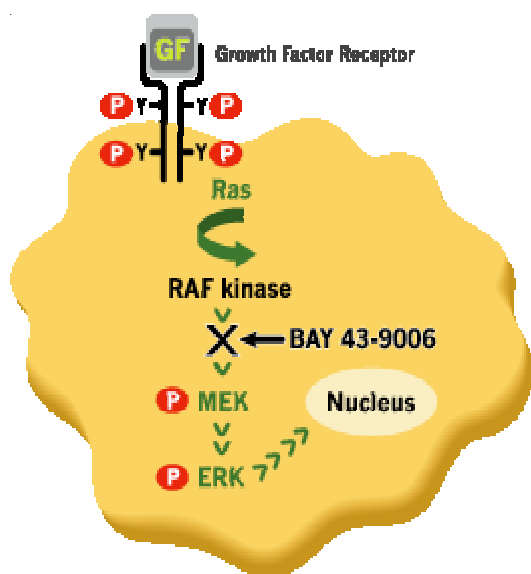


Figure 1. The RAF/MEK/ERK pathway which is usually activated by RAS and is inhibited by Sorafenib (BAY 43-9006).

RAS activation can be exploited by over expression of a variety of receptor tyrosine kinases (such as EGFR, PDGFR and VEGFR), or via mutational activation of the RAS oncogene (e.g. K-RAS). Either way, this initiates a

mitogenic kinase cascade through RAF/MEK/ERK that ultimately modulates gene expression via phosphorylation of transcription factors leading to cellular proliferation.⁴ The RAF kinase family is composed of 3 members: ARAF, BRAF and Raf-1 (also termed c-Raf). RAS mutations have long been known to occur in a variety of solid tumours, however only recently somatic activating mutations of BRAF have been demonstrated in malignant cells. All BRAF mutations occur within the kinase domain, with a single substitution (V599E) accounting for the vast majority. These BRAF mutations result in MAPK signalling independent of RAS and are found in 70% of all melanomas.⁵

Mode of Action

Sorafenib was originally designed as a Raf-1 inhibitor, however has subsequently been shown to inhibit a range of molecules. It is a potent inhibitor of both wild-type and mutated BRAF and, in addition, inhibits proangiogenic RTK's such as VEGFR-2, VEGFR-3 and PDGFR- α by preventing receptor phosphorylation.⁵ Taken together, this suggests that Sorafenib functions as both a RAF kinase inhibitor targeting the RAF/MEK/ERK pathway and an anti-angiogenic agent.

Clinical Studies of Sorafenib

Pre-clinical studies of Sorafenib demonstrated anti-tumour activity against a broad spectrum of cancers including colon, breast, ovarian, pancreatic and melanoma.^{6,7} Based on these findings, Sorafenib moved quickly into clinical studies. In phase I studies the main toxicities were rash, palmar-plantar erythrodysesthesia, diarrhoea, and hypertension, while a dose of 400mg twice daily on a continuous schedule was recommended for phase II evaluation.

In 2004 the randomised discontinuation study (phase II) was initially reported. Patients with advanced solid tumours who had progressive

disease prior to enrolment were all treated with Sorafenib for 12 weeks. Patients with stable disease were then randomised to either continue study drug or switch to placebo. In this study responses were seen in melanoma, renal cell cancer, colorectal cancer, thyroid cancer and sarcoma, however the response rate in tumours other than renal cell and thyroid cancers was less than 10%.⁸

Given the promising results seen in renal cell cancer, the study was extended to include 202 patients with advanced kidney cancer. After 12 weeks of treatment 67% had stable disease and 8 cases (4%) had partial responses. 65 patients then entered the randomisation phase of the trial which demonstrated a significant improvement in time to progression favouring Sorafenib ($p=0.0087$).⁸ Based on this study, it was concluded that Sorafenib inhibited tumour growth in renal cell cancer and occasionally caused tumour shrinkage although rarely sufficient to meet the definition of a "partial response".

At this year's ASCO meeting the first phase III study evaluating Sorafenib was presented.⁹ In this trial 884 patients with advanced renal cell cancer were randomised in a 1:1 fashion to receive Sorafenib 400mg twice a day on a continuous schedule, or placebo. Patients needed to have failed one prior therapy and have measurable metastatic or unresectable disease. Diarrhoea and skin reactions were the most common toxicities occurring in 30 and 31% of patients respectively, however grade III or IV toxicity was rare. 672 patients were evaluable for response having received at least 6 weeks of therapy. Partial responses were infrequent (2% for the Sorafenib treated group) but stable disease was significantly increased compared with placebo (78% vs. 55%). As a result, Sorafenib improved progression free survival by about 3 months (24 vs. 12 weeks; $p<0.00001$). A recent update of this study was presented at this year's ECCO meeting by Dr Escudier with preliminary survival data demonstrating a 28% reduction in the risk of death in favour of Sorafenib.

Sorafenib in Melanoma

It has been recently shown that BRAF is mutated in around 70% of all melanomas,⁵ while RAS is mutated in only 15–20% of tumours. Furthermore, BRAF mutations stimulate ERK

activity (see above) and transform melanocytes in vitro,¹⁰ together these findings have lead researchers to examine the role of Sorafenib in this malignancy.

The outcomes of melanoma patients treated with single agent Sorafenib have been disappointing. The results of the first 20 patients treated as part of the randomised discontinuation study at The Royal Marsden were reported last year. After 12 weeks of treatment only one patient had a partial response, while 15 had progressed.¹¹ An update with a total of 37 melanoma patients reported one partial response and 6 with stable disease.

Results have been a little more encouraging when Sorafenib has also been examined in combination with chemotherapy. Perhaps the most interesting data comes from combining it with Carboplatin and Paclitaxel. A phase II trial looking at this combination warrants further discussion.¹² In this trial 54 patients with stage IV melanoma were treated with Carboplatin AUC 6 day 1, Paclitaxel 225 mg/m² day 1 and Sorafenib 400mg BD days 2–19 repeated every 21 days. Fifty-seven percent of cases had received prior chemotherapy and 68% were stage IIIc. Partial responses were seen in 37% all of which lasted greater than 6 months, with a further 48% having stable disease (for at least 2 cycles). Overall progression free survival marginally exceeded 6 months. In a sub-study, 31 cases had tumour samples analysed for BRAF mutations and demonstrated that the presence or absence of a mutation did not predict for response.

On the basis of these results, a phase III study using Carboplatin and Paclitaxel with or without Sorafenib following DTIC or Temozolomide failure has recently opened for metastatic melanoma. In addition, a first line study using DTIC plus or minus Sorafenib has also started.

Conclusions

Sorafenib is a promising new drug with dual modality anti tumour activity. As a BRAF inhibitor it exerts an anti-proliferative effect by targeting the RAF/MEK/ERK pathway, while inhibition of the VEGF and PDGF receptors disrupts angiogenesis. Similar to other new targeted agents, the clinical data suggest it acts mainly by preventing disease progression. Although early in its development, Sorafenib has proven

efficacy as a single agent in renal cell cancer and shown promising results combined with chemotherapy in melanoma.

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Fotemustine: A step forward for treatment of patients with advanced melanoma?

Associate Professor Grant McArthur

Consultant Medical Oncologist / Head, Medical Oncology Skin & Melanoma Service

Head, Molecular Oncology & Translational Research Laboratories

Divisions of Haematology & Medical Oncology and Research

Peter MacCallum Cancer Centre

Fotemustine (Muphoran) was recently listed for reimbursement on the pharmaceutical benefits scheme for “disseminated malignant melanoma”. This represents the first listing of a drug on the PBS for the management of advanced melanoma. This article will evaluate the current evidence for the use of Fotemustine in melanoma and place this agent in the context of our ongoing search for effective agents to manage this difficult disease.

What is Fotemustine?

Fotemustine is a nitrosourea chemotherapeutic agent that acts by forming covalent cross-links to cellular DNA at the O6-guanine position. This

class of chemotherapeutic drugs have previously attracted interest in melanoma because they readily penetrate the blood-brain barrier and so have modest activity against cerebral metastases. Clinical trials performed over 10 years ago showed modest activity of Fotemustine in patients with advanced melanoma including those with cerebral metastases. Overall 24% of patients had objective responses, however unfortunately very few were durable.¹ Clinical trials to determine if Fotemustine is superior in terms of overall survival to best supportive care or other agents such as DTIC have never been performed, leading to this agent playing a small role in our therapeutic repertoire against advanced melanoma.

How does Fotemustine compare to DTIC?

In 2004, a European collaborative group published results of a randomised trial comparing Fotemustine to DTIC, the most commonly used agent in patients with advanced disease. The study was designed to determine if Fotemustine had a superior response rate to DTIC, so was not designed to determine if there was any difference in overall survival. Fotemustine displayed a superior response rate to DTIC with 15% of patients on the Fotemustine arm achieving a partial response and 7% on the DTIC arm.² Interestingly, there was trend towards superior overall survival in the Fotemustine arm but this was not statistically significant. Fotemustine was equivalent to DTIC in quality of life analyses, and in progression free survival but was associated with more severe haematological toxicity. However, this toxicity was manageable and overall Fotemustine is well tolerated with <5% of patients developing clinically significant toxicity.

...given the absence of data showing benefits of Fotemustine on overall survival, it is vital that the melanoma community continues to evaluate novel therapies on clinical trials

Development of brain metastases

As Fotemustine crosses the blood-brain barrier one intriguing outcome of the European study was a delay and possible reduction in the development of cerebral metastases on the Fotemustine arm. These results are similar to a previous randomised trial that compared DTIC to temozolomide, another alkylating agent that crosses the blood brain barrier. In that study, temozolomide also was associated with lower rate of development of cerebral metastases.³ However, in neither study did this observation impact on overall survival of the entire study population.⁴

Implications of these data for clinical practice?

Oncologists are now left in an unusual situation with approval of an agent that has not been shown to improve overall or progression free survival

but offers some palliative benefit for a subset of patients. Whilst it is satisfying to see the PBS approve agents for melanoma, given the absence of data showing benefits of Fotemustine on overall survival, it is vital that the melanoma community continues to evaluate novel therapies on clinical trials. Moreover as DTIC, but not Fotemustine, is approved by the FDA in the

... first line therapy with DTIC remains acceptable clinical practice and may offer the patient greater options for participation in later clinical trials

USA, many clinical trials continue to have prior therapy with DTIC as a requirement for eligibility for participation in the clinical trial. Moreover, prior treatment with Fotemustine excludes patients from some clinical trials. Taken together all these factors indicate that first line therapy with DTIC remains acceptable clinical practice and may offer the patient greater options for participation in later clinical trials.

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Disclosure

Grant McArthur is an active investigator in clinical trials of melanoma, including trials that exclude patients with prior treatment with Fotemustine. He has been a consultant for Schering-Plough, the manufacturer of Temozolomide.

TROG 02.01 – A randomised clinical trial of surgery versus surgery plus adjuvant radiotherapy for regional control in patients with completely resected high risk regional melanoma

Associate Professor Michael A Henderson
Division of Surgical Oncology
Peter MacCallum Cancer Centre

This study which is NHRMC funded and supported by the Trans-Tasman Radiation Oncology Group (TROG) and the Australia and New Zealand Melanoma Trials Group is a randomised study which aims to answer the question whether radiotherapy is beneficial for patients with regional failure at high-risk of subsequent relapse following surgery. Data from previous reports suggest that RT does decrease the risk of further regional recurrence significantly but the effect on survival is unknown. Quality of life issues of which nothing is known are likely to be of major importance in assessing the utility of RT.

The study is open throughout Australia and New Zealand and at least one international site has expressed considerable interest in participating.

As at the end of October 2005, 143 patients of a proposed 220 have been randomised.

The study is limited to patients with a regional recurrence who are at high-risk for subsequent recurrence. In addition to survival and regional control quality of life is a major endpoint.

Eligibility Criteria

The risk of subsequent regional recurrence (at least 25%) is defined by the site, number of lymph nodes involved, largest nodal tumour deposit, significant extracapsular extension and/or significant contamination at the time of surgery.

- Parotid 1 or more nodes involved,
- Cervical lymph nodes 2 or more involved, any node 30mm or more in size
- Axillary lymph nodes 3 or more involved, any node 30mm or more in size
- Inguinal lymph nodes 4 or more nodes or any node 40 mm or more in size

This is a very important study, which aims to resolve a significant issue in the management of patients with high-risk melanoma.

Virtually all Radiotherapy Centres throughout Australia are participating in this study and if you are interested in considering a patient for this study, in the first place discussions should occur with the Radiation Oncologist to whom the patient is referred for an opinion. Further information is available from Associate Professor Michael A Henderson, Division of Surgical Oncology, Peter MacCallum Cancer Centre.

Phone: 03 9656 3527 / Fax: 03 9654 8457

E-mail: Michael.Henderson@petermac.org

Site	Accrual to 31 Oct
Netherlands	University Medical Centre Groningen 0
NZ	Auckland Hospital 0
	Christchurch Hospital 4
	Dunedin Hospital 0
	Wellington Hospital 2
NSW	Illawarra Hospital 0
	Mater Hospital (Newcastle) 2
	Prince of Wales Hospital 0
	Royal Prince Alfred Hospital 38
	Westmead Hospital 0
QLD	East Coast Cancer Centre 2
	Mater QRI 4
	Princess Alexandra Hospital 63
	Royal Brisbane Hospital 0
SA	Royal Adelaide Hospital 2
TAS	Launceston General Hospital 0
VIC	Alfred Hospital 2
	Andrew Love Cancer Centre 0
	Peter MacCallum Cancer Centre 23
WA	Sir Charles Gairdner Hospital 0
	Royal Perth Hospital 1
Total 143	



SunSmart Program Update

Ms Kylie Strong
 Manager, SunSmart Program
 The Cancer Council Victoria

National Skin Cancer Action Week (13–19 November 2005)

National Skin Cancer Action Week (NSCAW) is an initiative of The Cancer Council Australia's Skin Cancer Committee, aiming to raise awareness of skin cancer and sun protection issues at the start of the summer season.

In 2004, the Cancer Council launched data from the first National Sun Survey. The data provided insight into the attitudes and behaviours of Australians in relation to sun protection – the first time such data has been collated at a national level.

This year, The Cancer Council Victoria will launch the results of the National Adolescent Sun Survey. The survey provides interesting insights into teenagers' beliefs about skin cancer and sun protection and subsequent actions to protect themselves.

- Almost 90% of teenagers are now aware of the risk of skin cancer through sun exposure.
- 68% of teenagers did not go out and actively attempt to get a tan.
- However, 25% of teenagers are still getting sunburnt on a typical summer weekend.
- 24% of all cancers in people aged 15–19 are melanomas, the highest rate of any cancer in this age group.
- Not only are teenagers more aware of the link between skin cancer risk and sun exposure, fewer teenagers (41%) than adults (50%) believe a tanned person looks more healthy.
- The most consistent predictor of children's sun protection was of the parent's own sun protection behaviour.
- Males were four and a half times more likely to be sunburnt compared with females; most likely due to the time they spent in outdoor activities.
- Nearly a third of adolescents (32%) and a similar number of adults (27%) wore SPF30+ sunscreen.

Solariums – Fashion to Die For

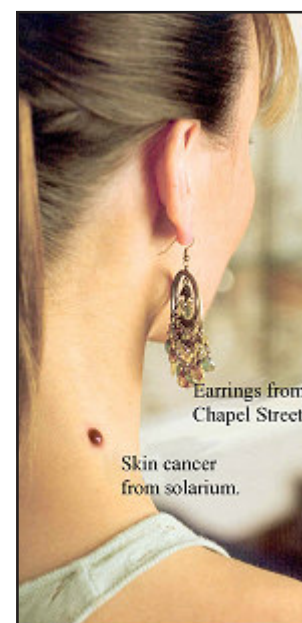
In the last VCOG Skin Cancer Update, the SunSmart program reported on the development of interventions related to solariums. Since then, a joint campaign with the Department of Human Services and SunSmart was launched by the Hon Bronwyn Pike MP, Minister for Health, *Solariums – Fashion to Die For*.

The campaign intends to create awareness and educate Victorians about the dangers of contracting skin cancer from solariums aimed at fashion conscious young women – but applies to anyone who uses a solarium or is thinking about using one. The campaign is also being used as an opportunity to put pressure on the solarium industry to ensure better compliance with the Australia Standard.

The launch generated fantastic media coverage:

- Television – Channel 9 and Channel 7
- Newspaper – Herald Sun and The Age Online
- Radio – Interviews on Radio National, FoxFM, 3AW, VEGA and NOVA
- Other State media coverage – NSW, QLD, TAS and SA
- Editorials – in several health publications, especially GP newsletters.

To support the campaign, a letter with a poster and brochures were distributed to beauty salons, school nurses, fitness and sport centres, pharmacies, GPs and community health centres. The brochure informs people of the dangers of using solariums and



challenges some of the common 'myths' associated with solariums. If you are interested in obtaining your own copies please email radiation.safety@dhs.vic.gov.au or contact Ms Gabrielle Bright at DHS.

<http://www.health.vic.gov.au/environment/radiation/solarium.htm>

SunSmart Local Government Shade Awards

Shade is an essential component of healthy urban planning. Local Government plays a key role in planning and providing sun protection for our communities. Research shows that many outdoor facilities and venues in Victoria have inadequate levels of shade.

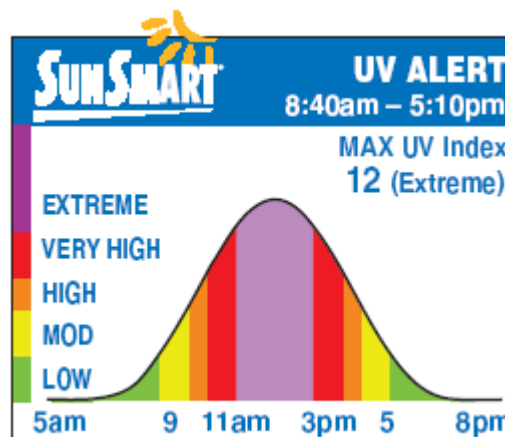
The SunSmart Shade Awards aim to increase the understanding of the importance of shade and to encourage Local Government to consider shade provision in urban planning and design. More information about the shade awards can be found at:

<http://www.sunsmart.com.au/browse.asp?ContainerID=1686>.

SunSmart UV Alert

The SunSmart UV Alert is now reported daily in newspaper weather forecasts across Australia. The alert is used to raise public awareness of the risk of exposure to UV radiation and to encourage people to adopt appropriate sun protection measures.

The SunSmart UV Alert is issued when the UV Index forecast for the day is 3 or above, which can apply to most days. When the UV Index reaches 3 or above, skin damage and particularly sunburn can occur and the risk of skin cancer increases, so sun protection is required. The alert identifies the times during the day that the UV index will reach 3 or above, so people know when to adopt sun protection measures.



The UV Index forecast which provides the information for the SunSmart UV Alert for capital cities and major towns across Australia is issued by the Bureau of Meteorology. The UV rating system used by the Bureau has been adapted from the World Health Organisation Global Solar UV Index.

<http://www.sunsmart.com.au/browse.asp?ContainerID=1684>

Cancer Control in General Practice

Introduction

While the work of GPs spans the full spectrum of cancer control – prevention, detection, treatment and palliation – the largest component of this work involves dealing with patients who have suspicious symptoms, concerns about possible cancer or are at increased risk due to family

history or lifestyle factors (smoking, nutrition, alcohol and physical activity levels).

A new report documents the wisdom of an important stakeholder consultation meeting held by The Cancer Council Victoria in partnership with the National Cancer Control Initiative in June this year to look at how to enhance cancer control activity in primary care. The experiences and insights shared and resulting

recommendations have helped to inform planning for the sector and will be useful to other organisations working with general practice.

Media Release – 11 November 2005

With more than 85 per cent of the population visiting a GP at least once per year, GPs are at the frontline of cancer prevention.

“The Cancer Council Victoria is committed to working with an increased focus on primary care,” said Ms Rebecca Russell, Primary Health Care Coordinator with The Cancer Council Victoria.

The Cancer Council and the National Cancer Control Initiative conducted a meeting in June with GPs, practice nurses and staff, cancer specialists and other stakeholders to look at how to enhance cancer control activity within general practice.

The recently released report of this meeting, ‘Cancer Control in General Practice’, captures the experiences and insights of participants and has informed the Cancer Council’s planning for the sector.

“This report highlights the commitment, passion and enthusiasm of the stakeholders to work collaboratively in enhancing the capacity of primary care,” said Ms Russell. “It provides a positive foundation for future cancer control work in general practice and will be useful to other organisations working with general practice.”

Professor Brian McAvoy, National Cancer Control Initiative Deputy Director and general practitioner in St Kilda said, “The majority of a cancer patient’s journey takes place in the community, with medical and psychosocial care being provided by GPs and nurses. With cancer now seen as a chronic disease, GPs have a critical role to play across the whole continuum of cancer control.”

Professor McAvoy was one of three presenters at the meeting. He provided an overview of the National Cancer Control Initiative and its primary care strategies, information on cancer incidence, costs, mortality and survival rates, and the level of cancer related activity in general practice.

Dr Chris Hogan, a Cancer Council Councilor and general practitioner in Sunbury, looked at the changing and diverse nature of general practice and the challenges faced when undertaking preventive activities in general practice.

Ms Russell covered the Cancer Council’s primary care focus including an outline of its existing primary care strategies.

The ‘Cancer Control in General Practice’ report contains a synopsis of the presentations given at the meeting, a summary of key discussion points and participant recommendations covering education, communication, multidisciplinary teams and future directions.

The report is available for download at http://www.ncci.org.au/pdf/Primary%20care/GP_program_report05.pdf.

Clinical Trials Update

LUD2002-013 – Phase II NY-ESO-1 ISCOM® in melanoma patients with ESO+ tumours and measurable disease

Completed accrual – on hold pending approval of an amendment.

Eligibility criteria:

- Stage IV (metastatic) or unresectable stage III malignant melanoma
- Measurable disease using RECIST criteria
- No other effective therapy available or appropriate

- Expression of NY-ESO-1 or LAGE-1 by immunohistochemistry or RT-PCR
- Expected survival of at least 4 months
- KPS \geq 70%
- Hb \geq 100g/L
- Platelets \geq 100 \times 10⁹/L
- INR \leq 2.0
- Creatinine \leq 0.2 mmol/L
- Bilirubin \leq 30 mmol/L

- Age \geq 18 years and able to give consent
- No other serious illness e.g. serious infections requiring antibiotics, bleeding disorders, or any condition that would compromise completion of study requirements
- No other malignancy within 3 years, except treated or non-melanoma skin cancer, or cervical CIS
- No known immunodeficiency
- No known HIV positivity
- No concomitant treatment with corticosteroids, anti-histaminic drugs or NSAIDs. Specific COX-2 inhibitors permitted. Low dose aspirin used in low doses for the prevention of an acute cardiovascular event is permitted. Topical or inhalational steroids are permitted.
- No chemotherapy, radiotherapy, immunotherapy within 4 weeks prior
- No mental impairment which may compromise consent ability
- Available for immunological and clinical follow-up assessments
- No trial with other investigational agent within 4 weeks prior
- Not pregnant or lactating, must use contraception
- Ocular melanoma
- Other known malignancy within 3 years prior to entry into the study, except for treated non-melanoma skin cancer and cervical carcinoma in situ
- Use of immuno-suppressive drugs
- Anticoagulation
- Known HIV positivity
- Chemotherapy or radiation therapy within the preceding four weeks (6 weeks for nitrosourea drugs)
- Participation in any other clinical trial involving another investigational agent within 4 weeks prior to first dosing
- Previous isolated limb perfusion (ILP)

[Contact: Ian Davis / Jonathan Cebon, Austin Health, Ph: 9496 5726; Grant McArthur, Peter Mac, Ph: 9656 1195]

Treatment of lentigo maligna with 5% imiquimod cream

Investigation of the treatment of histologically proven lentigo maligna with 5% imiquimod cream over a period of 12 weeks. Patients will have their lesions excised at the completion of treatment to determine whether or not imiquimod has achieved histological clearance.

Screening for accrual at the Victorian Melanoma Service, Alfred Hospital. Current accrual 16 out of a target of 40.

Inclusion criteria:

- Age 18–90 years
- Biopsy proven diagnosis of lentigo maligna on the face, torso or limbs OR lesions suspicious of being lentigo maligna
- Lesions $>$ 5mm diameter which have not been previously treated
- Capable of attending the Alfred Hospital for all required visits
- Patient consent gained

Exclusion criteria:

- Age less than 18 or unable to give consent
- Lesions impinging on orbits/lips or other mucous membranes
- Biopsy proven invasive lesions
- Recurrent lesions
- Infected lesions
- Breast feeding or pregnant

LUD2003-009 – Randomised, double-blind phase II trial of NY-ESO-1 ISCOMATRIX® vaccine and ISCOMATRIX® adjuvant alone in patients with resected stage IIc, III or IV malignant melanoma

Open for accrual at Austin and Peter Mac.

Inclusion criteria:

- Histologically proven malignant melanoma
- Fully resected AJCC stage IIc, III or IV melanoma
- Tumour expression of NY-ESO-1 antigen by immuno-histochemistry or RT-PCR, or of LAGE-1 by IHC
- Within six months of surgery for melanoma
- Full recovery from surgery
- No prior immunotherapy or systemic adjuvant therapy for melanoma following most recent relapse and/or resection of melanoma
- Haemoglobin \geq 100, platelets \geq 100, INR \leq 2.0
- Creatinine \leq 0.2 mmol/L
- Bilirubin \leq 30, ALT/AST \leq 1.5 \times ULN

Exclusion criteria:

- Other clinically serious or significant illnesses
- Resected cerebral metastases.

- Immuno-suppression (drug induced)
- Immuno-suppression (disease induced)
- HIV positive status

[Contact: Martin Haskett, Frankston Rooms, Ph: 03 9770 9788 / Nathan Curr, Alfred Hospital, Ph: 0402 229 469 / Sister Merran Tyler, Alfred Hospital, Ph: 03 9530 5940 (AH).]

Open-label, dose escalation safety and tolerability study of recombinant human Interleukin-21 (phase 1) followed by an open-label treatment study (phase 2a) in patients with stage IV malignant melanoma

Open for accrual at Cancer Trials Australia sites (Austin, Peter Mac, RMH).

Eligibility criteria:

- Histologically confirmed surgically incurable metastatic malignant melanoma
- Stage IV melanoma according to AJCC except resected stage IV patients with no evidence of disease
- Age ≥ 18 years
- Life expectancy at least 4 months
- ECOG 0–1
- Hb ≥ 100 , WBC ≥ 2.5 , neutrophils ≥ 1.5 , platelets ≥ 100 , lymphocytes ≥ 1.0
- Creatinine (Calculated) ≥ 60 mL/min
- Bilirubin $\leq 1.25 \times$ ULN, AST $\leq 2.5 \times$ ULN, LDH $\leq 2 \times$ ULN
- Not pregnant or breast-feeding women
- Effective contraception required
- No active infection requiring systemic treatment
- No HIV, Hepatitis B/C, or autoimmune disease
- No history of and signs/symptoms of uncontrolled brain metastases
- No chemotherapy within 4 weeks prior to entering the study
- No radiotherapy within 4 weeks prior to entering the study
- No major surgery requiring general anaesthesia within 4 weeks prior to entering study
- No concurrent systemic corticosteroids
- No symptomatic cardiac failure (NYHA) ≥ 2 , no Serious cardiac arrhythmias, no myocardial infarction within 12 months prior entering the study
- No prior malignancy (except BCC, SCC, carcinoma insitu of the cervix)

- No known or suspected allergy to IL-21 or related products
- No receipt of any investigational drug within 3 months prior to this trial

[Contact: Ian Davis, Austin Health, Ph: 9496 5726 / Grant McArthur, Peter Mac, Ph: 9656 1195 / Peter Gibbs, Royal Melbourne Hospital, Ph: 9347 6301]

Phase II, multi-centre open-label randomised study evaluating the anti-tumour activity of SB-485232, rhIL-18, administered as five daily intravenous infusions every 28 days in subjects with previously untreated metastatic melanoma

Open for accrual at Peter Mac.

Inclusion criteria:

A subject will be eligible for inclusion in this study only if **ALL** of the following criteria apply:

- Histologically confirmed metastatic melanoma not curable by other means.
- Presence of radiologically and/or clinically documented disease with at least one measurable lesion as defined by RECIST criteria (i.e., $= 2$ cm in diameter by conventional technique or $= 1$ cm in diameter by spiral computed tomography (CT))
- ECOG performance status of 0 or 1
- Male or female, at least 18 years of age or older
- Predicted life expectancy of at least 12 weeks in the estimation of the Investigator
- 12-lead ECG taken after at least a 10 minute rest with corrected Q-T interval (QTc) interval < 480 msec
- A female is eligible to enter and participate in the study if she is of a non-childbearing potential (i.e., physiologically incapable of becoming pregnant) including any female who:
 - has had a hysterectomy
 - has had a bilateral oophorectomy (ovariectomy)
 - has had a bilateral tubal ligation
 - is post-menopausal (demonstrate total cessation of menses for greater than 1 year), or if childbearing potential, has a negative serum pregnancy test at the Screen Visit, and agrees to one of the following GSK acceptable contraceptive methods:
 - complete abstinence from sexual intercourse for 14 days before exposure to the study drug, throughout the clinical trial, and for a period after the trial to account for the elimination of the study drug (minimum of 5 half-lives)

- any intrauterine device (IUD) with a documented failure rate of less than 1% per year
- vasectomised partner who is sterile prior to the female subject's entry and is the sole sexual partner for that female
- oral contraceptive (either combined or progesterone only)
- double barrier contraception (condom with spermicidal jelly, foam, suppository, or film; diaphragm with spermicide; or male condom and diaphragm)
- A male is eligible to enter and participate in the study if he either agrees to abstain from sex, use a condom with spermicide, or is surgically sterile
- A signed and dated written informed consent is obtained from the subject or the subject is legally acceptable representative prior to beginning Screen Visit assessments

Exclusion Criteria:

A subject will not be eligible for inclusion in this study if **ANY** of the following criteria apply:

- Received any prior chemotherapy (including regional therapy) or prior systemic therapy (including, but not limited to, hormonal therapy, immunotherapy, biological or investigational agents) for metastatic melanoma
- Ocular melanoma is the primary site of melanoma
- Only non-measurable disease (e.g., bone metastases) or only cutaneous or subcutaneous lesions less than 1 cm are present
- Known brain metastases or leptomeningeal disease
- Absolute neutrophil count less than 1,500/mm³
- Haemoglobin less than 9 g/dL (after transfusion if needed)
- Platelet count less than 75,000/mm³
- Creatinine clearance less than 50 mL/min as calculated by the Cockcroft-Gault Formula (see Appendix 2, Section 14.2). (Measured creatinine clearance greater than or equal to 50 mL/min by 24-hour urine collection will be acceptable in lieu of a calculated value.)
- Total bilirubin greater than or equal to 1.5 times the upper limit of normal (ULN)
- Known hepatitis B, hepatitis C, human T-cell lymphotropic viruses-1 and/or human immunodeficiency virus (HIV) infection
- Alanine aminotransferase or aspartate aminotransferase level greater than 2.5 times the ULN in the absence of liver metastases. Subjects with serum transaminase levels greater than 5 times the ULN in the presence of liver metastases may be enrolled following approval by the GSK Medical Monitor.
- Pregnant or lactating female
- Subject of reproductive potential not agreeable to using an effective contraceptive method as described above
- Any unstable, pre-existing major medical condition which in the judgement of the Investigator would render the subject inappropriate for study participation
- History of other malignancies except curatively excised carcinoma in situ of the cervix, non-melanomatous skin carcinoma, T1a or b prostate carcinoma noted incidentally during a trans-urethral resection of the prostate (TURP) with prostate-specific antigen values within normal limits since TURP, or superficial bladder cancer or other solid tumours curatively treated with no evidence of disease for 5 years
- Pre-existing clinically significant auto-immune or antibody-mediated disease
- History of ventricular arrhythmias requiring drug or device therapy OR history of angina, myocardial infarction, congestive heart failure (NYHA Class III or IV), or stroke within the past 6 months
- Psychological, familial, social, or geographical condition(s) not permitting compliance with the study protocol
- Concomitant anticoagulant therapy (except for warfarin 1 mg/day for central line prophylaxis)
- Requiring either concurrent systemic corticosteroids including oral steroids (e.g., prednisone or dexamethasone) OR continuous use of topical steroid creams or ointments or any steroid-containing inhalers
- Systemic corticosteroids including oral steroids OR continuous use of topical steroid creams or ointments or any steroid-containing inhalers within 14 days of study entry
- Major surgery within 28 days of study entry
- Palliative radiation therapy within 14 days of study entry
- Failure to recover from prior therapy including but not limited to major surgery, radiotherapy, immunotherapy, biological therapy, or investigational agents

[Contact: Grant McArthur, Peter Mac, Ph: 9656 1195]

Phase III randomised, placebo controlled study of sorafenib (BAY 43-9006) with paclitaxel / carboplatin chemotherapy in unresectable stage III or stage IV melanoma

Open for accrual at Alfred, Austin and Peter Mac.

Inclusion criteria:

- Histologically or cytologically confirmed unresectable (Stage III) or metastatic (Stage IV) cutaneous melanoma
Measurable disease (RECIST). Cutaneous lesions measuring at least 1 cm will be considered measurable
- ECOG performance status 0–1
- Life expectancy 12 weeks
- Progression after DTIC (minimum total dose 850 mg/m²) or temozolomide (minimum total dose 750 mg/m²)
- Not more than one prior regimen in either the adjuvant or metastatic setting, including biologicals or other investigational treatment
- Recovery from previous chemotherapy, biologic therapy, or radiation treatment
- At least 4 weeks since prior therapy
- Adequate bone marrow, liver and renal function

Exclusion criteria:

- Primary ocular or mucosal melanoma
- Other previous or concurrent cancer
- Significant cardiac disease (CCF, arrhythmia, IHD).
- Uncontrolled hypertension.
- Clinically serious infections
- Seizure disorder requiring medication
- History of or suspected HIV infection or chronic hepatitis B or C

- Active CNS metastatic or meningeal tumours
- History of organ allograft or stem cell transplantation
- Prior treatment with a Ras pathway inhibitor (including trastuzumab, farnesyl transferase inhibitors or MEK inhibitors), or treatment with a drug which targets VEGF (such as bevacizumab)
- Radiotherapy, except palliative radiotherapy during study participation (see protocol)
- Major surgery within 4 weeks of study entry
- Biological response modifiers within 3 weeks of study entry
- Use of St John's Wort and rifampicin during the study or within 3 weeks of the first dose of study entry
- Known or suspected allergy to the investigational agent or any agent given in association with this trial
- Unresolved chronic toxicity

[Contact: Andrew Haydon, Alfred Hospital, Ph: 9276 2000 / Jonathan Cebon, Austin Health, Ph: 9496 5726 / Grant McArthur, Peter Mac, Ph: 9656 1195]

TROG 05.01 (POST)—Post-operative concurrent chemo-radiotherapy versus post-operative radiotherapy in high-risk cutaneous squamous cell carcinoma of the head and neck

The main eligibility criteria are that patients are post-operative, have a high-risk feature and suitable for weekly carboplatin and 6 weeks of radiotherapy. Patients must have undergone complete resection of all visible, palpable and image-able gross disease, with or without microscopic positive margins.

[Contact: Lester Peters, Peter MacCallum Cancer Centre, Ph: 9656 1004]

Guidelines for the Management of Cutaneous Melanoma (1999)

The chapter leaders to revise these guidelines have been recruited and their teams established. This document will be developed within the NHMRC program. Funding has been obtained from the Cancer Institute New South Wales to achieve this. The first Working Party meeting was held and enthusiasm is high.

Reprinted from Wong J Yabber Aug 2005; 12(3): 2.

Key Published Articles Listing—Skin Cancer

Title	Author & Journal
<p>Managing skin cancer: 23 golden rules <i>Excellent summary pitched at GPs for management of skin cancer.</i></p>	<p>Dixon AJ & Hall RS. Australian Family Physician Aug 2005; 34(8): 669–671.</p>
<p>Biology of desmoplastic melanoma: A case-control comparison with other melanomas <i>Case-control study of desmoplastic melanoma. Survival is similar, local control more difficult (no mention of radiotherapy), sentinel node involvement less common.</i></p>	<p>Livestro DP, Muzikansky A, Kaine EM, et al. Journal of Clinical Oncology 20 Sep 2005; 23(27): 6739–6746.</p>

Key Published Articles Listing—General

Title	Author & Journal
<p>Australia's media reporting of health and medical matters: A question of quality [Editorial]</p>	<p>Van Der Weyden MB & Armstrong RA. The Medical Journal of Australia Aug 2005; 183(4): 188–189.</p>
<p>Evidence-based journalism: A forlorn hope? [Commentary]</p>	<p>Swan N. The Medical Journal of Australia Aug 2005; 183(4): 194–195.</p>
<p>Attitudes on oncology health professionals to information from the Internet and other media</p>	<p>Newnham GM, Burns WI, Snyder RD, et al. The Medical Journal of Australia Aug 2005; 183(4): 197–200.</p>
<p>Keynote comment: Dumbing down of complementary medicine</p>	<p>Ernst E. The Lancet Oncology July 2005; 6(7): 442–443.</p>
<p>Protecting health information privacy in research: how much law do Australians need?</p>	<p>Thomson CJH. The Medical Journal of Australia Sep 2005; 183(6): 315–317.</p>

Forthcoming Meetings

Date / Place	Meeting / Contact
1–5 February 2006 Auckland, New Zealand	Annual Scientific Meeting of the New Zealand Dermatological Society Inc. E-mail: suepeck@xtra.co.nz Website: http://dermnetnz.org/doctors/meetings.html
9–12 February 2006 Lorne, VIC, Australia	18th Lorne Cancer Conference Secretariat: ASN Events Pty Ltd Ph: (03) 5983 2400 E-mail: cancer@asnevents.net.au Website: www.lornecancer.org
11–17 February 2006 St Julians, Malta	5th Masterclass in Clinical Oncology European School of Oncology (ESO) Ph: +41 91 811 8050 Fax: +41 91 811 8051 E-mail: masterclass@esoncology.org Website: www.cancerworld.org/eso
16–18 February 2006 St Gallen, Switzerland	4th International Conference on Cancer Prevention St Gallen Oncology Conferences c/o ZeTuP, Rorschacherstr. 150 CH-9006 St Gallen / Switzerland Ph: +41 071 243 08 90 Fax: +41 071 245 68 05 E-mail: info@oncoconferences.ch
16–19 February 2006 Amelia Island, Florida, USA	3rd Annual Conference of the American Psychosocial Oncology Society (APOS) Ph: +1 434 293 5350 Fax: +1 434 977 1856 E-mail: info@apos-society.org Website: www.apos-society.org
3–7 March 2006 San Francisco, California, USA	64th Annual Meeting of the American Academy of Dermatology Website: www.aad.org
12–18 March 2006 Lugano, Switzerland	3rd International Conference on Translational Research and Pre-Clinical Strategies in Radiation Oncology (ICTR2006) In collaboration with the European School of Oncology (ESO). Ph: +41 79 310 4330 Fax: +41 91 811 8678 E-mail: jacques.bernier@hcuge.ch Website: www.iosi.ch/ictr2006.html

Date / Place	Meeting / Contact
16–18 March 2006 Amsterdam, Netherlands	4th International Symposium on Targeted Anticancer Therapies Co-organised by the NDDO Research Foundation and the European Society for Medical Oncology (ESMO). Secretariat: Convenience Conference Management, PO Box 77, 3480 DB Harmelen, The Netherlands Ph: +31 348 567 667 Fax: +31 348 446 057 E-mail: congress@nddo.org Website: www.nddo.org/page_include_tat2006.shtml
23–26 March 2006 San Diego, California, USA	Annual Meeting of the Society of Surgical Oncology (SSO) Website: www.surgonc.org
1–5 April 2006 Washington DC, USA	97th Annual Meeting of the American Association for Cancer Research (AACR) AACR, Public Ledger Building, Suite 826, 150 South Independence Mall West, Philadelphia 19106 USA Ph: +1 215 440 9300 Fax: +1 251 351 9165 E-mail: meetings@aacr.org Website: www.aacr.org
7–11 May 2006 Cairns, QLD, Australia	Annual Scientific Meeting of the Royal Australasian College of Physicians (RACP) Website: www.racp.edu.au
14–17 May 2006 Melbourne, VIC, Australia	39th Annual Scientific Meeting of the Australasian College of Dermatologists – Occupational Dermatology and Cancers of the Skin Website: www.dermcoll.asn.au
15–19 May 2006 Sydney, NSW, Australia	Annual Scientific Congress of the Royal Australasian College of Surgeons (RACS) ASC Coordinator: Campbell Miles Ph: (03) 9276 7420 Fax: (03) 9276 7431 E-mail: campbell.miles@surgeons.org Website: www.surgeons.org
17–20 May 2006 Lindeman Island, QLD, Australia	Annual Scientific Meeting of the Trans-Tasman Radiation Oncology Group (TROG) TROG 2006; C/- Pharma Events, PO Box 265, Annandale NSW 2038 Ph: (02) 9280 0577 Fax: (02) 92800533 E-mail: trog@pharmaevents.com.au ; Website: http://trog.ranzcr.edu.au

Date / Place	Meeting / Contact
2–6 June 2006 Atlanta, Georgia, USA	42nd Annual Meeting of the American Society of Clinical Oncology (ASCO) American Society of Clinical Oncology, 1900 Duke Street, Suite 200, Alexandria Virginia 22314 USA Ph: +1 703 299 0150 Fax: +1 703 299 1044 E-mail: asco@asco.org Website: www.asco.org
15–17 June 2006 Stockholm, Sweden	6th International Conference on Adjuvant Therapy of Malignant Melanoma E-mail: 6icatmm@congrex.se Website: www.congrex.com
18–21 June 2006 Glasgow, Scotland	9th Cancer Research UK Beatson International Cancer Conference: 24 years of Ras and Human Cancer Beatson Institute for Cancer Research, Glasgow, United Kingdom Ph: +44 14 1942 0855 Fax: +44 14 1330 6426 E-mail: t.wheeler@beatson.gla.ac.uk Website: www.beatson.gla.ac.uk/seminars/conference.html
22–25 June 2006 Toronto, Ontario, Canada	18th International Symposium of the Multinational Association of Supportive Care in Cancer (MASCC) Website: www.mascc.org
1–4 July 2006 Budapest, Hungary	19th Meeting of the European Association for Cancer Research (EACR) EACR 19 Conference Secretariat, Federation of European Cancer Societies, Avenue E. Mounier 83, B-1200 Brussels Ph: +32 2 775 02 05 Fax: +32 2 775 02 00 E-mail: EACR19@fecs.be Website: www.fecs.be
8–12 July 2006 Washington DC, USA	UICC World Cancer Congress American Cancer Society, 1599 Clifton Rd, NE, Atlanta Georgia 30329-4251 USA Ph: +1 404 417 5998 Fax: +1 404 728 0133 E-mail: secretariat2006@cancer.org Website: www.worldcancercongress.org

The Cancer Council Victoria

The Cancer Council Victoria is a public institution set up by an Act of Parliament in 1936. It operates as a charity, relies heavily on volunteer support, and raises and spends \$3-\$4 per head of population annually. It is governed by the Council and Executive and other committees. It's mission is to lead, coordinate and evaluate action to minimise the human cost of cancer for all Victorians. The Cancer Council houses three research divisions (behavioural science, clinical research, epidemiology) and units undertaking public and professional education, cancer registration, cancer information and support services, anti-smoking campaign (QUIT), finance, administration and fund raising. It employs about 300 staff. The Cancer Council also auspices a cooperating network of cancer specialists through the Victorian Cooperative Oncology Group and resources an expert Medical & Scientific Committee to dispense studentships, scholarships, fellowships and research grants to other academic, research and medical institutions.

Centre for Clinical Research in Cancer — Victorian Cooperative Oncology Group

The Centre for Clinical Research in Cancer (CCRC) formed in 1997, provides a coordinated and effective resource for collaborative clinical research and development in Victoria. The Centre provides administrative and research support for the Victorian Cooperative Oncology Group, which brings together Victoria's cancer specialists. The Centre fosters and facilitates the development and promotion of a range of collaborative clinical measures to optimise cancer management.

The Victorian Cooperative Oncology Group (VCOG) established in 1976, provides advice to the Cancer Council Victoria, through the CCRC, on all clinical aspects of cancer control, in particular research, screening, diagnosis, treatment, palliative medicine, cancer genetics and professional education. The strategic role of VCOG is to have a 'parliament' of clinical cancer specialists with a view to promoting a range of cooperative measures to optimise cancer treatment in Victoria. VCOG consists of a primary committee, 9 cancer-site and 3 task-specific advisory committees, and 5 trial research sub-committees. These committees bring together in regular meetings approximately 400 key specialist health care professionals and scientists, representing the various treatment disciplines and centres in Victoria. VCOG has established unique linkages between public and private health care professionals, institutions and governments.

