CANCER CLINICAL TRIALS CENTRE

TRIALS OPEN FOR ACCRUAL
January 2016

Cancer Services
Austin Health

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Authorised by: Dr Niall Tebbutt, Austin Health Oncology Unit; and staff of Cancer Clinical Trials Centre, Austin Health.
Date authorised: January 2016
Review date: March 2016
Austin Intranet link: http://hub/cancerclinicaltrialstrials
Medical Oncology

Clinical Haematology
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<td>Dr Lawrence Cher</td>
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<td>Dr Geoff Chong</td>
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<td>A/Prof Tom John</td>
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## Clinical Haematology Principal Investigators

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<td>Prof Andrew Grigg</td>
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<td>A/Prof Carole Smith</td>
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Medical Oncology Cancer Clinical Trial Staff

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<thead>
<tr>
<th>Study Coordinators / Fellows</th>
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<td>Tina Cavicchiolo</td>
<td>9496 3575 / page 3575</td>
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<td>Catherine Johnston</td>
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<td>Lucy Demeo</td>
<td>9496 9916 / page 1733</td>
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<td>Elizabeth Cooch</td>
<td>9496 3576 / page 1101</td>
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<tr>
<td>Yali Liu</td>
<td>9496 9863 / page 1103</td>
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<tr>
<td>Jenni Flynn</td>
<td>9496 3651 / page 6745</td>
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<tr>
<td>Lotus Wannarath</td>
<td>9496 3084 / page 3084</td>
</tr>
<tr>
<td>Christine Vanrenenen</td>
<td>9496 9712 / page 1988</td>
</tr>
<tr>
<td>Jaren Caine</td>
<td>9496 3906 / page 1775</td>
</tr>
<tr>
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<td>9496 9918 / page 1503</td>
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<td>Trish Jenkins</td>
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<td><strong>Dr Surein Arulananda (MORF1)</strong></td>
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<td>Pager: 9496 5000 then page 3990</td>
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<td>E: <a href="mailto:Surein.Arulananda@austin.org.au">Surein.Arulananda@austin.org.au</a></td>
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Trials Open for Accrual January 2016

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Clinical Haematology Cancer Clinical Trial Staff

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<thead>
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<td>9496 6731 / page 6731</td>
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<td>9496 9902 / page 1770</td>
</tr>
<tr>
<td>Stephanie O’ Brien</td>
<td>9496 4352 / page 4354</td>
</tr>
<tr>
<td>Laura Katherine Johnston</td>
<td>9496 6732 / page 6732</td>
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<td>Samantha Soggee</td>
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<tr>
<td>Peter Shuttleworth</td>
<td>9496 5236 / 0416 013 927</td>
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<tr>
<td>Priscilla Gates</td>
<td>9496 4617/ page 3460</td>
</tr>
<tr>
<td>Faye Putt</td>
<td>9496 3230</td>
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                                         E: Matthew.Ku@austin.org.au |

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Clinical Trials Screening Line

(03) 9496 3088

Please leave a message to record details of patients screened for oncology clinical trials.

Please leave the following details:

Patient contact information

- Referrer’s contact details and provider number
- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

NOTE: Any patient on a clinical trial admitted to any hospital for any reason (for at least one overnight stay) requires a Serious Adverse Event report to be submitted within 24 hours of our becoming aware of it. Notify Trials Centre staff as soon as possible if this occurs. After hours, use the 9496 3088 line to notify SAEs.
# Brain

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Brain: Glioblastoma Multiforme (GBM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td><strong>M12-356: A Phase 1 Study Evaluating the Safety and Pharmacokinetics of ABT-414 for Subjects with Glioblastoma Multiforme</strong></td>
</tr>
</tbody>
</table>

**Study Synopsis:**

This is a Phase 1 open-label study evaluating the safety and pharmacokinetics of ABT-414 (an anti-EGFR drug conjugate) as monotherapy or in combination with TMZ in patients with recurrent GBM. ABT-414 will be given every 2 weeks by intravenous (IV) infusion.

**Key eligibility criteria:**

**Inclusion Criteria:**

- Subject has a histologically proven, WHO grade IV glioblastoma or WHO grade IV gliosarcoma.
- The tumour must be supratentorial in location
- Subject has a Karnofsky Performance Status (KPS) 70 or above.
- Tumours must be EGFR amplified and/or have EGFRvIII deletion mutation by central laboratory testing.
- Subject has adequate bone marrow, renal, and hepatic function
- Subject has one of the following available for pharmacodynamic analyses.  
  o Archived diagnostic or freshly obtained formalin-fixed paraffin embedded (FFPE) or frozen tumour tissue
  o Tumour tissue biopsy collected prior to study drug administration
- Patient has measurable and/or non-measurable lesion per RANO criteria
- Must have radiological progression within 3 months of last dose of temozolomide

**Exclusion Criteria:**

- Prior treatment with bevacizumab or nitrosourea for GBM
- Subject has secondary GBM
- Prior EGFR therapy for GBM, including EGFR vIII immunotherapies

**Contact:**

A/Prof Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P:9496 9929; Pager: 94965000 then page 3248; or E: Malaka.ameratunga@austin.org.au)

**To refer patient:**

To minimise delays, please fax a referral to the 03-9457-6698 with:

- Patient contact information
- Referrer’s contact details and provider number
- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>A/Prof Hui Gan</th>
<th>After hours contact:</th>
<th>via Austin switch: 9496 5000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Study Co-ordinator:</td>
<td>Jenni Flynn</td>
<td>P: 9496 3651</td>
<td>Pg: 6745</td>
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<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>LUD2013-006: Phase 2 study to Evaluate the Clinical Efficacy and Safety of MEDI4736 in Patients with Glioblastoma (GBM)</strong></td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>This is a Phase 2 open-label study evaluating the safety and pharmacokinetics of MEDI4736 (antibody targeting PD-L1). 2 cohorts are currently recruiting – Arm A (adjuvant, in MGMT unmethylated disease) and Arm C (post bevacizumab).</td>
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<tr>
<td><strong>Key eligibility criteria:</strong></td>
<td><strong>Inclusion Criteria:</strong></td>
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<td></td>
<td>• Arm A:</td>
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<td>o Newly diagnosed unmethylated GBM, eligible for radiotherapy (full course)</td>
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<td>• Arm C</td>
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<td>o 1st or 2nd recurrence by RANO criteria or biopsy</td>
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<td>o One bevacizumab containing regimen</td>
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<td>• All Arms:</td>
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<td>o Measurable or non-measurable disease</td>
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<td>• Brainstem or spinal cord GBM; metastatic disease or leptomeningeal disease</td>
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<td>• Local therapies including: stereotactic radiosurgery, gliadel, re-irradiation within 6 months</td>
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<td>• Autoimmune disorders</td>
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<td>• Active or chronic hepatitis; cleared hepatitis is allowed</td>
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<td>• High dose steroids/immunosuppressive agents (use for cerebral oedema is allowed)</td>
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<tr>
<td><strong>Contact:</strong></td>
<td>A/Prof Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: <a href="mailto:Malaka.ameratunga@austin.org.au">Malaka.ameratunga@austin.org.au</a>)</td>
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# Breast - Early

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<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>KAITLIN (BO28407): A Randomized, Open-Label Phase III Trial Comparing Trastuzumab plus Pertuzumab plus Taxane Vs. A Taxane Following Anthracyclines vs. Trastuzumab Emtamsine plus Pertuzumab Following Anthracyclines as Adjuvant Therapy in Operable HER2-positive Breast Cancer</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Randomised Phase III trial of adjuvant systemic therapy in early (operable) Her2+ breast cancer. Patients are randomised to trastuzumab+pertuzumab+taxane VS TDM-1+pertuzumab after adjuvant anthracycline.</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | Inclusion Criteria:  
- Her2+  
- Node+ with any receptor status; OR node negative with T2 primary (>2cm) and ER/PR negative  
- Synchronous bilateral disease is allowed if all lesions Her2+  
- Randomized within 9 weeks of surgery  
Exclusion Criteria:  
- T4 or inflammatory breast cancer  
- Any prior invasive breast cancer  
- Non-breast malignancies within 5yrs (except if in situ or SCC/BCC)  
- Cardiac dysfunction, poorly controlled hypertension |
| **Contact:** | Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au) |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:  
- Patient contact information  
- Referrer’s contact details and provider number  
- Brief clinical history  
- Whether the patient has been discussed with a particular trials personnel already |
| **Principal Investigator:** | A/Prof Shane White |
| **Primary Study Co-ordinator:** | Lucy Demeo |
| **After hours contact:** | P: 9496 9916 |
| **via Austin switch:** | 9496 5000 |
| **Pg:** | 1733 |
Breast - Advanced

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Breast: Advanced, Triple Negative</th>
</tr>
</thead>
</table>

**Protocol & Title:** METRIC (CDX011-04): A Randomized Multicentre Pivotal Study of CDX-011 (CR011vcMMAE) in Patients with Metastatic, GPNMB Over-Expressing, Triple-Negative Breast Cancer

**Study Synopsis:** Randomised Phase 3 trial in metastatic triple negative breast cancer which overexpresses GPNMB (pre-screening required). 2:1 randomisation to glembatumumab vedotin (CDX-011, a monoclonal antibody drug conjugate) or capecitabine.

**Key eligibility criteria:**

**Inclusion Criteria:**
- Metastatic Biopsy required: GPNMB overexpression in tumour sample obtained in advanced disease (ie not WLE from primary surgery if relapsed disease) – **pre-screening for this**
- 0-2 prior chemo regimens for advanced disease
- Prior anthracycline and taxane received (may have been in adjuvant/neoadjuvant setting)
- Documented disease progression after last anticancer regimen
- ECOG 0-1
- Measurable disease by RECIST 1.1

**Exclusion Criteria:**
- Progression within 6/12 adjuvant/neoadjuvant chemo
- >G1 neuropathy
- Brain metastases untreated or within 2 months
- QTc>450 or predisposing conditions, medications

**Contact:** Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)

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<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Shane White</th>
<th>After hours contact:</th>
<th>via Austin switch: 9496 5000</th>
</tr>
</thead>
</table>

<p>| Primary Study Co-ordinator: | Catherine Johnstone | P: 9496 3038 | Pg: 3038 |</p>
<table>
<thead>
<tr>
<th><strong>Tumour Type:</strong></th>
<th><strong>Breast:</strong> Advanced, BRCA1/2 carrier</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>BIOMARIN/EMBRACA (673-301):</strong> A Phase 3, Open-Label, Randomized, Parallel, 2-Arm, Multi-Centre Study of BMN 673 versus Physician’s Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, Who Have Received No More than 2 Prior Chemotherapy Regimens for Metastatic Disease</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Randomised Ph III trial in Locally advanced and/or Metastatic Breast Cancer in germline BRCA1/2 carriers. Patient receive BMN-673 (novel oral PARP-inhibitor) vs physician’s choice chemo (gemcitabine/capecitabine/vinorelbine) in a 2:1 randomisation</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**  
- Known BRCA1/2 carrier OR meets NCCN guidelines for testing (Biomarin will fund testing through Myriad)  
- 0, 1 or 2 prior lines of chemotherapy (does not include endocrine therapy)  
- Prior taxane and/or anthracycline exposure (in adjuvant or metastatic setting)  
**Exclusion Criteria:**  
- De novo Stage IV breast cancer ie no prior chemo  
- Prior PARP-inhibitor  
- Prior platinum for metastatic disease OR within 12mths  
- Her2+ breast cancer  
- Inflammatory breast cancer  
- Untreated brain metastases  
- Leptomeningeal disease |
| **Contact:** | **Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)** |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:  
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- Brief clinical history  
- Whether the patient has been discussed with a particular trials personnel already |
| **Principal Investigator:** | Shane White |
| **After hours contact:** | via Austin switch: 9496 5000 |
| **Primary Study Co-ordinator:** | Elizabeth Cooch |
| **P:** | 9496 3576 |
| **Pg:** | 1101 |
**Tumour Type:** Breast: Advanced

**Protocol & Title:** GO29058 – (SANDPIPER): A phase III, double-blind, placebo-controlled, randomized study of Teselisib plus Fulvestrant versus placebo plus Fulvestrant in postmenopausal women with estrogen receptor-positive and HER2-negative locally advanced or metastatic breast cancer who have disease recurrence or progression during or after aromatase inhibitor therapy

**Study Synopsis:** Randomised phase III trial of Fulvestrant plus Taselisib/placebo (oral PI3Ki) for treatment of hormone receptor positive, HER2-negative advanced breast cancer in postmenopausal women after treatment with AI

**Key eligibility criteria:**

**Inclusion Criteria:**
- Postmenopausal
- Tissue block available and appropriate for PIK3CA mutation testing (a cohort of wild type patients will also be included)
- Advanced breast cancer that is ER+ve and HER2-negative
- Progression while on or within 12 months of the end of adjuvant treatment with an AI, or while on or within 1 month of the end of prior AI treatment in the advanced setting
- Measurable disease or non-measurable, evaluable disease with at least one evaluable bone lesion that has not been previously irradiated

**Exclusion Criteria**
- Prior mTOR inhibitor
- Prior treatment with > 1 cytotoxic chemotherapy regimen for MBC
- CNS metastases that have not been treated
- Type 1 or Type 2 diabetes mellitus requiring anti-hyperglycaemic medications

**Contact:** Dr Stephen Luen (Fellow; P:9496 9933) or Pager: 94965000 then page 5264; or E: Stephen.luen@austin.org.au

**To refer patient:** To minimise delays, please fax a referral to the 03-9457-6698 with:
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- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

**Principal Investigator:** A/Prof Shane White  
**After hours contact:** via Austin switch: 9496 5000

**Primary study Co-ordinator:** Lucy Demeo  
P: 9496 9916  
Pg: 1733

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Trials Open for Accrual January 2016

Colorectal - Advanced

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Colorectal - Advanced</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>AG0112CR – (ICECREAM): Randomised Phase II study of cetuximab alone or in combination with irinotecan in patients with metastatic CRC with either KRAS WT or G13D mutation.</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Randomised phase II study of Cetuximab alone or in combination with Irinotecan in patients with metastatic CRC</td>
</tr>
<tr>
<td><strong>Key eligibility criteria:</strong></td>
<td><strong>Inclusion Criteria:</strong></td>
</tr>
<tr>
<td></td>
<td>• Histologically confirmed colorectal cancer, not amenable to complete resection</td>
</tr>
<tr>
<td></td>
<td>• Measurable disease</td>
</tr>
<tr>
<td></td>
<td>• Prior confirmation of tumour RAS status as wild type</td>
</tr>
<tr>
<td></td>
<td>• ECOG 0-1</td>
</tr>
<tr>
<td></td>
<td>• Received and progressed on, or intolerant of a thymidylicate synthase inhibitor, and Irinotecan containing regimen, and an Oxaliplatin containing regimen (or deemed unsuitable; failure of a regimen is defined as progression within 6 months of prior therapy)</td>
</tr>
<tr>
<td></td>
<td><strong>Exclusion Criteria</strong></td>
</tr>
<tr>
<td></td>
<td>• Prior Cetuximab or drugs targeting the EGFR pathway</td>
</tr>
<tr>
<td></td>
<td>• Severe restrictive lung disease or interstitial lung disease</td>
</tr>
<tr>
<td></td>
<td>• Untreated or symptomatic brain metastases</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Dr Stephen Luen (Fellow; P:9496 9933) or Pager: 94965000 then page 5264; or E: <a href="mailto:Stephen.luen@austin.org.au">Stephen.luen@austin.org.au</a>)</td>
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<thead>
<tr>
<th>Principal Investigator:</th>
<th>A/Prof Niall Tebbutt</th>
<th><strong>After hours contact:</strong></th>
<th>via Austin switch: 9496 5000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Yali Liu</td>
<td>P: 9496 9863</td>
<td>Pg: 1103</td>
</tr>
</tbody>
</table>

Disclaimer: Printed Versions of this document can only be considered up-to-date for a period of one month from the printing date after which, the latest version should be downloaded and printed.
| **Tumour Type:** | Breast: Advanced |
| **Protocol & Title:** | CLEE011E2301 - (MONALEESA-7): A Phase III randomized, double-blind, placebo controlled study of LEE011 or placebo in combination with tamoxifen and goserelin or a non-steroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer |
| **Study Synopsis:** | Randomised phase III trial of 1st line endocrine therapy plus LEE011/placebo (oral CDK4/6i) for first line treatment of hormone receptor positive, HER2 negative advanced breast cancer in premenopausal women |

### Key eligibility criteria:

**Inclusion Criteria:**
- Premenopausal or perimenopausal
- Advanced breast cancer not amenable to curative therapy
- ≤ 1 lines of chemotherapy in the advanced setting
- ER+ve and/or PR+ve breast cancer that is HER2-negative
- Measurable disease or at least one predominantly lytic bone lesion

**Exclusion Criteria**
- Postmenopausal
- Inflammatory breast cancer at screening
- Any prior hormonal anti-cancer therapy (except ≤ 14 days prior to randomisation)
- CNS metastases

**Contact:**
Dr Stephen Luen (Fellow; P:9496 9933) or Pager: 94965000 then page 5264; or E: Stephen.luen@austin.org.au

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**Principal Investigator:**
A/Prof Shane White

**Primary study Co-ordinator:**
Yali Liu
P: 9496 9863
Pg: 1103

**After hours contact:**
via Austin switch: 9496 5000
# Gastro-Oesophageal - Early

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Gastric &amp; Gastroesophageal: Early Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>TOPGEAR (AG0407GR TROG 08.08): A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer</td>
</tr>
</tbody>
</table>

| Study Synopsis: | A two arm randomised phase II/III trial in which patients are randomised to either preoperative chemotherapy alone (ECF or ECX) or preoperative chemoradiation (2 cycles ECF or ECX followed by 5FU continuous with 45Gy Radiotherapy). Acceptable surgery is total gastrectomy, a subtotal gastrectomy, and an esophagogastrectomy, minimum D1+ lymph node dissection. Post-operative chemotherapy with 3 cycles ECF or ECX is then recommended. Primary endpoint is overall survival. |

<table>
<thead>
<tr>
<th>Key eligibility criteria:</th>
<th>Inclusion Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Stage IB (T1N1 only, not T2N0) to IIIC cancer of the stomach or gastroesophageal junction</td>
</tr>
<tr>
<td></td>
<td>ECOG 0-1</td>
</tr>
<tr>
<td></td>
<td>Disease that can be radically treated with radiotherapy 45Gy</td>
</tr>
<tr>
<td>Exclusion Criteria:</td>
<td>Cardiac failure or other epirubicin contraindication</td>
</tr>
<tr>
<td></td>
<td>Impaired GI absorption</td>
</tr>
<tr>
<td></td>
<td>Medically unfit for cisplatin (including GFR &lt;50ml/min)</td>
</tr>
</tbody>
</table>

| Contact: | Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au) |

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<td>Brief clinical history</td>
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<td>After hours contact:</td>
</tr>
<tr>
<td></td>
<td>via Austin switch: 9496 5000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primary Study Co-ordinator:</th>
<th>Donna Haberl / Julie Costantin</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>P: 9496 3762 / 9496 3548</td>
</tr>
<tr>
<td></td>
<td>Pg: 6746 / 6746</td>
</tr>
</tbody>
</table>

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# Gastro-Esophageal - Advanced

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Gastric &amp; Gastroesophageal: Advanced</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>BRIGHTER (BBI608-336): A Phase III randomized, double-blind, placebo-controlled clinical trial of BBI608 plus weekly Paclitaxel vs. Placebo plus weekly Paclitaxel in Adult patients with advanced, previously treated Gastric and Gastro-Esophageal Junction Adenocarcinomas</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>This is a phase III, randomized, double blind study of pre-treated advanced Gastric and Gastroesophageal adenocarcinoma with weekly Paclitaxel plus BBI608/placebo. BBI608 is a novel oral small molecule stem cell inhibitor. Primary end point is overall survival.</td>
</tr>
</tbody>
</table>

## Key eligibility criteria:

<table>
<thead>
<tr>
<th>Inclusion Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Histologically confirmed metastatic or locally advanced and unresectable Gastric or Gastroesophageal adenocarcinoma</td>
</tr>
<tr>
<td>• Failed at least one regimen containing at least a platinum/fluoropyrimidine doublet for unresectable or metastatic disease</td>
</tr>
<tr>
<td>• Measurable disease or non-measurable evaluable disease</td>
</tr>
<tr>
<td>• ECOG 0 or 1</td>
</tr>
<tr>
<td>• Adequate bone marrow, renal, and hepatic function</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prior treatment with a taxane in the advanced setting or within 6 months if used in the neoadjuvant or adjuvant setting</td>
</tr>
<tr>
<td>• More than one prior chemotherapy regimen administered in the metastatic setting</td>
</tr>
<tr>
<td>• Symptomatic brain metastases</td>
</tr>
<tr>
<td>• Peripheral neuropathy ≥ grade 2 CTCAE</td>
</tr>
</tbody>
</table>

**Contact:**

Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)

## To refer patient:

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• Referrer’s contact details and provider number
• Brief clinical history
• Whether the patient has been discussed with a particular trials personnel already

## Principal Investigator:

A/Prof Niall Tebbutt

**After hours contact:** via Austin switch: 9496 5000

## Primary Study Co-ordinator:

Catherine Johnston

P: 9496 3038  
Pg: 3038
# Genito-urinary - Prostate Cancer

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>PROPS (GAP02-01.1): PET /MRI pre-Radiotherapy for Post-Prostatectomy Salvage</td>
</tr>
</tbody>
</table>
| Study Synopsis:  | • For patients with PSA failure post radical prostatectomy who are candidates for salvage radiotherapy  
                   • Non-interventional study using choline PET and whole body / pelvic MRI to lx metastatic disease to guide clinical decision making |
| Key eligibility criteria: |  |
| Inclusion Criteria: | • No metastatic disease on conventional imaging (CT and WBBS)  
                           • N0 or Nx based on original prostatectomy  
                           • PSA rise x3 and ≥ 0.2ng/mL at enrolment  
                           • At least 1 adverse feature: current PSA≥1, Gleason≥8, pT3b or PSADT≤10m |
| Exclusion Criteria: | • Histo: significant sarcomatoid spindle cell or neuroendocrine small cell components  
                           • post void bladder vol >150ml  
                           • any ADT within 6months of enrolment  
                           • contraindications for radical radiotherapy or MRI  
                           • sickle cell disease or other anaemias, GFR <30 |
| Contact:         | Dr Andrew Weickhardt or (PI) Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au) |
| To refer patient:| To minimise delays, please fax a referral to the 03-9457-6698 with:  
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<th>After hours contact:</th>
<th>via Austin switch: 9496 5000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Study Co-ordinator:</td>
<td>Trish Jenkins</td>
<td>P: 9496 4301</td>
<td>Pg: 4300</td>
</tr>
<tr>
<td>Tumour Type:</td>
<td>Prostate Cancer</td>
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</tr>
<tr>
<td>Protocol &amp; Title:</td>
<td>PROSPER (MDV3100-14): A Multinational, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Enzalutamide in Patients with Nonmetastatic Castration-Resistant Prostate Cancer</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Study Synopsis: | • Phase III of Enzalutamide vs placebo (2:1) in patients with M0 CRPC  
• Consider ceasing anti-androgen therapy on referral of patient, as 4 weeks washout required |
| Key eligibility criteria: |  
**Inclusion Criteria:**  
• Medical or surgical castration  
• PSA progression – PSA rise x3 and ≥ 2ng/mL and PSADT ≤ 10months  
• M0 on CT/MRI and WBBS. LN <15cm below aortic bifurcation permissible  
• Asymptomatic prostate ca. ECOG 0 or 1  

**Exclusion Criteria:**  
• prior chemo/ abiraterone/ enzalutamide/ ketoconazole  
• known or suspected CNS metastasis  
• h/o invasive cancer last 3 years  
• ANC <1.0, platelet <100, Hb <100, bili ≥ 1.5xULN, ALT/ AST ≥ 2.5xULN, Albumin <30, Cr >177  
• h/o seizure or predisposing conditions (eg stroke, ABI; h/o LOC or TIA within 12months)  
• clinically significant CVS disease |
| Contact: | Dr Andrew Weickhardt or (PI) Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au) |
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• Referrer’s contact details and provider number  
• Brief clinical history  
• Whether the patient has been discussed with a particular trials personnel already |
| Principal Investigator: | Dr Andrew Weickhardt  
After hours contact: via Austin switch: 9496 5000 |
| Primary Study Co-ordinator: | Chris Vanrenen  
P: 9496 9712  
Pg: 1988 |
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>ENZAMET (ANZUP 1304): Randomised phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer</td>
</tr>
</tbody>
</table>
| Study Synopsis: | • Phase III of Enzalutamide vs conventional ant androgen (1:1) in M1 hormone-naive prostate cancer (de novo metastatic prostate ca)  
• Must enrol within 12 weeks of starting hormone therapy |
| Key eligibility criteria: | Inclusion Criteria:  
• Evidence of prostate ca (histology or typical metastatic pattern + rising PSA >20)  
• Target or non-target lesions allowed  
• ECOG 2 allowed if decline in performance status due to prostate ca  
• Hb ≥ 100, WCC ≥ 4.0, platelets ≥ 100, ALT <2x ULN (<5x ULN if liver mets), bili <1.5x ULN, CrCl >30  
Exclusion Criteria:  
• Significant sarcomatoid / spindle cell/ small cell components  
• any prior ADT (unless started <12wk prior to randomization and PSA stable or falling, or completion of adjuvant ADT >12m prior)  
• h/o seizure or predisposing conditions (including LOC or TIA within 12 months)  
• clinically significant CVS disease  
• DVT/PE within last 3m  
• Another malignancy within 5 years |
| Contact: | Dr Andrew Weickhardt or (PI) Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au) |
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Principal Investigator: Dr Andrew Weickhardt | After hours contact: via Austin switch: 9496 5000 |
Primary Study Co-ordinator: Lotus Wannarath | P: 9496 3084 | Pg: 3084 |

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## Tumour Type:
Prostate Cancer

## Protocol & Title:
MOVEMBER FDHT: [18F]-dihydro-testosterone pet imaging in patients with progressive prostate cancer

### Study Synopsis:
Open label study in patients with progressive prostate adenocarcinoma and radiologically evident metastatic castrate-resistant disease to receive (PET) with [18F]-dihydrotestosterone (FDHT) twice, at baseline and again at either day 2, day 8 or day 28 to study the accumulation, biodistribution and kinetics of FDHT in patients with progressive prostate cancer.

### Key eligibility criteria:

#### Inclusion Criteria:
- Histologically confirmed diagnosis of prostate cancer (castrate or non-castrate).
- Disease progression manifest by either bone scan, CT scan, MRI or biochemical progression with a minimum of 3 rising PSAs from baseline ≥ 1 week apart.
- Target or non-target lesions based on RECIST 1.1.
- Written informed consent.
- Adequate organ function.

#### Exclusion Criteria:
- Previous anaphylactic reaction to FDHT.
- Contraindications to MRI.
- Current androgen receptor inhibitor use, including but not limited to bicalutamide, nilutamide, flutamide, cyproterone acetate, enzalutamide or experimental therapy. Participants must have been off such treatments for at least 28 days in order to be eligible for the study.
- Planned or probable commencement of new cytotoxic or hormonal therapy between the initial D1 FDHT PET and the follow up FDHT PET at D2, D8 or D22.

### Contact:
Andrew Weickhardt (Principal Investigator)
Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)

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<td>via Austin switch: 9496 5000</td>
</tr>
<tr>
<td>Primary Study Co-ordinator:</td>
<td>Sarah Healy</td>
</tr>
<tr>
<td></td>
<td>P: 9496 9918</td>
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<td></td>
<td>Pg: 1503</td>
</tr>
</tbody>
</table>
**Genito-Urinary - Other**

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Bladder Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>CBGJ398X2101: A Phase I, open-label, multicenter, dose escalation study of oral BGJ398, a pan FGFR kinase inhibitor, in adult patients with advanced solid malignancies</td>
</tr>
</tbody>
</table>
| **Study Synopsis:** | - FGFR3 mutant/fusion metastatic bladder cancer (dose expansion arm 4)  
- Phase I of an oral FGFR inhibitor BGJ398 125mg 3 weeks on, 1 week off  
- Requires tumour pre-screening for FGFR (mutation rate 5-15%). |
| **Key eligibility criteria:** | **Inclusion Criteria:**  
- Progression on prior platinum chemo OR platinum intolerance / contraindication  
- No more than 2 prior lines of systemic therapy  
- Measurable disease  
- WHO 0-2  
- Hb ≥ 100, ANC ≥ 1.5, platelets ≥ 75, ALT/AST ≤2.5x ULN (≤5x ULN if liver mets), bilirubin <1.5x ULN, Creatinine ≤1.5x ULN, proteinuria ≤ G1  
- Stable CNS metastasis (>1 month) allowed  

**Exclusion Criteria:**  
- Corneal disorders  
- Abnormal calcium, phosphate and albumin  
- H/o alteration of calcium-phosphate homeostasis (eg. Parathyroid disorders) or significant ectopic calcification  
- Active CVS disease  
- Radiotherapy >30% of bone marrow |
| **Contact:** | Dr Andrew Weickhardt or (PI) Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au) |
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<tr>
<td>Primary Study Co-ordinator:</td>
<td>Lotus Wannarath</td>
</tr>
<tr>
<td>P: 9496 3084</td>
<td>Pg: 3084</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Urothelial/Bladder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>MK3475-052: A Phase II Clinical Trial of Pembrolizumab (MK-3475) in Subjects with Advanced/Unresectable or Metastatic Urothelial Cancer</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase 2, non-randomized, open-label trial of pembrolizumab (MK-3475) in subjects with advanced/unresectable (inoperable) or metastatic urothelial cancer in first line, who are not eligible to receive cisplatin</td>
</tr>
<tr>
<td>Key eligibility criteria:</td>
<td>Inclusion Criteria:</td>
</tr>
<tr>
<td></td>
<td>• Histologically or cytologically-confirmed diagnosis of advanced/unresectable (inoperable) or metastatic urothelial cancer of the renal pelvis, ureter, bladder, or urethra</td>
</tr>
<tr>
<td></td>
<td>• Cisplatin-ineligible based on having at least one of the following criteria:</td>
</tr>
<tr>
<td></td>
<td>o ECOG performance status of 2</td>
</tr>
<tr>
<td></td>
<td>o Creatinine clearance &lt; 60 mL/min but &gt;30 mL/min</td>
</tr>
<tr>
<td></td>
<td>o CTCAE v.4, Grade &gt;2 audiometric hearing loss</td>
</tr>
<tr>
<td></td>
<td>o CTCAE v.4, Grade &gt;2 peripheral neuropathy</td>
</tr>
<tr>
<td></td>
<td>o NYHA Class III heart failure</td>
</tr>
<tr>
<td></td>
<td>• No prior systemic chemotherapy for advanced/unresectable or metastatic urothelial cancer</td>
</tr>
<tr>
<td></td>
<td>o Adjuvant/Neoadjuvant platinum based chemotherapy, following radical cystectomy, with recurrence &gt; 12 months from completion of therapy</td>
</tr>
<tr>
<td></td>
<td>• Subject has adequate bone marrow, renal, and hepatic function</td>
</tr>
<tr>
<td></td>
<td>• Have provided tissue for biomarker analysis from a newly obtained core or excisional biopsy of a tumour lesion not previously irradiated (mandatory).</td>
</tr>
<tr>
<td></td>
<td>• Patient has measurable RECIST 1.1</td>
</tr>
<tr>
<td>Exclusion Criteria:</td>
<td>• Prior treatment with mAb or anti-neoplastic within 4 weeks</td>
</tr>
<tr>
<td></td>
<td>• Subject has active CNS metastasis</td>
</tr>
<tr>
<td></td>
<td>• Subject has routine exclusions for immunotherapies</td>
</tr>
<tr>
<td>Contact:</td>
<td>Dr Andrew Weickhardt or (PI) Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or: <a href="mailto:Babak.Tamjid2@austin.org.au">Babak.Tamjid2@austin.org.au</a>)</td>
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<td>Primary Study Co-ordinator:</td>
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Page 25
Trials Open for Accrual January 2016

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Urothelial/Bladder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>GO29294: Atezolizumab compared with chemotherapy in patients with metastatic urothelial carcinoma</td>
</tr>
</tbody>
</table>

**Study Synopsis:**
A phase III, open-label, multicenter, randomized study to investigate the efficacy and safety of MPDL3280A (anti–PD-L1 antibody) compared with chemotherapy (paclitaxel/docetaxel/vinflunine) in patients with locally advanced or metastatic urothelial bladder cancer after failure of treatment with platinum-containing chemotherapy.

**Inclusion Criteria:**
- Histologically confirmed diagnosis of advanced/unresectable or metastatic urothelial ca of the renal pelvis, ureter, bladder or urethera. Both TCC and mixed histologies are allowed
- Disease progression during or following treatment with at least one platinum-containing regimen and no more than 2 lines of treatment
- Progression after platinum based treatment (adj/neoadj) <12 months
- Have provided tissue for biomarker analysis (adequacy of the biopsy specimen for PD-L1 biomarker must be confirmed by central laboratory)
- Have measurable disease RECIST 1.1
- ECOG 0-1
- Adequate organ function
- Men and women, > 18 years of age.
- Life expectancy ≥ 12 weeks

**Exclusion Criteria:**
- Any approved treatment within 3 weeks or radiotherapy within 7 days
- Active cerebral metastases
- Other known additional malignancy, except for treated non-melanoma skin cancer
- Active autoimmune disease
- Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures
- Pregnant/breastfeeding, or not adequate contraception
- Prior treatment with anti PD1/PD-L1 agents
- Known HIV positivity, Hepatitis B or Hepatitis C
- Received live vaccine in last 30 days
- Uncontrolled tumour-related pain
- Grade ≥2 peripheral neuropathy as defined by NCI CTCAE v4.0 criteria
- Treatment with systemic immunosuppressive agents or corticosteroids

**Contact:** Andrew Weickhardt (Principal Investigator)  
Dr Stephen Luen (Fellow; P: 9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)

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**Principal Investigator:** Andrew Weickhardt  
**After hours contact:** via Austin switch: 9496 5000

**Primary Study Coordinator:** Sarah Healy  
P: 9496 9918  
Pg: 1503

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<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Germ cell tumour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>P3BEP (ANZUP 1302): Phase 3 Accelerated BEP Trial: A randomised phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumour</td>
</tr>
</tbody>
</table>
| Study Synopsis: | • Phase III. Of accelerated (Q2W) vs standard BEP in first line intermediate and poor-risk metastatic GCT (IGCCC classification)  
• All other treatments (e.g. surgery) per standard of care |
| Key eligibility criteria: | **Inclusion Criteria:**  
• Age 16-45 years  
• Non-seminoma or seminoma (exceptionally raised tumour markers allowed in absence of histocytology if need for therapy urgent)  
• ANC ≥ 1.0, platelets ≥ 100, ALT <2.5x ULN (<5x ULN if liver mets), bili <1.5x ULN, CrCl ≥ 60  
• ECOG 0-3  
• Relapse after RT for pure seminoma allowed  
**Exclusion Criteria:**  
• Other malignancy within 5 years  
• Contraindications to cisplatin or bleomycin |
| Contact: | Dr Andrew Weickhardt or (PI) Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au) |
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| Principal Investigator: | Dr Andrew Weickhardt |
| After hours contact: | via Austin switch: 9496 5000 |
| Primary Study Co-ordinator: | Jaren Caine |
| P: 9496 3906 | Pg: 1775 |
# Head and Neck

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Head and Neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>MK3475-048: Pembrolizumab as First Line Treatment in Subjects with Recurrent/Metastatic HNSCC</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a randomized, active-controlled, multi-site, open-label trial of pembrolizumab, or pembrolizumab plus platinum plus 5-FU chemotherapies versus platinum plus 5-FU plus cetuximab in subjects with advanced head and neck cancer</td>
</tr>
</tbody>
</table>

### Key eligibility criteria:

<table>
<thead>
<tr>
<th>Inclusion Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Histologically or cytologically proven head and neck squamous cell cancer, incurable by local therapy</td>
</tr>
<tr>
<td>• Oropharynx, oral cavity, hypopharynx and larynx are allowed</td>
</tr>
<tr>
<td>• Measurable disease</td>
</tr>
<tr>
<td>• ECOG 0-1</td>
</tr>
<tr>
<td>• Tissue available (within 90 days) or biopsy</td>
</tr>
<tr>
<td>• Adequate organ function</td>
</tr>
<tr>
<td>• 1st line treatment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion Criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Progressive disease within 6 months of completion of curatively intended systemic treatment for locoregionally advanced disease</td>
</tr>
<tr>
<td>• On steroids</td>
</tr>
<tr>
<td>• CNS metastases</td>
</tr>
<tr>
<td>• Auto-immune disease</td>
</tr>
<tr>
<td>• Prior PD-1 inhibitor</td>
</tr>
</tbody>
</table>

### Contact:

| A/Prof Hui Gan (0448 048 266) or Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au) |

### To refer patient:

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<tr>
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<tr>
<td>Brief clinical history</td>
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<td>Whether the patient has been discussed with a particular trials personnel already</td>
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</tbody>
</table>

### Principal Investigator:

| A/Prof Hui Gan |

### Primary study Co-ordinator:

| Sarah Healy | P: 9496 9918 | Pg: 1503 |

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<table>
<thead>
<tr>
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<th>Head and Neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>TROG 12.01 A RANDOMISED TRIAL OF WEEKLY CETUXIMAB AND RADIATION VERSUS WEEKLY CISPLATIN AND RADIATION IN GOOD PROGNOSIS LOCOREGIONALLY ADVANCED HPV-ASSOCIATED OROPHARYNGEAL</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a randomised study evaluating de-intensifying therapy in low risk oropharyngeal cancer, comparing cetuximab with weekly cisplatin in combination with radiation therapy.</td>
</tr>
</tbody>
</table>

### Key eligibility criteria:

**Inclusion Criteria:**
- Stage III (excluding T1-2N1) or Stage IV (excluding T4, N3 and M1) if smoking history < 10 pack/years. If >10pack/years, nodal disease must be N0-N2a.
- P16+
- Clinical measurable disease (ie not adjuvant treatment)
- Previously untreated
- ECOG 0-1
- Subject has adequate bone marrow, renal, and hepatic function

**Exclusion Criteria:**
- Peripheral neuropathy G2
- Tinnitus G2
- Hearing loss G2
- Interstitial lung disease

### Contact:
A/Prof Hui Gan (0448 048 266) or Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au)

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### Principal Investigator:
A/Prof Hui Gan

### After hours contact:
via Austin switch: 9496 5000

### Primary study Co-ordinator:
Trish Jenkins

### Phone:
P: 9496 4301
Pg: 4300

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**Tumour Type:** Head and Neck

**Protocol & Title:** *Eagle (D4193C00002):* A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Therapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

**Study Synopsis:** This is a randomized, open-label, multi-center, global, Phase III study to determine the efficacy and safety of MEDI4736 as monotherapy and MEDI4736 + tremelimumab combination therapy versus standard of care (1 of 4 choices) therapy metastatic SCC.

**Inclusion Criteria:**
- Histologically or cytologically proven head and neck squamous cell cancer, incurable by local therapy
- Oropharynx, oral cavity, hypopharynx and larynx are allowed
- Either 1 previous line of systemic therapy for recurrent disease, or progression within 6 months of curative treatment.
- Measurable disease
- ECOG 0-1
- Tissue available (within 90 days) or biopsy
- Adequate organ function
- No prior immunotherapy

**Exclusion Criteria:**
- Progressive disease within 6 months of completion of curatively intended systemic treatment for locoregionally advanced disease
- On immunosuppressive treatment
- CNS metastases
- Auto-immune disease
- QTc > 470

**Contact:** A/Prof Hui Gan (0448 048 266) or Anis Hamid (Fellow; P: 9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au)

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**Principal Investigator:** A/Prof Hui Gan

**Primary study Co-ordinator:** Lotus Wannarath

**After hours contact:** via Austin switch: 9496 5000

**P:** 9496 3084  
**Pg:** 3084
Lung (NSCLC) - Advanced

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>FLAURA (D5160C00007): A Phase III, Double-Blind, Randomised Study to Assess the Efficacy and Safety of AZD9291 versus a Standard of Care EGFR TKI as First-Line Treatment in Patients with EGFR Mutation Positive, Locally Advanced or Metastatic NSCLC (FLAURA)</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase 3 open label trial of AZD9291 (a novel EGFR tyrosine kinase inhibitor) in the first-line vs standard therapy. Randomisation is 1:1.</td>
</tr>
</tbody>
</table>

**Key eligibility criteria:**

**Inclusion Criteria:**
- Male or female, aged at least 18 years.
- Pathologically confirmed adenocarcinoma of the lung. Patients with mixed histology are eligible if adenocarcinoma is the predominant histology.
- Locally advanced or metastatic NSCLC without local therapy options
- The tumour harbours one of the 2 common EGFR mutations known to be associated with EGFR-TKI sensitivity (Ex19del, L858R).
- Mandatory provision central analysis of EGFR mutation status.
- Patients must be treatment-naïve.
- ECOG 0 or 1
- At least one lesion, not previously irradiated and not chosen for biopsy during Screening, that can be measured as ≥10 mm in the longest diameter

**Exclusion Criteria:**
- Prior treatment with any systemic anti-cancer therapy for advanced NSCLC excluding adjuvant chemotherapy
- Radiotherapy treatment to more than 30% of the bone marrow or with a wide field of radiation within 4 weeks
- Major surgery within 4 weeks of the first dose of study drug.
- Any malignancy that has required systemic treatment within 2 years
- Spinal cord compression or symptomatic brain metastases, requiring steroids over the preceding 4 weeks
- Past history of ILD or pneumonitis

**Contact:**
A/Prof Tom John or Gareth Rivalland (Fellow; P:9496 9932; or Pager: 94965000 then page 4393; or E: Gareth.rivalland@austin.org.au)

**To refer patient:**
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<td>via Austin switch: 9496 5000</td>
</tr>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Ebru Ugrasbul</td>
</tr>
<tr>
<td>P: 9496 9912</td>
<td>Pg: 1105</td>
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# Melanoma - Advanced

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</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>LUD2012-003: Phase I Study of Intralesional Bacillus Calmette-Guerin (BCG) and Followed by Ipilimumab Therapy in Patients with Advanced Metastatic Melanoma</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>Phase I study of intralesional BCG and ipilimumab in patients with histologically confirmed Stage III or IV melanoma</td>
</tr>
</tbody>
</table>

## Key eligibility criteria:

**Inclusion Criteria:**
- Histologically confirmed stage III (unresectable) or stage IV melanoma
- Minimum one metastatic lesion, cutaneous or subcutaneous, but ideally three or more lesions, to accommodate intralesional injection (1 lesion), accessibility for biopsy (1 lesion), and evaluability for response by RECIST v.1.1 (1 lesion) and immune modified RECIST (irRC).
- Performance status of ECOG 0-1

**Exclusion Criteria:**
- Active cerebral metastases unless stable after radiation for at least one month and not requiring steroid treatment for 30 days prior to enrolment
- Other known malignancy within 3 years of study entry, except for treated non-melanoma skin cancer and cervical carcinoma in situ
- History of TB, hypersensitivity to BCG or contraindication use of isoniazid
- Autoimmune disease except vitiligo, type I diabetes, pernicious anaemia (treated).
- Prior immunotherapy or systemic adjuvant therapy for melanoma following most recent relapse and/or resection of melanoma
- Chemotherapy or radiation therapy within the preceding 4 weeks (6 weeks for nitrosourea drugs)

## Contact:
Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au)

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## Principal Investigator:
Prof J. Cebon
After hours contact: via Austin switch: 9496 5000

## Primary Study Co-ordinator:
Noel Micallef
P: 9496 3081
Pg: 6741

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<th>Tumour Type:</th>
<th>Melanoma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>Sirtex (04888): A pilot study of combined treatment for hepatic metastases of uveal melanoma with intrahepatic Yttrium-90 microsphere radioembolisation and intravenous cisplatin</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Phase 1 study of SIR-Spheres® microspheres with IV cisplatin (20mg/m2) D1 to 5.</td>
</tr>
</tbody>
</table>
| **Inclusion Criteria:** | • Histologically proven stage IV uveal melanoma, with hepatic-only metastases.  
• Either no previous trans-hepatic arterial treatment or progressive hepatic metastasis after prior regional treatment with trans-arterial embolisation.  
• Performance status of ECOG 0-1  
Subject has adequate bone marrow, renal, and hepatic function |
| **Exclusion Criteria:** | • Significant shunting to the lung (>20%) identified on the MAA scan  
• Failure to block collateral blood flows from the hepatic artery to non-target organs, such as the GI tract  
• Oligo-metastatic disease amenable to surgical or local (eg: RFA) therapy  
• Liver cirrhosis or symptomatic liver failure e.g. ascites, encephalopathy  
• Occlusion of the main portal vein, or insufficient collateral flow around an occluded branch of the portal vein as determined by angiography  
• Uncontrolled hypertension or congestive heart failure, or acute myocardial infarction within 6 months of entry  
• Known other malignancy (other than non-melanoma skin cancers, superficial bladder cancer, or cervical cancer in situ) within the last 3 years  
• Significant allergic reaction to iodinated contrast  
• Previous systemic therapy for metastatic disease that included cisplatin  
• Previous radiation treatment that includes the liver in the radiation field  
• Biliary obstruction, biliary stent, or prior biliary surgery including sphincterotomy, but excluding cholecystectomy  
• Previous treatment with isolated hepatic perfusion  
• Local anti-neoplastic therapy within 28 days |
| **Contact:** | Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au) |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:  
• Patient contact information  
• Referrer’s contact details and provider number  
• Brief clinical history  
• Whether the patient has been discussed with a particular trials personnel already |
| **Principal Investigator:** | Prof J. Cebon |
| **After hours contact:** | via Austin switch: 9496 5000 |
| **Primary study Co-ordinator:** | N/A | P: 9496 ---- | Pg: N/A |

Disclaimer: Printed Versions of this document can only be considered up-to-date for a period of one month from the printing date after which, the latest version should be downloaded and printed.
**Tumour Type:** Melanoma

**Protocol & Title:** Amgen 20110265: Phase 1b/2 Trial of Talimogene Laherparepvec (T-VEC) in Combination with MK-3475 for Untreated, Unresected, IIIB to IVM1c Melanoma

**Study Synopsis:** To assess the safety and efficacy of TVEC in combination with MK-3475

**Key eligibility criteria:**

**Inclusion Criteria (Phase 1b and Part 1 of Phase 2):**
- Histologically confirmed melanoma stage IIIB to IVM1c for whom surgery is not recommended. Exclude uveal or mucosal melanoma
- Subject must be treatment naïve (prior adjuvant therapy must have been completed therapy at least 6 months prior to enrolment)
- Subject must have measurable disease and be a candidate for intralesional therapy administration into cutaneous, subcutaneous, or nodal lesions.

**Exclusion Criteria (Phase 1b and Part 1 of Phase 2):**
- Subject with up to 3 cerebral metastases, and neurological performance status of 0 may be enrolled, provided that all lesions have been adequately treated and have not required steroids for at least 2 months.
- Immunodeficiency states (eg, hereditary immune deficiency, organ transplant, or leukaemia), or history of other malignancy within past 3 years
- Symptomatic autoimmune disease or syndrome requiring systemic steroids or immunosuppression (except vitiligo or resolved childhood asthma/atopy).
- Subject must not have active herpetic skin lesions and must not require treatment with an antiherpetic drug (eg, acyclovir), except topical use.

**Inclusion Criteria (Part 2 of Phase 2):**
- Subject randomized to arm 2 (MK-3475 monotherapy arm) of part 1 of the phase 2 study must have confirmed evidence of PD at week 12 using modified irRC.

**Contact:** Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au)

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- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

**Principal Investigator:** Prof J. Cebon  
**Primary study Co-ordinator:** Noel Micallef  
**After hours contact:** via Austin switch: 9496 5000

**P:** 9496 3081  
**Pg:** 6741

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### Tumour Type:
Melanoma

### Protocol & Title:
**Amgen 20110266:** Talimogene Laherparepvec (T-VEC) Neoadjuvant Treatment Plus Surgery Versus Surgery Alone for Resectable, Stage IIIB to IVM1a Melanoma

### Study Synopsis:
A Phase 2, Multicenter, Randomized, Open-label Trial Assessing the Efficacy and Safety of T-VEC Treatment Plus Surgery Versus Surgery Alone for Resectable, Stage IIIB to IVM1a Melanoma

### Inclusion Criteria:
- Histologically confirmed diagnosis of stage IIIB, IIC, and IVM1a melanoma and eligible for complete surgical resection
- Men and women, > 18 years of age.
- Prior systemic treatments must have been completed ≥ 3 months
- Candidates for intrallesional treatment, with at least one injectable lesion ≥ 10mm
- Have measurable disease with at least one lesion ≥ 10mm
- ECOG 0-1
- Adequate organ function
- Serum LDH level ≤ 1.0 upper limit of normal (ULN) within 28 days prior to randomization

### Exclusion Criteria:
- Primary ocular or mucosal melanoma
- Other known additional malignancy within 3 years, except for treated non-melanoma skin cancer
- History of autoimmune disorders or immunosuppressive treatments
- Known HIV positivity, Hepatitis B or Hepatitis C
- Active herpetic skin lesions or prior complications of HSV-1 infection
- Requires intermittent or chronic systemic (intravenous or oral) treatment with an antiviral drug (eg, acyclovir), other than intermittent topical use
- Prior treatment with T-VEC or other tumour vaccine
- Female subject is pregnant or breast-feeding, or planning to become pregnant during talimogene laherparepvec treatment and through 3 months after the last dose of talimogene laherparepvec

### Contact:
Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)

### To refer patient:
To minimise delays, please fax a referral to the 03-9457-6698 with:
- Patient contact information
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### Principal Investigator:
Mr David Gyorki
**After hours contact:** via Austin switch: 9496 5000

### Primary study Co-ordinator:
Noel Micallef
P: 9496 3081
Pg: 6741

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Page 35
## Pancreatic

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Pancreatic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>ABI-007-PANC-003: A Phase 3, Multicenter, Open-Label, Randomized Study Of nab®-Paclitaxel Plus Gemcitabine Versus Gemcitabine Alone As Adjuvant Therapy In Subjects With Surgically Resected Pancreatic Adenocarcinoma</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>Randomised phase III trial of adjuvant Abraxane plus Gemcitabine versus Gemcitabine alone after resection of pancreatic adenocarcinoma</td>
</tr>
<tr>
<td>Key eligibility criteria:</td>
<td></td>
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<tr>
<td>Inclusion Criteria:</td>
<td></td>
</tr>
<tr>
<td>• Histologically confirmed ductal pancreatic adenocarcinoma with macroscopic complete resection (R0 and R1)</td>
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<tr>
<td>• Able to start no later than 12 weeks post surgery</td>
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<td>• ECOG 0 or 1</td>
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<td>• AST and ALT ≤ 2.5x ULN; Bilirubin ≤ ULN</td>
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<tr>
<td>Exclusion Criteria</td>
<td></td>
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<tr>
<td>• Prior neoadjuvant treatment or radiotherapy</td>
<td></td>
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<tr>
<td>• Peripheral neuropathy ≥ grade 2</td>
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<tr>
<td>Contact:</td>
<td>Dr Stephen Luen (Fellow; P:9496 9933) or Pager: 94965000 then page 5264; or E: <a href="mailto:Stephen.luen@austin.org.au">Stephen.luen@austin.org.au</a></td>
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<tr>
<td>Principal Investigator:</td>
<td>A/Prof Niall Tebbutt</td>
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<tr>
<td>After hours contact:</td>
<td>via Austin switch: 9496 5000</td>
</tr>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Brie Jelbart</td>
</tr>
<tr>
<td></td>
<td>P: 9496 3297</td>
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<td>Pg: 1769</td>
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<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>ctDNA Pancreas – Circulating Tumour DNA as a Biomarker Pancreatic Cancer</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Prospective trial collecting blood samples for the purposes of measuring circulating tumour DNA from patients with pancreatic adenocarcinoma who are planned to undergo surgical resection</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**  
| | • Patients with resectable stage I or II pancreatic adenocarcinoma who are to have a resection of their tumour  
| | • ECOG 0-2  
| | **Exclusion Criteria**  
| | • History of another primary cancer within the last 5 years, with the exception of non-melanomatous skin cancer and carcinoma in situ of the cervix |
| **Contact:** | Dr Stephen Luen (Fellow; P:9496 9933) or Pager: 94965000 then page 5264; or E: Stephen.luen@austin.org.au) |
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<p>| <strong>Principal Investigator:</strong> | A/Prof Niall Tebbutt |
| <strong>After hours contact:</strong> | via Austin switch: 9496 5000 |
| <strong>Primary study Co-ordinator:</strong> | Brie Jelbart |
| <strong>P:</strong> | 9496 3297 |
| <strong>Pg:</strong> | 1769 |</p>
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<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>JANUS 1 – Randomized, Double-Blind, Phase 3 Study of the JAK1/2 Inhibitor, Ruxolitinib or Placebo in Combination With Capecitabine in Subjects With Advanced or Metastatic Adenocarcinoma of the Pancreas Who Have Failed or Are Intolerant to First-Line Chemotherapy (The JANUS 1 Study)</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Phase III randomised trial of Capecitabine + Ruxolitinib/placebo (oral JAK1/2 inhibitor) as 2nd line treatment for advanced pancreatic adenocarcinoma</td>
</tr>
<tr>
<td><strong>Key eligibility criteria:</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Inclusion Criteria:** | • Histologically confirmed adenocarcinoma of the pancreas that is inoperable or metastatic  
• CRP > 10 on centralised blood test (after consent)  
• Received 1 prior chemotherapy regimen for advanced or metastatic disease  
• Bilirubin < 1.5 x ULN; ALP < 3 x ULN, ALT/AST < 2.5 x ULN |
| **Exclusion Criteria:** | • More than 1 prior regimen for advanced or metastatic disease  
• Known brain or CNS metastases  
• Recent (<3 months) history or ongoing partial or complete bowel obstruction, unless due to the disease understudy and surgically corrected |
| **Contact:** | Dr Stephen Luen (Fellow; P:9496 9933) or Pager: 94965000 then page 5264; or E: Stephen.luen@austin.org.au |
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<tr>
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<th>After hours contact:</th>
<th>via Austin switch: 9496 5000</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary study Co-ordinator:</strong></td>
<td>Yali Liu</td>
<td>P: 9496 9863</td>
<td>Pg: 1103</td>
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# Phase 1

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Solid Tumours: Glioblastoma Multiforme (GBM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>BGB-A317: A Phase 1, Open Label, Multiple Dose, Dose Escalation and Expansion Study to Investigate the Safety, Pharmacokinetics and Antitumor Activities of the anti-PD-1 Monoclonal Antibody BGB-A317 in Subjects with Advanced Tumors</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase 1 dose-escalation, open label study evaluating BGB-A317 (anti PD-1 antibody) in advanced refractory malignancies.</td>
</tr>
</tbody>
</table>

### Key eligibility criteria:

**Inclusion Criteria:**
- Treatment refractory solid malignancy
- Stable brain metastases allowed (for 4 weeks- no anti-seizure medications or steroids)
- Archival tissue or agree to biopsy
- Measurable disease
- Adequate organ function

**Exclusion Criteria:**
- Prior malignancy within 2 years
- Prior PD-1 or PD-L1 inhibitors
- Auto-immune conditions (some exceptions)
- Steroids >10mg prednisolone equivalent/day
- Active Hep B (+ SAg,) or Hep C (+ RNA)
- Live vaccine within 28 days

### Contact:
A/Prof Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: Malaka.ameratunga@austin.org.au)

### To refer patient:
To minimise delays, please fax a referral to the 03-9457-6698 with:
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- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

### Principal Investigator:
A/Prof Hui Gan

### After hours contact:
via Austin switch: 9496 5000

### Primary study Co-ordinator:
Jaren Caine

### P: 9496 3906

### Pg: 1755
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Metastatic Squamous Cell Carcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>ABT-806 in SCC. A Phase 2 Study of ABT-806, a tumour specific anti-EGFR antibody, in Subjects with Recurrent or Metastatic Head and Neck, and other Squamous Cell Carcinomas</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase 2 open-label study evaluating the efficacy of ABT-806 in subjects with recurrent/metastatic SCC of the head and neck or other sites.</td>
</tr>
</tbody>
</table>

**Key eligibility criteria:**

**Inclusion Criteria:**
- Subject must have a histologically or cytologically proved squamous cell carcinoma of the head and neck (Arm A) or other sites (Arm B)
- Patient with H&NC must have received prior platinum based chemotherapy for recurrent/metastatic disease or have progressed within 6 months of concurrent chemo-radiotherapy incorporating cisplatin-based chemotherapy
- For the last 4 patients of Arm A, patients must have disease amenable to biopsy/resection and consent to participation in a PD/bioimaging substudy
- Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2.
- Subject must have measurable disease per RECIST version 1.1.
- Patient has tumour tissues available (archival or fresh).
- Subject has adequate bone marrow, renal, and hepatic function

**Exclusion Criteria**
- Subjects with brain metastases are eligible provided they have shown clinical and radiographic stable disease for at least 1 month after definitive therapy.
- Anticancer therapy within 21 days prior to the first dose of ABT-806.
- Subject has received a prior EGFR-directed monoclonal antibody within a period of 4 weeks prior to the first dose of ABT-806.
- Subject has a clinically significant uncontrolled condition(s)
- History of major immunologic reaction to any IgG containing agent.

**Contact:**
A/Prof Hui Gan (0448 048 266) or Dr Stephen Luen (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264; or E: Stephen.Luen@austin.org.au)

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- Whether the patient has been discussed with a particular trials personnel already

**Principal Investigator:**
A/Prof Hui Gan

**After hours contact:**
via Austin switch: 9496 5000

**Primary study Co-ordinator:**
TBA

**Primary study Co-ordinator:**
P: 9496
Pg:
## Tumour Type:
**Advanced Solid Tumour** (BRAF, NRAS or KRAS mutation present)

## Protocol & Title:
**BGB -283 (BGB-283-AU-001):** A Phase I, Open-Label, Multiple-Dose, Dose Escalation Study to Investigate the Safety and Pharmacokinetics of the B-RAF Inhibitor BGB-283 in Subjects with Solid Tumours

## Study Synopsis:
Phase I study to determine safety and tolerability of BGB-283, a novel BRAF inhibitor (oral). Currently in dose expansion

## Key eligibility criteria:

### Inclusion Criteria:
- BRAF, NRAS or KRAS mutation positive solid tumour
- ECOG ≤ 1
- Platelets ≥ 100, bili ≤ 1.5xULN, AST/ALT ≤ 2.5x (or ≤ 5x ULN if liver mets), CrCl ≥ 45

### Exclusion Criteria:
- Required washout periods for previous treatments
  - Chemo: one cycle length
  - Biologic / investigational agents: 4wks or 5x half life of the agent (whichever is shorter)
  - Major surgery: 28 days
  - Radiotherapy: 14 days
- Untreated leptomeningeal or brain metastasis. Ie. must be asymptomatic and off steroids/ anti-epileptics for >28 days.
- Prohibited meds: CYP2C8/2C9 substrates and CYP3A inhibitors (eg, sulfonylureas, warfarin, multiple NSAIDs, amitriptyline, A2blockers, verapamil, diltiazem).

## Contact:
A/Prof Hui Gan (0448 048 266) or Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or E:Babak.Tamjid2@austin.org.au)

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- Whether the patient has been discussed with a particular trials personnel already

## Principal Investigator:
A/Prof Hui Gan

## After hours contact:
via Austin switch: 9496 5000

## Primary study Co-ordinator:
Rajani Iywan

P: 9496 3544

Pg: 3544
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Advanced Solid Tumours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td><strong>BGB-290 (BGB-290-AU-002): A Phase IA, Open-Label, Multiple-Dose, Dose Escalation Study to Investigate the Safety and Pharmacokinetics of the PARP Inhibitor BGB-290 in Subjects with Solid Tumours</strong></td>
</tr>
</tbody>
</table>

**Study Synopsis:**
- Phase I study to determine safety and tolerability of BGB-290, a novel PARP inhibitor (oral)
- Preferential recruitment for BRCA 1/2 mutations, SCLC, high grade serous ovarian ca and triple negative breast ca.
- GBM patients may be eligible after discussion with sponsor
- Frequent visits cycle 1 including long PK days

**Key eligibility criteria:**

**Inclusion Criteria:**
- ECOG ≤ 1
- Platelets ≥ 100, bili ≤ 1.5xULN, AST/ALT ≤ 2.5x (or ≤ 5x ULN if liver mets), CrCl ≥ 45
- 3 main cohorts of patients will be recruited – BRCA mutant breast cancer, ovarian cancer and prostate cancer (BRCA mutant or other deficiencies in homologous recombination); other patients may be suitable after discussion with the sponsor.

**Exclusion Criteria:**
- Required washout periods for previous treatments
  - Chemo: one cycle length
  - Biologic / investigational agents: 4wks
  - Major surgery/ Radiotherapy: 28 days
- Untreated leptomeningeal or brain metastasis. Ie. Must be asymptomatic, stable on CT or MRI and stable or reducing dose of steroids for >28 days.
- Prohibited meds: CYP3A inhibitors (eg. verapamil, diltiazem, fluconazole)

**Contact:**
Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: Malaka.ameratunga@austin.org.au)

**To refer patient:**
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- Whether the patient has been discussed with a particular trials personnel already

**Principal Investigator:** A/Prof Hui Gan
**After hours contact:** via Austin switch: 9496 5000

**Primary study Co-ordinator:** Jaren Caine
**P:** 9496 3906
**Pg:** 1775
Tumour Type: Solid Tumours

Protocol & Title: LUD2014-002: A phase I safety and bioimaging trial of DS-8895a in patients with advanced or metastatic EphA2 positive cancers

Study Synopsis: This is a Phase 1 study of DS-8895a in patients with advanced or metastatic EphA2 positive cancers. DS-8895 is an agonistic EphA2 antibody with ADCC activity also.

Key eligibility criteria:

Inclusion Criteria:
- Advanced or metastatic EphA2 positive cancer (based on IHC of archived or fresh tumour tissue)
- At least one reference tumour > 1cm in size for assessment of tumour uptake of 89Zr-DS-8895a.
- ECOG Performance Status ≤ 1
- Adequate haematological, biochemical parameters

Exclusion Criteria:
- Active central nervous system metastases. Definitively treated metastases are allowed if stable for 6 weeks off therapy.
- Known immunodeficiency or HIV positivity.
- Other malignancy, apart from non-melanoma skin cancer, within 3 years prior to first study drug administration, that in the opinion of the investigator has >10% risk of relapse within 12 months
- Chemotherapy, radiotherapy or investigational agent within 4 weeks prior to first study drug administration.
- Regular corticosteroid, NSAID (other than paracetamol or low-dose aspirin) or other immunosuppressive treatment within 3 weeks prior to first drug administration (intermittent dosing permitted if less than 4 doses within a 3 day period).

Contact: A/Prof Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: Malaka.ameratunga@austin.org.au)

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Principal Investigator: Prof Andrew Scott
A/Prof Hui Gan

After hours contact: via Austin switch: 9496 5000

Primary study Co-ordinator: Jaren Caine

P: 9496 3906  Pg: 1775
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Solid Tumours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>MOXR0916 (OX40 agonist): A Phase I Clinical Trial, dose-escalation study of the safety and pharmacokinetics of MOXR0916 in patients with locally advanced or metastatic solid tumors</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>A Phase I Clinical Trial, dose-escalation study of the safety and pharmacokinetics of MOXR0916 in patients with locally advanced or metastatic solid tumors</td>
</tr>
<tr>
<td><strong>Key eligibility criteria:</strong></td>
<td><strong>Inclusion Criteria:</strong></td>
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<tr>
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<td>- Histologically confirmed locally advanced, recurrent or metastatic incurable solid malignancy that has progressed after all available standard therapy or for which standard therapy has proven to be ineffective or intolerable, or is considered inappropriate</td>
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<td>- For Part I expansion cohort: lesions accessible for at least two core biopsies with no significant risk to the patient</td>
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<td>o ECOG 0-1</td>
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<td>o Subject has adequate bone marrow, renal, and hepatic function</td>
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<td>o Have provided tissue for biomarker analysis from a newly obtained core or excisional biopsy of a tumour lesion not previously irradiated (mandatory).</td>
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<td>o Patient has measurable RECIST 1.1</td>
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<td><strong>Exclusion Criteria:</strong></td>
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<td>- Uncontrolled pain</td>
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<td>- Subject has active CNS metastasis or primary CNS disease, or leptomeningeal disease</td>
</tr>
<tr>
<td></td>
<td>- Subject has routine exclusions for immunotherapies</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Dr Andrew Weickhardt or Dr Babak Tamjid (Fellow; P: 9496 9928; or Pager: 9496 5000 then page 3990; or: <a href="mailto:Babak.Tamjid2@austin.org.au">Babak.Tamjid2@austin.org.au</a>)</td>
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<tr>
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<td>Rajani IYWAN</td>
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<td>P: 9496 3544</td>
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<td>Pg: 3544</td>
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### Tumour Type:
**Advanced Solid Tumours**

### Protocol & Title:
**Starpharma (DTX-SPL8783-001):** A phase 1 dose-escalation study to evaluate the safety, tolerability and pharmacokinetics of DTX-SPL8783 (a docetaxel (DTX)-dendrimer conjugate) in patients with advanced solid tumours

### Study Synopsis:
- Phase I study to determine safety and tolerability of DTX-SPL8783
- IV Q3W

### Key eligibility criteria:

#### Inclusion Criteria:
- ECOG ≤ 1
- No taxane chemotherapy in last 6 months

#### Exclusion Criteria:
- Required washout periods for previous anti-cancer therapies: 30 days, except 2 weeks in the case of palliative radiation to bone metastases
- Untreated leptomeningeal or brain metastasis. I.e. Must be ≥ 4 weeks post-surgery or radiation, stable on MRI and not on steroids.
- Neut < 1.5, Hb < 90, plt < 100, bili > ULN, AST/ALT > 1.5xULN and ALP > 2.5xULN or AST/ALT > 2.5xULN irrespective of ALP, Cr >1.5xULN or CrCl <50, INR/APTT >1.5 xULN
- Therapeutic anticoagulation, except low molecular weight heparin
- Congenital long-QT syndrome, myocardial infarction in last 6 months, CCF ≥ NYHA class II, unstable angina or arrhythmias
- Ascites, pericardial or pleural effusions ≥ grade 2

### Contact:
Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: Malaka.ameratunga@austin.org.au)

### To refer patient:
To minimise delays, please fax a referral to the 03-9457-6698 with:
- Patient contact information
- Referrer’s contact details and provider number
- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

### Principal Investigator:
A/Prof Hui Gan

### After hours contact:
via Austin switch: 9496 5000

### Primary study Co-ordinator:
Catherine Johnson

### P:
9496 3038

### Pg:
3038

---

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Thyroid

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Thyroid: Medullary</th>
</tr>
</thead>
</table>

**Protocol & Title:** EXAMINER: A Randomized, Double Blind Study Comparing Cabozantinib (XL184) at 60mg daily compared to 140mg daily in Progressive Medullary Thyroid Cancer

**Study Synopsis:** This is a study comparing the efficacy of Cabozantinib between the approved dose (140mg/d) versus an alternate dose level.

**Key eligibility criteria:**

**Inclusion Criteria:**
- Subject has a histologically proven MTC.
- Availability of tissue for RET M198T mutation (negative prognostic marker) testing, either archival or fresh
- Subject has a ECOG Performance Status (KPS) of 0-1
- Subject has adequate bone marrow, renal, and hepatic function
- Subject has documented Progressive Disease by RECIST 1.1 compared to a scan within the last 14 months
- Patients with brain metastases are allowed so long as adequately treated and not on anti-coagulation

**Exclusion Criteria:**
- Prior treatment with another agent or modality within 28 days
- Use of anticoagulation except low dose aspirin and LMWH that has been on a stable dose for 12 weeks

**Contact:** A/Prof Hui Gan (0448 048 266) or Mal Ameratunga (Fellow; P: 9496 9929; or Pager: 9496 5000 then page 3248; or E: Malaka.ameratunga@austin.org.au)

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**Principal Investigator:** A/Prof Hui Gan

**Primary study Co-ordinator:** Christine Vanrenen

**After hours contact:** via Austin switch: 9496 5000

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>After hours contact</th>
<th>via Austin switch</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/Prof Hui Gan</td>
<td></td>
<td>9496 5000</td>
</tr>
<tr>
<td>Christine Vanrenen</td>
<td>P: 9496 9712</td>
<td>Pg: 1988</td>
</tr>
</tbody>
</table>

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## Acute Myeloid Leukaemia

<table>
<thead>
<tr>
<th>Haematology</th>
<th>AML</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>AML M16: A phase 2 randomised double-blind placebo controlled multi-centre study of Sorafenib in combination with intensive chemotherapy for previously untreated adult FLT3-ITD positive AML</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Investigate the clinical benefit and safety of frontline oral sorafenib (vs placebo) in combination with HiDAC-based chemotherapy during maintenance therapy in adult FLT3-ITD positive AML</td>
</tr>
<tr>
<td><strong>Key eligibility criteria:</strong></td>
<td><strong>Inclusion Criteria:</strong></td>
</tr>
<tr>
<td></td>
<td>• Age 18-65. ECOG 0-2</td>
</tr>
<tr>
<td></td>
<td>• Newly diagnosed AML (include secondary/therapy-related, exclude APML)</td>
</tr>
<tr>
<td></td>
<td>• FLT3-ITD mutant allelic burden ≥0.05</td>
</tr>
<tr>
<td></td>
<td>• Started HIDAC-3 or 7+3 induction chemotherapy</td>
</tr>
<tr>
<td></td>
<td>• Life expectancy &gt;3 months</td>
</tr>
<tr>
<td></td>
<td><strong>Exclusion Criteria:</strong></td>
</tr>
<tr>
<td></td>
<td>• CNS leukaemia</td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of cancer within last 5 years</td>
</tr>
<tr>
<td></td>
<td>• Cardiac disease: complete LBBB, PPM, congenital long QT syndrome, history of ventricular tachyarrhythmia, resting bradycardia (&lt;50bpm), RBBB + left anterior hemiblock</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Dr Simon He (PI) via Austin switch (<a href="mailto:simon.he@austin.org.au">simon.he@austin.org.au</a>)</td>
</tr>
</tbody>
</table>

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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Primary study Co-ordinator:</strong></th>
<th>Jean Cameron</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>P:</strong></td>
<td>+613 9496 6731</td>
</tr>
<tr>
<td><strong>Pg:</strong></td>
<td>6731</td>
</tr>
</tbody>
</table>

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Haematology | AML
---|---
Protocol & Title: | AML M18 (REGISTRY): Acute Myeloid Leukaemia registry
Study Synopsis: | Establish a common registration platform for patients with AML in Australia and New Zealand
Key eligibility criteria: | Inclusion Criteria:
• Male or female with a suspected, or known, or diagnosed AML
• Age 15 and over
• Each patient must be registered in the Registry once only
Contact: | Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au)
To refer patient: | To minimise delays, please fax a referral to the 03-9457-6698 with:
• Patient contact information
• Referrer’s contact details and provider number
• Brief clinical history
• Whether the patient has been discussed with a particular trials personnel already
Principal Investigator: | Andrew Grigg
After hours contact: | via Austin switch: +613 9496 5000
Primary study Co-ordinator: | Jean Cameron
P: +613 9496 6731
Pg: 6731

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# Haematology

## Protocol & Title:

**CC-486-AML-001:** Oral Azacitidine - A randomised double-blind placebo - controlled study to compare efficacy and safety of oral Azacitidine plus best supportive care versus best supportive care as maintenance therapy in subjects with AML in CR

## Study Synopsis:

- Phase 3 oral azacitidine tablet vs placebo plus best supportive care as maintenance therapy in AML
- For subject aged 55 years and over, who are in complete remission

## Key eligibility criteria:

### Inclusion Criteria:

- ≥55 years of age, ECOG 0-3
- Newly diagnosed, histologically confirmed *de novo* AML or AML secondary to prior MDS
- Underwent induction therapy with intensive chemotherapy
- Achieved first CR/CRi status within 3 months prior to randomisation
- ANC ≥0.5x10^9/L and platelet counts ≥20,000 x10^9/L

### Exclusion Criteria:

- Suspected or proven APML or previous haematologic disorder (excluding MDS)
- AML associated with inv(16), t(8;21), t(16;16), t(15;17) or t(9;22) karyotypes
- Prior bone marrow or stem cell transplantation
- Have achieved CR/CRi with hypomethylating agents
- AML developed within four months of discontinuing hypomethylating agents for MDS
- Proven CNS leukaemia
- Candidate for allogeneic bone marrow or stem cell transplant

## Contact:

Dr Daniela Zantomio (PI) via Austin switch (see below)
(Daniela.zantomio@austin.org.au)

## To refer patient:

To minimise delays, please fax a referral to the 03-9457-6698 with:
- Patient contact information
- Referrer’s contact details and provider number
- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

## Principal Investigator:

Daniela Zantomio  
After hours contact: via Austin switch: +613 9496 5000

## Primary study Co-coordinator:

Stephanie O’Brien  
P: +613 9496 4352  
Pg: 4354
Chronic Lymphocytic Leukaemia

<table>
<thead>
<tr>
<th>Haematology</th>
<th>CLL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>CLL6: A phase 3 multicentre, randomised trial comparing Lenalidomide consolidation vs no consolidation in patients with CLL and residual disease following induction chemotherapy</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>To investigate if lenalidomide consolidation is capable of extending progression free survival in patients with previously untreated or minimally treated CLL with residual disease after chemotherapy</td>
</tr>
</tbody>
</table>
| Key eligibility criteria: | **Inclusion Criteria:**
| | • B-CLL  
| | • Age ≥18 years; ECOG 0-1  
| | • Completed 4 to 6 cycles of FC or FCR and achieved ≥PR  
| | • Evidence of residual disease: clinical or CT lymphadenopathy/ hepatosplenomegaly, positive bone marrow histology, detectable MRD  
| | • Hb>100g/L, neutrophils >1.5x10^9/L, platelets >100 x10^9/L  
| | • Life expectancy >6months  
| **Exclusion Criteria**
| | • Prior chemotherapy (except for FCR, prednisolone)  
| | • Transformation to aggressive B-cell malignancy  
| | • Severe or debilitating CNS disease  
| Contact: | Dr Paul Turner (PI) via Austin switch (paul.turner@austin.org.au) or Dr Matthew Ku (Lymphoma Fellow) via Austin switch (matthew.ku@austin.org.au)  
| To refer patient: | To minimise delays, please fax a referral to the 03-9457-6698 with:
| | • Patient contact information  
| | • Referrer’s contact details and provider number  
| | • Brief clinical history  
| | • Whether the patient has been discussed with a particular trials personnel already  

Principal Investigator: Paul Turner  
After hours contact: via Austin switch: +613 9496 5000  
Primary study Co-ordinator: Laura Johnston  
P: +613 9496 6732  
Pg: 6732
# Chronic Myeloid Leukaemia

<table>
<thead>
<tr>
<th>Haematology</th>
<th>CML</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>Pinnacle (CML11):</strong> Phase II study of Nilotinib plus pegylated interferon alfa-2b as first-line therapy in chronic phase CML aiming to maximize CMR and MMR</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>Open label single arm, prospective study aiming to measure rates of disease response by adding pegylated interferon alfa-2b to nilotinib in the frontline treatment of chronic phase CML</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**  
- Age ≥18 years; ECOG≤2  
- Newly diagnosed Ph+ CML in chronic phase within 3 months of study entry with a quantifiable BCR-ABL transcript  
- No prior therapy for CML/other leukaemia  
- No signs of extramedullary leukaemia (except for hepatosplenomegaly)  
- Life expectancy >12months  
**Exclusion Criteria:**  
- Previous radiotherapy to >25% of bone marrow  
- Major surgery within 4 weeks prior to study entry  
- History of cardiac disease, impaired GI function, pancreatitis, CNS infiltration  
- Prior allogeneic stem cell transplantation  
- Known history of uncontrolled depression or psychiatric disease likely to be exacerbated by study treatment |
| **Contact:** | Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au) |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:  
- Patient contact information  
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<th>Andrew Grigg</th>
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<th>via Austin switch: +613 9496 5000</th>
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<tbody>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Alicia Lavery</td>
<td>P: +613 9496 9902</td>
<td>Pg: 1770</td>
</tr>
</tbody>
</table>
**Haematology**

<table>
<thead>
<tr>
<th>Protocol &amp; Title:</th>
<th>TKI: Defining the mechanisms by which some tyrosine kinase inhibitor, nilotinib but not others potentiate a prothrombotic state</th>
</tr>
</thead>
</table>

**Study Synopsis:**

Assess platelet activation, ex vivo platelet thrombus formation, platelet-leukocyte interactions and thrombogenic biomarkers in patients with CML receiving nilotinib, imatinib, dasatinib or ponatinib.

**Key eligibility criteria:**

**Inclusion Criteria:**

- Subjects with CML receiving nilotinib, imatinib, dasatinib or ponatinib treatment who are able to grant informed consent

**Exclusion Criteria:**

- Not fulfilling the above criteria

**Contact:**

Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au)

**To refer patient:**

To minimise delays, please fax a referral to the 03-9457-6698 with:

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**Principal Investigator:** Andrew Grigg

**After hours contact:** via Austin switch: +613 9496 5000

**Primary study Co-ordinator:** Peter Shuttleworth

**P:** +613 9496 5236  
**M:** +614 1601 3927

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# Lymphoma

<table>
<thead>
<tr>
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<th>Lymphoma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>Beigene (BGB-3111-AU-003):</strong> A Phase 1, open label, multiple–dose, dose escalation and expansion study to investigate the safety in Pharmacokinetics of the BTK inhibitor BGB-3111 in subjects with B-cell lymphoid malignancies</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>To characterise the safety profile and efficacy of BGB-3111 in humans</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**  
  - Age ≥18 years; ECOG 0–2  
  - WHO classification of B-lymphoid malignancy (exclude below)  
  - Relapsed or refractory following at least one line of therapy  
  - ANC ≥ 1.0x10^9/L, platelets ≥ 50x10^9/L  
  **Exclusion Criteria:**  
  - Burkitt lymphoma, plasma cell myeloma, ALL, lymphoblastic lymphoma and plasmablastic lymphoma  
  - CNS involvement by disease  
  - Histologically transformed disease  
  - Allogeneic HSCT within 6 months, or active GVHD requiring immunosuppression  
  - Corticosteroids within 7 days, chemo/radiotherapy within 2 weeks, monoclonal Ab within 4 weeks |
| **Contact:** | Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au) or Dr Matthew Ku (Lymphoma fellow) via Austin switch (matthew.ku@austin.org.au) |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:  
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| **Principal Investigator:** | Andrew Grigg | **After hours contact:** | via Austin switch: +613 9496 5000 |
| **Primary study Co-ordinator:** | Laura Johnston | **P:** | +613 9496 6732 |
| | | **Pg:** | 6732 |
Haematology | Lymphoma
---|---
**Protocol & Title:** | Echelon 2 (SGN35-014): A randomised, double-blind, placebo–controlled, phase 3 study of Brentuximab vedotin and CHP (A+ CHP) vs CHOP in the frontline treatment of patients with CD30+ve mature T-Cell lymphomas

**Study Synopsis:** | To compare the brentuximab vedotin + CHP vs CHOP in the frontline treatment of CD30-positive TCL

**Key eligibility criteria:**

**Inclusion Criteria:**
- Age ≥18 years; ECOG 0-2
- Newly diagnosed CD30+ve TCL
- FDG-avid disease by PET and measurable disease at least 1.5cm by CT
- ANC≥1000/µL and platelet≥50,000/µL

**Exclusion Criteria:**
- Current diagnosis of primary cutaneous CD30+ve TCL
- Mycosis fungoides including transformed MF
- History of PML
- Prior treatment with brentuximab vedotin
- CNS involvement
- Baseline peripheral neuropathy≥Grade 2 or demyelinating form of Charcot-Marie-Tooth

**Contact:** | Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au) or Dr Matthew Ku (Lymphoma Fellow) via Austin switch (matthew.ku@austin.org.au)

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<td>Primary study Co-ordinator:</td>
<td>Stephanie O’Brien</td>
<td></td>
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Page 54
**Haematology** | Lymphoma
---|---
**Protocol & Title:** | MK-3475-087: A Phase II clinical trial of MK-3457 (Pembrolizumab) in subjects with relapsed or refractory (R/R) classical Hodgkin Lymphoma
---|---
**Study Synopsis:** | To determine safety, tolerability and overall response rate of pembrolizumab in relapsed and/or refractory classical Hodgkin Lymphoma (HL).
---|---
**Inclusion Criteria:**
- Age ≥18 years; ECOG 0-1
- Have relapsed or refractory de novo classical HL and meet one of the following cohort inclusions:
  - Cohort 1: failed to achieve a response or progressed after auto-SCT; and relapsed/refractory to brentuximab vedotin post auto-SCT
  - Cohort 2: ineligible for auto-SCT, and relapsed/refractory to brentuximab vedotin
  - Cohort 3: failed to achieve a response or progressed after auto-SCT and have not received brentuximab vedotin post auto-SCT
- Measurable disease
- Provide an evaluable core or excisional lymph node biopsy
**Exclusion Criteria:**
- Diagnosis of immunosuppression or receiving immunosuppressive therapy within 7 days prior to first dose of trial treatment
- Had prior monoclonal Ab within 4 weeks, prior chemo/radiotherapy within 2 weeks
- Allogeneic HSCT within last 5 years
- Known CNS involvement
- Active autoimmune disease that required systemic treatment in the last 2 years
- Active non-infectious pneumonitis
- Prior therapy with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137 or anti-CTLA-4 Ab
---|---
**Contact:** | Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au) or Dr Matthew Ku (Lymphoma Fellow) via Austin switch (matthew.ku@austin.org.au)
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| After hours contact: | via Austin switch: +613 9496 5000 |
| Primary study Co-ordinator: | Stephanie O’Brien |
| P: | +613 9496 4352 |
| Pg: | 4354 |

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## Multiple Myeloma (MM)

<table>
<thead>
<tr>
<th>Haematology</th>
<th>Myeloma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>C16019</strong>: A phase 3, randomised, placebo-controlled, double-blind study of oral Ixazomib (MLN9708) maintenance therapy in patients with MM following autologous stem cell transplant</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>To determine the effect of MLN9708 maintenance therapy on overall survival compared to placebo in patients with MM who have undergone induction therapy followed by a single autologous stem cell transplantation.</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**  
- Age ≥18 years; ECOG≤2  
- Underwent induction therapy followed by a single ASCT with a high dose melphalan conditioning regimen within 12 month of diagnosis (exclude VAD as induction therapy)  
- ANC≥1, platelet ≥75  
**Exclusion Criteria:**  
- Post-ASCT consolidation therapy  
- MM which has refractory/relapsed following primary therapy  
- Double (tandem) ASCT  
- CNS involvement  
- Diagnosis of Waldenström’s macroglobulinemia, POEMS syndrome, MDS, MPN or plasma cell leukaemia |
| **Contact:** | Dr Simon He (PI) via Austin switch (simon.he@austin.org.au) |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:  
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<td><strong>P:</strong> 9496 9902</td>
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</table>
### Myelodysplastic Syndrome

<table>
<thead>
<tr>
<th>Haematology</th>
<th>AML/MDS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>TetraLogic – Blast (TL32711-RAN-0094-PTL): A phase 2 randomised double-blind placebo-controlled study of Azacitidine with or without Birinapant in a single arm open-label run-in phase in subjects with Higher-Risk MDS or CMML</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>To compare the relative effect of azacitidine with or without Birinapant on response rate in patients with previously untreated higher-risk MDS, secondary MDS or CMML</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**
- ≥18 years of age; ECOG 0-2
- Morphologically confirmed diagnosis of MDS or CMML
- IPSS-R of ≥3.5 (intermediate, high or very high)
- No prior treatment with hypomethylating agents
- Adequate liver and renal function

**Exclusion Criteria:**
- Relapsed or refractory to hypomethylating agents
- AML (except for RAEB-t who are not candidates for intensive AML therapy)
- Received hematopoietic growth factors within 14 days prior to screening
- Malignancy within the prior 2 years
- Received investigational agent within 4 weeks of randomisation or 5 half lives
- Uncontrolled hypertension, impaired cardiac function
- History of cranial nerve palsy
- Concomitant anti-TNF therapy |
| **Contact:** | Dr Daniela Zantomio (PI) via Austin switch (Daniela.zantomio@austin.org.au) |
| **To refer patient:** | To minimise delays, please fax a referral to the 03-9457-6698 with:
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## Myeloproliferative Neoplasm

<table>
<thead>
<tr>
<th>Haematology</th>
<th>Myeloproliferative Neoplasm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>Myeloproliferative neoplasms registry</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>Registry for patients with recently diagnosed myeloproliferative neoplasms</td>
</tr>
</tbody>
</table>

### Key eligibility criteria:

**Inclusion Criteria:**
- Age ≥18 years
- Recently (<3 months) diagnosed with
  - Essential thrombocythaemia
  - Polycythaemia vera
  - Primary myelofibrosis
  - Myeloproliferative neoplasm
- New or pre-existing diagnosis of
  - Chronic eosinophilic leukaemia
  - Hypereosinophilic syndrome
  - RARS-T

**Exclusion Criteria:**
- Not fulfilling criteria above

### Contact:
Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au)

### To refer patient:
To minimise delays, please fax a referral to the 03-9457-6698 with:
- Patient contact information
- Referrer’s contact details and provider number
- Brief clinical history
- Whether the patient has been discussed with a particular trials personnel already

### Principal Investigator:
Andrew Grigg

### After hours contact:
via Austin switch: +613 9496 5000

### Primary study Co-ordinator:
Faye Putt

P: +613 9496 3230
E: faye.putt@austin.org.au
Stem Cell Transplant

Haematology | Transplant
---|---
Protocol & Title: | PK Sampling BMT: A multicentre study investigation the pharmacokinetics (PK) of various chemotherapeutic agents used as conditioning in allogeneic and autologous stem cell transplant recipients
Study Synopsis: | To establish the PK of fludarabine, busulphan and/or melphalan in patients undergoing pre-stem cell transplant conditioning and determine the pre-transplant factors that affect the PK
Key eligibility criteria: | Inclusion Criteria:
• Any age
• Undergoing autologous or allogeneic SCT using a conditioning regimen containing Bu, Flu or Mel
Exclusion Criteria:
• Not meeting the above inclusion criteria
Contact: | Prof Andrew Grigg (PI) via Austin switch (andrew.grigg@austin.org.au)
To refer patient: | To minimise delays, please fax a referral to the 03-9457-6698 with:
• Patient contact information
• Referrer’s contact details and provider number
• Brief clinical history
• Whether the patient has been discussed with a particular trials personnel already
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