CANCER CLINICAL TRIALS CENTRE

TRIALS OPEN FOR ACCRUAL
August 2016

Cancer Services
Austin Health

Author: Dr Hui Gan, Cancer Clinical Trials
Contributors: A.Woods & N.Prasad, Cancer Clinical Trials
Authorised by: Dr Niall Tebbutt, Austin Health Oncology Unit; and staff of Cancer Clinical Trials Centre, Austin Health.
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Austin Intranet link: http://hub/cancerclinicaltrailstrials
Table of Contents

Contact Phone Numbers ........................................................................................................................................ 4
Medical Oncology Principal Investigators ........................................................................................................ 4

Brain .......................................................................................................................................................................... 7

LUD2013-006: Phase 2 study to Evaluate the Clinical Efficacy and Safety of MEDI4736 in Patients with Glioblastoma (GBM) ........................................................................................................................................ 7
PMC_TTAC-0001_02 : A Multicenter, 3-arm, Open-Label, Phase IIa Clinical Trial to Evaluate the Safety and Efficacy of TTAC-0001 in Patients with Recurrent Glioblastoma .................................................................................. 8
M13-813: A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 with Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects with Newly Diagnosed Glioblastoma (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification ......................................................................................................................... 9

Breast ........................................................................................................................................................................ 10

BIOMARIN/EMBRACA (673-301): 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 ........................................................................................................................................ 10
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 ........................................................................................................... 11
WO29479: PHASE II STUDY EVALUATING THE SAFETY & EFFICACY OF COBIMETINIB IN COMBINATION WITH PACLITAXEL AS FIRST-LINE TREATMENT FOR PATIENTS WITH METASTATIC TRIPLE-NEGATIVE BREAST CANCER (COLET) ........................................................................................................................................ 12
ANZ 1002: Post-operative Radiotherapy Omission in Selected Patients with Early breast Cancer Trial (PROSPECT) ........................................................................................................................................ 13
ANZ 1401 (ELIMINATE) Oestrogen Lowering Intervention May Increase NeoAdjuvant Therapy Efficacy ........................................................................................................................................ 14

Colorectal .................................................................................................................................................................. 15

ICR02 / ASCOLT: Aspirin for Dukes C and High Risk Dukes B Colorectal Cancers An International, Multi-centre, Double Blind, Randomised Placebo Controlled Phase III Trial ........................................................................................................... 15
EViCT (Erlotinib and Vemurafenib In Combination Trial): A Phase I/II Trial of the combination of BRAF and EGFR inhibition in BRAF V600E mutant metastatic colorectal, advanced or metastatic lung adenocarcinoma and other cancers: The EViCT (Erlotinib and Vemurafenib In Combination Trial) Study ........................................................................................................................................ 16
AG0214ANL/CTC 0124 (InterAACT): An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5- fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease ........................................................................................................................................ 17

Gastro-Intestinal ........................................................................................................................................................ 18

TOPGEAR (AG0407GR TROG 08.08): A randomised phase II/III trial of preoperative chemoradiotherapy versus preoperative chemotherapy for resectable gastric cancer ........................................................................................................................................ 18

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.
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 Juction Adenocarcinomas ........................................ 19

MK 3475-062: Ph III Trial of Pemrolizumab (MK-3475), pemrolizumab+FP/XP vs.......................... 20 Placebo+FP/XP in Biomarker Select, Advanced Gastric or GEJ Adenocarcinoma ......................................... 20

I3O-MC-JSB: Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestinib or Placebo plus Cisplatin and Gemcitabine as First-Line Treatment in Patients with Advanced or Metastatic Biliary Tract Cancer ........................................................................................................... 21

Genito-Urinary - Prostate Cancer .................................................................................................................. 22

BAY 88-8223/15396 - Radium 223: A Phase III trial of radium-223 dichloride in combination with abiraterone and prednisolone for asymptomatic/mildly symptomatic, chemotherapy-naïve, bone-predominant metastatic castrate-resistant prostate cancer................................................................. 22

PROPS (GAP02-01.1): PET /MRI pre-Radiotherapy for Post-Prostatectomy Salvage .................. 23

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 ................................................................................................................. 24

ENZAMET (ANZUP 1304): Randomised phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer ........................................................................................................... 25

MOVEMBER FDHT: [ 18f]-dihydro-testosterone pet imaging in patients with progressive prostate cancer ........................................................................................................................................... 26

EMBARK: A Phase III randomised study of enzalutamide plus leuprolide, enzalutamide monotherapy and placebo plus leuprolide in men with high-risk nonmetastatic prostate cancer, 27

Genito-Urinary - Other ........................................................................................................................................ 28

WO29636: A Phase III Study of Atezolizumab versus Observation as Adjuvant Therapy in Patients with PD-L1-selected High-Risk Muscle-Invasive Bladder Cancer ........................................................................................................ 28

PCR-MIB: A Phase II single-arm study of pemrolizumab with chemoradiotherapy as treatment for nonmetastatic, muscle invasive bladder cancer ........................................................................................................... 29

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 ........................................................................................................... 30

WO29637: A Phase III Study of MPDL3290A in Combination with Bevacizumab versus Sunitinib in Patients with Untreated Advanced Renal Cell Carcinoma................................................................................................................................. 31

Head and Neck.............................................................................................................................................. 32

MK3475-048: Pemrolizumab as First Line Treatment in Subjects with........................................... 32 Recurrent/Metastatic HNSCC ........................................................................................................................... 32

TROG 12.01 A RANDOMISED TRIAL OF WEEKLY CETUXIMAB AND RADIATION VERSUS WEEKLY CISPLATIN AND RADIATION IN GOOD PROGNOSIS LOCOREGIONALLY ADVANCED HPV-ASSOCIATED OROPHARYNGEAL ........................................................................................................... 33

Eagle (D4193C00002): A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of

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.
Liver ................................................................................................................................. 35

CA209-459-002: A Randomized, Multi-center Phase III Study of Nivolumab versus Sorafenib as First-Line Treatment in Patients with Advanced Hepatocellular Carcinoma (CheckMate 459: CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 459)......................................................... 35

Lung (NSCLC) ........................................................................................................................................ 36

BLOOM (D6030C00001): A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-Tumour Activity of AZD3759 or AZD9291 in Patients with EGFR Mutation Positive Advanced NSCLC ................................................................. 36

Melanoma ......................................................................................................................................... 37

Sirtex (04888): A pilot study of combined treatment for hepatic metastases of uveal melanoma with intrahepatic Yttrium-90 microsphere radioembolisation and intrahepatic cisplatin ............... 37

Amgen 20110265: Phase 1b/2 Trial of Talimogene Laherparepvec (T-VEC) in Combination with MK-3475 for Untreated, Unresected, IIIB to IVM1c Melanoma ............................................................................. 38

Amgen 20110266: Talimogene Laherparepvec (T-VEC) Neoadjuvant Treatment Plus Surgery Versus Surgery Alone for Resectable, Stage IIIB to IVM1a Melanoma ........................................................................ 39

Pancreatic ......................................................................................................................................... 40

CL-SBP-101-01: A PHASE 1A/1B STUDY OF SBP-101 IN PREVIOUSLY TREATED SUBJECTS WITH LOCALLY ADVANCED OR METASTATIC PANCREATIC ........................................................................... 40

DUCTAL ADENOCARCINOMA ............................................................................................................. 40

YOSEMETHE: A Phase 3 RCT: Gemcitabine, Abraxane +/- Demicizumab as 1st line treatment in metastatic pancreatic cancer ................................................................................................................................. 41

cT
dNA Pancreas – Circulating Tumour DNA as a Biomarker Pancreatic Cancer ........................................ 42

Phase 1 ............................................................................................................................................. 43

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 ................................................................................................................................. 43

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 ................................................................................................................... 44

CMD-2015-001: A Phase 1 Dose-Finding and Pharmacokinetic Study of DpC, Administered Orally to Patients with Advanced Solid Tumors ................................................................................................................................. 45

GO29674: A Phase 1B open-label study of the safety and pharmacokinetics of MOXR0916 and MPDL3280A (atezolizumab) in patients with advanced/metastatic solid tumours ................................................................................................................................. 46

INCSHR 1210-101: A Phase 1 study to evaluate safety and tolerability of INCSHR01210 (PD-1 inhibitor) in patients with advanced solid tumours ................................................................................................................................. 47

Thyroid ............................................................................................................................................. 48

EXAMINER: A Randomized, Double Blind Study Comparing Cabozantinib (XL184) at 60mg daily compared to 140mg daily in Progressive Medullary Thyroid Cancer ........................................................................... 48

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## Contact Phone Numbers

### Medical Oncology Principal Investigators

<table>
<thead>
<tr>
<th>Principal Investigators</th>
<th>Contact Phone No</th>
</tr>
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<tbody>
<tr>
<td>Prof Jonathan Cebon</td>
<td>9496 5763</td>
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<tr>
<td>Dr Lawrence Cher</td>
<td>9496 5763</td>
</tr>
<tr>
<td>Dr Geoff Chong</td>
<td>9496 5763</td>
</tr>
<tr>
<td>A/Prof Farshad Foroud</td>
<td>9496 2428</td>
</tr>
<tr>
<td>Dr Serene Foo</td>
<td>9496 5763</td>
</tr>
<tr>
<td>A/Prof Hui Gan</td>
<td>9496 5763</td>
</tr>
<tr>
<td>Dr Eliza Hawkes</td>
<td>9496 5763</td>
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<tr>
<td>A/Prof Tom John</td>
<td>9496 5763</td>
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<tr>
<td>Dr Daryl Lim Joon</td>
<td>9496 2428</td>
</tr>
<tr>
<td>Dr Oliver Klein</td>
<td>9496 5763</td>
</tr>
<tr>
<td>A/Prof Paul Mitchell</td>
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</tr>
<tr>
<td>Prof Andrew Scott</td>
<td>9496 5763</td>
</tr>
<tr>
<td>Dr Jo Stewart</td>
<td>9496 5763</td>
</tr>
<tr>
<td>A/Prof Niall Tebbutt</td>
<td>9496 5763</td>
</tr>
<tr>
<td>Dr Mori Wada</td>
<td>9496 2428</td>
</tr>
<tr>
<td>A/Prof Shane White</td>
<td>9496 5763</td>
</tr>
<tr>
<td>A/Prof Andrew Weickhardt</td>
<td>9496 5763</td>
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### Medical Oncology Cancer Clinical Trial Staff

<table>
<thead>
<tr>
<th>Study Coordinators / Fellows</th>
<th>Contact Phone No/ Pager</th>
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<tbody>
<tr>
<td>Clare Healy</td>
<td>9496 9912 / page 1105</td>
</tr>
<tr>
<td>Noel Micallef</td>
<td>9496 3081 / page 6741</td>
</tr>
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<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Helen Norris</td>
<td>9496 9913</td>
<td>6747</td>
</tr>
<tr>
<td>Vivian Smith</td>
<td>9496 9911</td>
<td>1732</td>
</tr>
<tr>
<td>Rajani Iywan</td>
<td>9496 3544</td>
<td>3544</td>
</tr>
<tr>
<td>Julie Watson</td>
<td>9496 3575</td>
<td>3575</td>
</tr>
<tr>
<td>Julie Costantin</td>
<td>9496 3548</td>
<td>6746</td>
</tr>
<tr>
<td>Donna Haberl</td>
<td>9496 3762</td>
<td>6746</td>
</tr>
<tr>
<td>Brie Jelbart</td>
<td>9496 3297</td>
<td>1769</td>
</tr>
<tr>
<td>Catherine Johnston</td>
<td>9496 3038</td>
<td>3038</td>
</tr>
<tr>
<td>Lucy Demeo</td>
<td>9496 9916</td>
<td>1733</td>
</tr>
<tr>
<td>Elizabeth Cooch</td>
<td>9496 3576</td>
<td>1101</td>
</tr>
<tr>
<td>Yali Liu</td>
<td>9496 9863</td>
<td>1103</td>
</tr>
<tr>
<td>Jenni Flynn</td>
<td>9496 3651</td>
<td>6745</td>
</tr>
<tr>
<td>Lotus Wannarath</td>
<td>9496 3084</td>
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</tr>
<tr>
<td>Jaren Caine</td>
<td>9496 3906</td>
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</tr>
<tr>
<td>Sarah Healy</td>
<td>9496 9918</td>
<td>1503</td>
</tr>
<tr>
<td>Tanya Redman</td>
<td>9496 3549</td>
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</tr>
<tr>
<td>Lisa Walker</td>
<td>9496 9712</td>
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<tr>
<td>Jenny Kaiser</td>
<td>9496 9862</td>
<td>1503</td>
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<tr>
<td>Trish Jenkins</td>
<td>9496 4301</td>
<td>4300</td>
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<tr>
<td>Dr Surein Arulananda</td>
<td>9496 9933</td>
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<tr>
<td></td>
<td>Pager: 9496 5000 then page 3990</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E: <a href="mailto:Surein.Arulananda@austin.org.au">Surein.Arulananda@austin.org.au</a></td>
<td></td>
</tr>
<tr>
<td>Dr Alysson Wann</td>
<td>9496 9999</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pager: 9496 5000 then page 4393</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E: <a href="mailto:Alysson.Wann@austin.org.au">Alysson.Wann@austin.org.au</a></td>
<td></td>
</tr>
<tr>
<td>Dr Anis Hamid</td>
<td>9496 9932</td>
<td></td>
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<td>Pager: 9496 5000 then page 3248</td>
<td></td>
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<tr>
<td></td>
<td>E: <a href="mailto:Anis.Hamid@austin.org.au">Anis.Hamid@austin.org.au</a></td>
<td></td>
</tr>
<tr>
<td>Dr George Iatropoulos</td>
<td>9496 9931</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pager: 9496 5000 then page 1726</td>
<td></td>
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<tr>
<td></td>
<td>E: <a href="mailto:George.Iatropoulos@austin.org.au">George.Iatropoulos@austin.org.au</a></td>
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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>LUD2013-006: Phase 2 study to Evaluate the Clinical Efficacy and Safety of MEDI4736 in Patients with Glioblastoma (GBM)</td>
</tr>
<tr>
<td>Study Synopsis:</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>
</tr>
</tbody>
</table>

## Key eligibility criteria:

**Inclusion Criteria:**
- Arm A:
  - Newly diagnosed unmethylated GBM, eligible for radiotherapy (full course)
- Arm C:
  - 1st or 2nd recurrence by RANO criteria or biopsy
  - One bevacizumab containing regimen
- All Arms:
  - Measurable or non-measurable disease
  - Subject has a Karnofsky Performance Status (KPS) 70 or above.
  - Subject has adequate bone marrow, renal, and hepatic function

**Exclusion Criteria:**
- Brainstem or spinal cord GBM; metastatic disease or leptomeningeal disease
- Local therapies including: stereotactic radiosurgery, gliadel, re-irradiation within 6 months
- Previous immunotherapy
- Autoimmune disorders
- Active or chronic hepatitis; cleared hepatitis is allowed
- High dose steroids/immunosuppressive agents (use for cerebral oedema is allowed)

<table>
<thead>
<tr>
<th>Contact:</th>
<th>A/Prof Hui Gan (0448 048 266) or (Fellow; P:9496 9929; or Pager: 94965000 then page 3248)</th>
</tr>
</thead>
</table>
| 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
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<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>
</tr>
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**Tumour Type:** Brain: Glioblastoma Multiforme (GBM)  

**Protocol & Title:** PMC_TTAC-0001_02 : A Multicenter, 3-arm, Open-Label, Phase IIa Clinical Trial to Evaluate the Safety and Efficacy of TTAC-0001 in Patients with Recurrent Glioblastoma  

**Study Synopsis:** This is a Phase IIa open-label study evaluating the safety and efficacy of TTAC-0001 (an anti-VEGF-2 fully human monoclonal antibody) as monotherapy or in combination with TMZ in patients with recurrent GBM. TTAC-0001 is administered weekly with or without a one-week break every 4 weeks.  

### Inclusion Criteria:  
- Diagnosed with primary GBM by histopathological examination and confirmed recurrent glioblastoma by MRI scans after CCRT. One previous recurrence/progression of glioblastoma with reintroduction/altered schedule of temozolomide is allowable.  
- At least one confirmed measurable lesion or non-measurable lesion by RANO criteria  
- Karnofsky Performance Status (KPS) ≥ 80  
- A person who satisfies the adequate hematologic, renal, coagulation and hepatic function tests. Creatinine clearance (CrCl) ≥ 30 mL/min  
- At least 12 weeks of expected survival  

### Exclusion Criteria:  
- Previous therapy with vascular endothelial growth factor (VEGF)-targeted agents including (but not limited to) bevacizumab  
- Treatment with systemic chemotherapy, hormonal therapy, immunotherapy or biologic therapy except CCRT or temozolomide alone within 2 weeks prior to the baseline visit  
- The following concomitant diseases:  
  - Uncontrolled hypertension (systolic blood pressure [SBP] > 150 or diastolic blood pressure [DBP] > 90 mmHg)  
  - Uncontrolled seizures  
  - Class III or IV heart failure by New York Heart Association (NYHA) classification  
  - Oxygen-dependent chronic disease  
- Undergone major surgery requiring general anaesthesia or a respiratory assistance device within 4 weeks prior to the baseline visit  

**Contact:**  
Dr Lawrence Cher (PI) or Dr George Iatropoulos (Fellow; P:9496 9931; or Pager: 94965000 then page 1726; or E: George.Iatropoulos@austin.org.au)  

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<p>| Principal Investigator: | Dr Lawrence Cher |  | After hours contact: | via Austin switch: 9496 5000 |  | Primary study Co-ordinator: | Sarah Healy |  | P: 9496 9918 | Pg: 1503 |</p>
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</table>

**Study Synopsis:**
Study RTOG 3508/M13-813 is a clinical study of ABT-414 for subjects with newly diagnosed glioblastoma (GBM). ABT-414 is an antibody drug conjugate (ADC) against tumors harboring amplified EGFR. This is a Phase 2b/3 randomized double-blind, placebo-controlled trial comparing the efficacy and safety of ABT-414 versus placebo, each as concurrent treatment with of radiation/temozolomide (TMZ) plus adjuvant TMZ and followed by ABT-414/placebo monotherapy.

**Inclusion Criteria:**
- Histologically confirmed de novo Grade IV glioma (GBM, gliosarcoma or other subvariants)
- EGFR amplification in tumor tissue
- Supratentorial tumor
- Karnofsky performance status ≥ 70
- Subject has adequate bone marrow, renal, and hepatic function

**Exclusion Criteria:**
- Subject has multifocal GBM, Gliomatosis cerebri, recurrent GBM, infratentorial tumor, metastatic GBM
- Prior chemotherapy or radiosensitizers for cancers of the head and neck region
- Prior radiotherapy to the head or neck (except for T1 glottic cancer), resulting in overlap of radiation fields.
- Subject has had LASIK procedure within the last 1 year or cataract surgery within the last 3 months.
- Subject is unsuitable for receiving ocular steroids: active viral disease of the cornea or conjunctiva, mycobacterial infection of the eye; fungal diseases of ocular structures, primary open angle glaucoma or history of steroid-induced intraocular pressure elevation.
- Severe hepatic impairment, unstable angina and/or NYHA G2 or greater CCF, myocardial infarction, CVA or TIA within 6 months; Clinically defined AIDS-defining illness

**Contact:**
A/Prof Hui Gan (PI) or Dr George Iatropoulos (Fellow; P:9496 9931; or Pager: 94965000 then page 1726; or E: George.Iatropoulos@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

**Primary study Co-ordinator:**
Tanya Redman

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

**P:** 9496 3549

**Pg:** 1538

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Breast

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<tr>
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</tr>
<tr>
<td>Study Synopsis:</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:
(Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264)

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: Shane White
After hours contact:
via Austin switch: 9496 5000

Primary Study Co-ordinator: Elizabeth Cooch
P: 9496 3576
Pg: 1101
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Breast: Advanced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>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</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>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</td>
</tr>
<tr>
<td>Key eligibility criteria:</td>
<td>Inclusion Criteria:</td>
</tr>
<tr>
<td></td>
<td>• Postmenopausal</td>
</tr>
<tr>
<td></td>
<td>• Tissue block available and appropriate for PIK3CA mutation testing (a cohort of wild type patients will also be included)</td>
</tr>
<tr>
<td></td>
<td>• Advanced breast cancer that is ER+ve and HER2-negative</td>
</tr>
<tr>
<td></td>
<td>• 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</td>
</tr>
<tr>
<td></td>
<td>• Measurable disease or non-measurable, evaluable disease with at least one evaluable bone lesion that has not been previously irradiated</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria</td>
</tr>
<tr>
<td></td>
<td>• Prior mTOR inhibitor</td>
</tr>
<tr>
<td></td>
<td>• Prior treatment with &gt; 1 cytotoxic chemotherapy regimen for MBC</td>
</tr>
<tr>
<td></td>
<td>• CNS metastases that have not been treated</td>
</tr>
<tr>
<td></td>
<td>• Type 1 or Type 2 diabetes mellitus requiring anti-hyperglycaemic medications</td>
</tr>
<tr>
<td>Contact:</td>
<td>(Fellow; P:9496 9933) or Pager: 94965000 then page 5264</td>
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<td>After hours contact:</td>
<td>via Austin switch: 9496 5000</td>
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<tr>
<td>Primary study Co-ordinator:</td>
<td>Lucy Demeo</td>
</tr>
<tr>
<td>P:</td>
<td>9496 9916</td>
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<tr>
<td>Pg:</td>
<td>1733</td>
</tr>
</tbody>
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**Tumour Type:** Metastatic breast cancer – 1st line met breast cancer

**Protocol & Title:** WO29479: PHASE II STUDY EVALUATING THE SAFETY & EFFICACY OF COBIMETINIB IN COMBINATION WITH PACLITAXEL AS FIRST-LINE TREATMENT FOR PATIENTS WITH METASTATIC TRIPLE-NEGATIVE BREAST CANCER (COLET)

**Study Synopsis:** A MULTISTAGE, PHASE II STUDY EVALUATING THE SAFETY AND EFFICACY OF COBIMETINIB IN COMBINATION WITH PACLITAXEL AS FIRST-LINE TREATMENT FOR PATIENTS WITH METASTATIC TRIPLE-NEGATIVE BREAST CANCER

**Key eligibility criteria:**

**Inclusion Criteria:**
- Histologically confirmed estrogen receptor (ER)-negative, progesterone receptor (PR) negative, and human epidermal growth factor 2 (HER2)-negative adenocarcinoma of the breast with measurable metastatic or locally advanced disease (can use original tissue)
- Locally advanced disease must not be amenable to resection with curative intent
- Measurable disease
- Adequate organ function

**Exclusion Criteria:**
- Any prior chemotherapy, hormonal, or targeted therapy, for inoperable locally advanced or mTNBC
- Prior chemotherapy (including taxanes) and/or radiation in the neoadjuvant or adjuvant setting is allowable if treatment occurred ≥ 6 months prior to initiation of study treatment
- Any systemic anticancer therapy within 3 weeks
- Any radiation treatment to metastatic site within 28 days
- Major surgical procedure, open biopsy, or significant traumatic injury within 30 days
- Prior therapy with targeted therapies
- Grade ≥ 2 peripheral neuropathy

**Contact:** A/Prof Shane White (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@austin.org.au)

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

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

**Primary study Co-ordinator:** Yali Liu

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

**P:** 9496 9863

**Pg:** 1103

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**Tumour Type:** Early breast cancer  

**Protocol & Title:** ANZ 1002: Post-operative Radiotherapy Omission in Selected Patients with Early breast Cancer Trial (PROSPECT)  

**Study Synopsis:** A single arm phase II study using magnetic resonance imaging (MRI) to select patients with early breast cancer for omission of post-operative radiotherapy  

**Key eligibility criteria:**  

**Inclusion Criteria:**  
- >50 year old with histologically confirmed, unifocal, unilateral invasive breast cancer  
- Breast conserving surgery with invasive primary tumour <20mm  
- >2mm clear resection margins  
- pN0 by sentinel node biopsy and/or axillary dissection  
- Pre op MRI 6 weeks prior to surgery with nil or minimal parenchymal enhancement  
- Cease all hormonal contraception and HRT within 4 weeks of diagnosis.  

**Exclusion Criteria:**  
- Mammogram shows calcification in index lesion  
- Triple negative, prior in situ or invasive breast cancer, extensive DCIS (>25% volume), LVI, multicentric/multifocal.  
- Gene carriers  
- Contraindication to MRI  

**Contact:**  
Dr Caroline Baker (9496 5000) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@austin.org.au)  

**To refer patient:**  
To minimise delays, please fax a referral to the 03-9457-6698 with:  
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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 Caroline Baker  
**After hours contact:** via Austin switch: 9496 5000  

**Primary study Co-ordinator:** Catherine Johnston  
**P:** 9496 303  
**Pg:** 3038
**Tumour Type:** Early breast cancer

**Protocol & Title:** ANZ 1401 (ELIMINATE) Oestrogen Lowering Intervention May Increase NeoAdjuvant Therapy Efficacy

**Study Synopsis:** Randomised phase II trial of neoadjuvant chemotherapy +/- concurrent aromatase inhibitor endocrine therapy to down-stage large oestrogen receptor positive breast cancer

**Key eligibility criteria:**

**Inclusion Criteria:**
- Clinically stage 2 or 3, G2 or 3 histologically confirmed invasive breast cancer
- In situ ER+, Her2 negative, cT2-T4 primary breast cancer (multifocal allowed if largest lesion >20mm)
- Suitable for neoadjuvant chemotherapy with anthracycline and taxane for at least 18 weeks
- Is measurable radiologically
- Willing to undergo x2 core biopsies on trial
- Surgical expectation: will have WLE or mastectomy 6 weeks post chemotherapy, for axillary dissection if axilla still involved post chemotherapy.

**Exclusion Criteria:**
- Prior excision of breast tumour or axillary lymph node removal
- G1, bilateral, multicentric or male breast cancer
- Prior invasive breast cancer, chemotherapy or radiotherapy to affected breast.
- Current hormonal therapy (HRT, contraception)
- Prior treatment with SERM, aromatase inhibitor
- Contraindication for anthracycline or taxane.

**Contact:** Dr Josephine Stewart (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@austin.org.au)

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

**Principal Investigator:** Dr Josephine Stewart  
**After hours contact:** via Austin switch: 9496 5000

**Primary study Co-ordinator:** Elizabeth Cooch  
P: 9496 3576  
Pg: 1101
# Colorectal

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Colorectal Cancer</th>
</tr>
</thead>
</table>

| Protocol & Title: | ICR02 / ASCOLT: Aspirin for Dukes C and High Risk Dukes B Colorectal Cancers An International, Multi-centre, Double Blind, Randomised Placebo Controlled Phase III Trial |

| Study Synopsis: | Aspirin for Dukes C and High Risk Dukes B Colorectal Cancers: An International, Multi-centre, Double Blind, Randomised Placebo Controlled Phase III Trial |

## Key eligibility criteria:

**Inclusion Criteria:**
- Dukes C or high risk Dukes B colon cancer
- Dukes C or B rectal cancer
- Within 120 days of resection of primary and completed standard therapy (>3 months of chemo +/- radiotherapy)
- Completed colonoscopy and imaging of abdomen (within 16 months prior to randomisation).

**Exclusion Criteria:**
- Familial adenomatous polyposis, inflammatory bowel disease or ulcerative colitis, HN
- Gastritis, peptic ulcer disease, history of continuous PPI use (>12 months)
- GI bleed in the last 12 months, hemorrhagic diathesis, uncontrolled hypertension.
- History of recent cancer
- History of stroke, CAD, angina or vascular disease
- Currently on Aspirin, NSAIDs or COX2 inhibitors (consecutively for >4 weeks), antiplatelet agents, anti coagulants.

| Contact: | A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@austin.org.au) |

To minimise delays, please fax a referral to the 03-9457-6698 with:
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<tr>
<th>Primary study Co-ordinator:</th>
<th>Elizabeth Cooch</th>
</tr>
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<td>P: 9496 3576</td>
<td>Pg: 1101</td>
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<tr>
<th>Tumour Type:</th>
<th>Colorectal Cancer: BRAF mutated Metastatic Colorectal and Lung Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>EVICT (Erlotinib and Vemurafenib In Combination Trial): A Phase I/II Trial of the combination of BRAF and EGFR inhibition in BRAF V600E mutant metastatic colorectal, advanced or metastatic lung adenocarcinoma and other cancers: The EVICT (Erlotinib and Vemurafenib In Combination Trial) Study</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>A Phase I/II Trial of the combination of BRAF and EGFR inhibition in BRAF V600E mutant metastatic colorectal, advanced or metastatic lung adenocarcinoma and other cancers: The EVICT (Erlotinib and Vemurafenib In Combination Trial) Study</td>
</tr>
</tbody>
</table>
| Key eligibility criteria: | **Inclusion Criteria:**  
  - Be ≥ 18 years of age and can consent  
  - ECOG 0-1  
  - Measurable disease as per RECIST 1.1  
  - Adequate organ function  
  - BRAF V600E mutation  
  - Maximum 2 lines of therapy for metastatic disease (maintenance or oxaliplatin rechallenge is not considered a line)  
  - Suitable for oral medications  
| | **Exclusion Criteria:**  
  - Can swallow tablets  
  - <4 weeks of prior anti tumour treatment, <2 weeks prior radiotherapy or surgery.  
  - Significant cardiac disease  
  - Known CNS malignancy/involvement (unless treated with SRS or surgery and stable >1 month)  
  - Prior malignancies  
  - EGFR mutant lung adenocarcinoma  
  - On medications that are strong CYP3A4 inhibitors or inducers <14 days prior to treatment  
  - Sensitivities to Erlotinib or Vemurafenib |
| Contact: | A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@austin.org.au) |
| To refer patient: | To minimise delays, please fax a referral to the 03-9457-6698 with:  
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<tbody>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Brie Jelbart</td>
<td>P: 9496 3297</td>
<td>Pg: 1769</td>
</tr>
<tr>
<td>Tumour Type:</td>
<td>Metastatic/Locally recurrent anal squamous cell carcinoma</td>
<td></td>
<td></td>
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<tr>
<td>-------------</td>
<td>---------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td>AG0214ANL/CTC 0124 (InterAACT): An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>An International Multicentre Open Label Randomised Phase II Advanced Anal Cancer Trial Comparing Cisplatin plus 5-fluorouracil versus Carboplatin plus Weekly Paclitaxel in Patients with Inoperable Locally Recurrent or Metastatic Disease</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**  
- Be ≥ 18 years of age on day of signing informed consent  
- ECOG 0-2  
- Inoperable, locally recurrent or metastatic disease  
- Histological or cytological confirmation of epidermoid anal carcinoma  
- Relapse >6m post previous chemo-radiation for early stage tumour  
- <2 cycles of systemic chemotherapy as induction treatment prior to definitive chemo-radiation  
- HIV patients with CD4 count >200 or CD4 count <200 but undetectable viral load  
- Adequate organ function  

**Exclusion Criteria:**  
- Tumours of adenocarcinoma, melanoma, small cell and basal cell histology are excluded.  
- Tumour progression after systemic treatment but prior to definitive chemo-radiation  
- Previous systemic treatment for metastatic disease  
- No new target lesions outside of radiotherapy field or progression of irradiated lesions as per RECIST 1.1  
- Major surgery <28 days  
- Palliative radiotherapy <7 days  
- History of cardiac failure, interstitial lung disease, active viral hepatitis  
- Contraindications to cisplatin or paclitaxel including peripheral neuropathy >G1, pre existing hearing impairment |
| **Contact:** | A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@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:** | A/Prof Niall Tebbutt |
| **Primary study Co-ordinator:** | Elizabeth Cooch |

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# Gastro-Intestinal

<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>
<tr>
<td>Study Synopsis:</td>
<td>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 esophago-gastrectomy, minimum D1+ lymph node dissection. Post-operative chemotherapy with 3 cycles ECF or ECX is then recommended. Primary endpoint is overall survival.</td>
</tr>
</tbody>
</table>
| Key eligibility criteria: | **Inclusion Criteria:**  
- Stage IB (T1N1 only, not T2N0) to IIIC cancer of the stomach or gastroesophageal junction  
- ECOG 0-1  
- Disease that can be radically treated with radiotherapy 45Gy  
**Exclusion Criteria:**  
- Cardiac failure or other epirubicin contraindication  
- Impaired GI absorption  
- Medically unfit for cisplatin (including GFR <50ml/min) |
| Contact: | (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264) |
| 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>
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</thead>
<tbody>
<tr>
<td>Primary Study Co-ordinator:</td>
<td>Donna Haberl / Julie Costantin</td>
<td>P: 9496 3762 / 9496 3548</td>
<td>Pg: 6746 / 6746</td>
</tr>
</tbody>
</table>
Tumour Type: Gastric & Gastroesophageal: Advanced

Protocol & Title: 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

Study Synopsis: 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.

Key eligibility criteria:

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

Exclusion Criteria:
- Prior treatment with a taxane in the advanced setting or within 6 months if used in the neoadjuvant or adjuvant setting
- More than one prior chemotherapy regimen administered in the metastatic setting
- Symptomatic brain metastases
- Peripheral neuropathy ≥ grade 2 CTCAE

Contact: (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264)

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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
**Tumour Type:** Metastatic Gastric or GOJ Cancer

**Protocol & Title:** MK 3475-062: Ph III Trial of Pembrolizumab (MK-3475), pembrolizumab+FP/XP vs. Placebo+FP/XP in Biomarker Select, Advanced Gastric or GEJ Adenocarcinoma

**Study Synopsis:** A Randomized, Active-Controlled, Partially Blinded, Biomarker Select, Phase III Clinical Trial of Pembrolizumab as Monotherapy and in Combination with Cisplatin+5-Fluorouracil versus Placebo+Cisplatin+5-Fluorouracil as First-Line Treatment in Subjects with Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma

**Key eligibility criteria:**

**Inclusion Criteria:**
- Be ≥ 18 years of age on day of signing informed consent
- ECOG 0-1
- Have histologically or cytologically confirmed diagnosis of locally advanced or metastatic gastric or GEJ adenocarcinoma.
- Be HER2/neu negative and PD-L1 positive.
- Have measurable disease as defined by RECIST 1.1
- Demonstrate adequate organ function

**Exclusion Criteria:**
- Squamous cell or undifferentiated gastric cancer.
- Has had previous therapy for locally advanced or metastatic gastric/GEJ cancer. (Prior neoadjuvant or adjuvant therapy within 6 months)
- Additional malignancy in the last 5 years
- Systemic infection, HIV, Hep B, Hep C
- Autoimmune disorders requiring systemic treatment
- DPPD deficiency
- Steroid use (apart from physiological replacement)
- Previous PD1, PDL1, PDL2 therapy

**Contact:** A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@austin.org.au)

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Tumour Type: Metastatic biliary tract cancer

Protocol & Title: I3O-MC-JSBF: Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestinib or Placebo plus Cisplatin and Gemcitabine as First-Line Treatment in Patients with Advanced or Metastatic Biliary Tract Cancer

Study Synopsis: Randomized, Double-Blind, Phase 2 Study of Ramucirumab or Merestinib or Placebo plus Cisplatin and Gemcitabine as First-Line Treatment in Patients with Advanced or Metastatic Biliary Tract Cancer

Key eligibility criteria:

Inclusion Criteria:
- Be ≥ 18 years of age on day of signing informed consent
- ECOG 0-1
- Have a histologically or cytologically confirmed diagnosis of non-resectable, recurrent, or metastatic biliary tract adenocarcinoma (intrahepatic or extrahepatic cholangiocarcinoma, gallbladder cancer, or Ampulla of Vater).
- Resolution of all prior toxicity <G1
- Have measurable disease as defined by RECIST 1.1
- Demonstrate adequate organ function including adequate biliary drainage, AST/ALT/Bili <3ULN on 2 occasions 5 days apart during screening.
- Urinary protein <1+ or <2g on 24 hr protein collection
- Provide tumour for research purposes (biopsy within 28 days of consent)

Exclusion Criteria:
- Previous systemic therapy for locally advanced of metastatic disease; TACE, radiotherapy, radioactive beads not allowed
- Bypass surgery and adjuvant chemotherapy is allowed
- >G1 ascites, Child Pugh >B, hepatic encephalopathy
- Ongoing or recent hepatorenal syndrome (>6 months)
- Major surgery <28 days, radiotherapy <14 days
- Documented brain mets, leptomeningeal disease, spinal cord compression.
- Current therapeutic anticoagulation, NSAIDs, anti platelet agents
- Previous VEGF inhibitors
- <6 months from VTE, coronary event, CVA/TIA
- <3m major bleeding event (G3 or G4)
- Uncontrolled hypertension (>150 SBP or >90 DBP)
- History of GI perforation, fistulae <6m, uncontrolled thrombotic disorder
- Mixed hepatocellular biliary tract histology

Contact: A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@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: A/Prof Niall Tebbutt
After hours contact: via Austin switch: 9496 5000

Primary study Co-ordinator: Lucy Demeo
P: 9496 9916
Pg: 1733
## Genito-Urinary - Prostate Cancer

<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Prostate Cancer</th>
</tr>
</thead>
</table>

### Protocol & Title:

**BAY 88-8223/15396 - Radium 223:** A Phase III trial of radium-223 dichloride in combination with abiraterone and prednisolone for asymptomatic/mildly symptomatic, chemotherapy-naïve, bone-predominant metastatic castrate-resistant prostate cancer

### Study Synopsis:

This is a Phase III randomised, double-blind trial evaluating the efficacy of radium-223 dichloride (versus placebo) in combination with abiraterone and prednisolone in patients with symptomatic/mildly symptomatic, chemotherapy-naïve, bone-predominant mCRPC

### Inclusion Criteria:

- Histologically-proven prostate adenocarcinoma, progressive per PCWG2 criteria (despite anti-androgen withdrawal) or RECIST v1.1 criteria
- ECOG 0-1, life expectancy greater than 6 months
- Two or more bone metastases with no visceral metastases
- Asymptomatic or mildly symptomatic (Worst Pain Score 3 or less)
- Adequate end-organ function

### Exclusion Criteria:

- Prior chemotherapy, abiraterone, radium-223 for CRPC; immunotherapy within 4 weeks of randomisation
- History or presence of visceral metastases, incl brain metastases
- Malignant lymphadenopathy exceeding 3cm in short-axis diameter
- Use of opiate analgesia for cancer-related pain (within 4-weeks of randomisation)
- Imminent spinal cord compression on MRI
- Blood transfusion within 4 weeks of randomisation
- Active viral hepatitis, pituitary or adrenal dysfunction, significant heart disease (AMI or thrombosis within 6 months, unstable angina, NYHA II+ heart failure), atrial fibrillation (or other arrhythmia requiring therapy), cardiac ejection fraction <50%, inflammatory bowel disease, chronic liver disease, unmanageably faecal incontinence, uncontrolled hypertension
- Steroid dose greater than equivalent prednisolone to 5mg bd

### Contact:

A/Prof Andrew Weickhardt (PI) or Dr 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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- Referrer’s contact details and provider number
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- Whether the patient has been discussed with a particular trials personnel already

### Principal Investigator:

A/Prof Andrew Weickhardt

### Primary study Co-ordinator:

Sarah Healy

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

**P:** 9496 9918  
**Pg:** 1503

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<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 detect 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 Anis Hamid (Fellow; P: 9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au) |
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<p>| Principal Investigator: | Dr Andrew Weickhardt |
| After hours contact: | via Austin switch: 9496 5000 |
| Primary Study Co-ordinator: | Trish Jenkins |
| P: | 9496 4301 |
| Pg: | 4300 |</p>
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<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>PROSPER (MDV3100-14):</strong> A Multinational, Phase 3, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Enzalutamide in Patients with Nonmetastatic Castration-Resistant Prostate Cancer</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>• Phase III of Enzalutamide vs placebo (2:1) in patients with M0 CRPC&lt;br&gt;• Consider ceasing anti-androgen therapy on referral of patient, as 4 weeks washout required</td>
</tr>
<tr>
<td><strong>Key eligibility criteria:</strong></td>
<td><strong>Inclusion Criteria:</strong>&lt;br&gt;• Medical or surgical castration&lt;br&gt;• PSA progression – PSA rise x3 and ≥ 2ng/mL and PSADT ≤ 10months&lt;br&gt;• M0 on CT/MRI and WBBS. LN &lt;15cm below aortic bifurcation permissible&lt;br&gt;• Asymptomatic prostate ca. ECOG 0 or 1&lt;br&gt;<strong>Exclusion Criteria:</strong>&lt;br&gt;• prior chemo/ abiraterone/ enzalutamide/ ketoconazole&lt;br&gt;• known or suspected CNS metastasis&lt;br&gt;• h/o invasive cancer last 3 years&lt;br&gt;• ANC &lt;1.0, platelet &lt;100, Hb &lt;100, bili ≥ 1.5xULN, ALT/ AST ≥ 2.5xULN, Albumin &lt;30, Cr &gt;177&lt;br&gt;• h/o seizure or predisposing conditions (eg stroke, ABI; h/o LOC or TIA within 12months)&lt;br&gt;• clinically significant CVS disease</td>
</tr>
<tr>
<td><strong>Contact:</strong></td>
<td>Dr Andrew Weickhardt or (PI) Dr Anis Hamid (Fellow; P: 9496 9929; or Pager: 94965000 then page 3248; or E: <a href="mailto:anis.hamid@austin.org.au">anis.hamid@austin.org.au</a>)</td>
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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
**Tumour Type:** Prostate Cancer  

**Protocol & Title:** ENZAMET (ANZUP 1304): Randomised phase 3 trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer

**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 Anis Hamid (Fellow; P: 9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au)

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<td>P: 9496 3084</td>
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<tr>
<td>Tumour Type:</td>
<td>Prostate Cancer</td>
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<tr>
<td>Protocol &amp; Title:</td>
<td>MOVEMBER FDHT: [18f]-dihydro-testosterone pet imaging in patients with progressive prostate cancer</td>
<td></td>
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</tr>
<tr>
<td>Study Synopsis:</td>
<td>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</td>
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<tr>
<td>Key eligibility criteria:</td>
<td>Inclusion Criteria:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>• Histologically confirmed diagnosis of prostate cancer (castrate or non-castrate).</td>
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<td></td>
<td>• 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</td>
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<td>• Target or non-target lesions based on RECIST 1.1</td>
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<td>• Written informed consent</td>
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<td>• Adequate organ function</td>
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<td>Exclusion Criteria:</td>
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<tr>
<td></td>
<td>• Previous anaphylactic reaction to FDHT</td>
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<td>• Contraindications to MRI</td>
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<td>• 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.</td>
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<td>• 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.</td>
<td></td>
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</tr>
<tr>
<td>Contact:</td>
<td>Andrew Weickhardt (Principal Investigator) or Dr Anis Hamid (Fellow; P: 9496 9929; or Pager: 94965000 then page 3248; or E: <a href="mailto:anis.hamid@austin.org.au">anis.hamid@austin.org.au</a>)</td>
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<th>After hours contact:</th>
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<tbody>
<tr>
<td>Primary Study Co-ordinator:</td>
<td>Sarah Healy</td>
<td>P: 9496 9918</td>
<td>Pg: 1503</td>
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<th>Tumour Type:</th>
<th>Prostate Cancer</th>
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<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>EMBARK: A Phase III randomised study of enzalutamide plus leuprolide, enzalutamide monotherapy and placebo plus leuprolide in men with high-risk nonmetastatic prostate cancer.</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This Phase III study randomised patients with a rising PSA post definitive prostate therapy (prostatectomy and/or radiotherapy) to enzalutamide plus leuprolide, enzalutamide monotherapy and placebo plus leuprolide.</td>
</tr>
<tr>
<td>Key eligibility criteria:</td>
<td></td>
</tr>
</tbody>
</table>
| Inclusion Criteria:  | • Prostate adenocarcinoma initially treated with radical prostatectomy and/or radiotherapy with curative intent  
                      • PSA doubling time ≤ 9 months with PSA ≥ 2.0ng/ml  
                      • Serum testosterone at non-castrate levels  
                      • ECOG 0-1  |
| Exclusion Criteria: | • Metastatic disease  
                      • Prior hormonal therapy other than neoadjuvant/adjuvant therapy ≤ 36m and ≥ 9m before randomisation  
                      • Prior chemotherapy, abiraterone or enzalutamide, immunotherapy  
                      • Suitable for salvage radiotherapy  
                      • Other cancers within 3 years  
                      • History of seizure or significant cardiovascular disease (specific definitions)  |
| Contact:             | A/Prof Shomik Sengupta (via switch 9496 5000) or Dr Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au) |
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Genito-Urinary - Other

<table>
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<tr>
<th>Tumour Type:</th>
<th>Urothelial/Bladder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>WO29636: A Phase III Study of Atezolizumab versus Observation as Adjuvant Therapy in Patients with PD-L1-selected High-Risk Muscle-Invasive Bladder Cancer</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase III open-label randomised trial of adjuvant atezolizumab (q3w up to 1 year) versus observation after cystectomy for MIBC with pT2-4 or pN+ disease and PD-L1 IC2/3 expression.</td>
</tr>
</tbody>
</table>

**Key eligibility criteria:**

**Inclusion Criteria:**
- ypT2-3 or ypN+ (post neoadjuvant therapy) OR pT3-4 or pN+ (no prior neoadjuvant therapy, but must be due to refusal or cisplatin-ineligible based on eGFR, hearing loss, neuropathy or ECOG 2)
- Cystectomy tissue available for PD-L1 expression analysis
- PD-L1 score IC2/3 on cystectomy specimen
- No evidence of metastatic disease
- ECOG ≤ 2; Life expectancy ≥ 12 weeks
- Adequate end-organ function

**Exclusion Criteria:**
- Adjuvant chemotherapy or radiotherapy following cystectomy (neoadjuvant chemoradiation is allowed)
- Autoimmune disease (hypothyroidism and Type 1 Diabetes allowed)
- Active tuberculosis, idiopathic pulmonary fibrosis, HIV, active HBV/HCV
- Other malignancy within 5 years (with exceptions)
- Antibiotics within 2 weeks of randomisation
- Significant cardiovascular disease (NYHA 2+), unstable arrhythmia/angina
- Prior checkpoint inhibitors or immunostimulatory agents
- Treatment with systemic corticosteroids or other immunosuppressants (low-dose immunosuppressants incl steroids permitted after discussion)

**Contact:**
A/Prof Andrew Weickhardt (PI) or Dr 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 Andrew Weickhardt
**After hours contact:** via Austin switch: 9496 5000

**Primary study Co-ordinator:** Sarah Healy  
P: 9496 9918  
Pg: 1503

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<th>Tumour Type:</th>
<th>Urothelial/Bladder Cancer</th>
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<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>PCR-MIB: A Phase II single-arm study of pembrolizumab with chemoradiotherapy as treatment for nonmetastatic, muscle invasive bladder cancer</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase II single-arm study evaluating the safety and efficacy of the addition of pembrolizumab to chemoradiotherapy for patients with muscle invasive bladder cancer who are not planned for cystectomy.</td>
</tr>
</tbody>
</table>
| Key eligibility criteria: | Inclusion Criteria:  
- Histologically-confirmed muscle invasive urothelial carcinoma (T2-T4a, Nx or N0). Mixed transitional/non-transitional histology allowed if TCC predominates (>50%).  
- Undergone maximal TURBT within 42 days of planned treatment  
- Elected not to undergo radical cystectomy or unsuitable for radical cystectomy  
- Panned for definitive chemoradiotherapy  
- ECOG 0-1  

Exclusion Criteria:  
- Concurrent extra-vesical disease (e.g. ureter, urethra except resected prostatic urethra, renal pelvis) or extensive/multifocal bladder CIS  
- Moderate/severe tumour-related hydronephrosis  
- Bulky T3/T4a tumours unsuitable for curative treatment (e.g. >10cm dimension)  
- Metastatic disease  
- Unsuitable for cisplatin-based chemotherapy  
- Prior systemic therapy or radiotherapy for bladder cancer. BCG/mitomycin allowed.  
- Autoimmune diseases with noted exceptions |
| Contact: | A/Prof Andrew Weickhardt (9496 5763) or Dr 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 Andrew Weickhardt |
| After hours contact: | via Austin switch: 9496 5000 |
| Primary study Co-ordinator: | Jenni Flynn |
| P: | 9496 3651 |
| Pg: | 6745 |
**Tumour Type:** Germ cell tumour

**Protocol & Title:** 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

**Study Synopsis:**
- Phase III. Of accelerated (Q2W) vs standard BEP in first line intermediate and poor-risk metastatic GCT (IGCCC classification)
- All other treatments (eg. 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 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:** Dr Andrew Weickhardt
**Primary Study Co-ordinator:** Jaren Caine

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<td>9496 5000</td>
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<tr>
<td>Jaren Caine</td>
<td>P: 9496 3906</td>
<td>Pg: 1775</td>
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## Tumour Type:
Renal Cell Carcinoma

## Protocol & Title:
**WO29637**: A Phase III Study of MPDL3290A in Combination with Bevacizumab versus Sunitinib in Patients with Untreated Advanced Renal Cell Carcinoma

## Study Synopsis:
This is a Phase III open-label randomised study evaluating the efficacy of MPDL3290A (Anti-PD-L1 antibody) in combination with bevacizumab compared with sunitinib in patients with untreated mRCC (1st-line therapy).

## Inclusion Criteria:
- Unresected advanced or metastatic RCC (clear-cell and/or sarcomatoid histology)
- FFPE tissue available for PD-L1 expression analysis
- Evaluable MSKCC risk score
- Measurable disease (RECIST v1.1)
- KPS ≥ 70
- Adequate end-organ function

## Exclusion Criteria:
- Prior treatment with active systemic agents including in the neoadjuvant or adjuvant setting
- Radiotherapy for RCC within 2 weeks
- Active or untreated CNS metastases
- Untreated hypercalcemia
- Uncontrolled effusions (pleural, pericardial, ascites) requiring recurrent drainage (>1/month)
- Autoimmune disease (hypothyroidism and Type 1 Diabetes allowed)
- Active tuberculosis, idiopathic pulmonary fibrosis, HIV, active HBV/HCV
- Other malignancy within 5 years (with exceptions)
- Antibiotics within 2 weeks of randomisation
- Significant cardiovascular disease (NYHA II+), unstable arrhythmia/angina
- Inadequately controlled hypertension (>150mg systolic / >100mg diastolic)
- Evidence of clinically significant coagulopathy. Stable use of anticoagulant therapy is permitted. Clopidogrel or dipyramidole are not permitted.
- Proteinuria >1.0g / 24h collection
- Prior checkpoint inhibitors or immunostimulatory agents (for RCC)
- Treatment with systemic corticosteroids or other immunosuppressants (low-dose immunosuppressants incl steroids permitted after discussion)

## Contact:
A/Prof Andrew Weickhardt (PI) or Dr 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 Andrew Weickhardt

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

## Primary study Co-ordinator:
Sarah Healy

## P: 9496 9918

## Pg: 1503

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Page 31
Head and Neck

Tumour Type: Head and Neck

Protocol & Title: MK3475-048: Pembrolizumab as First Line Treatment in Subjects with Recurrent/Metastatic HNSCC

Study Synopsis: 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

Key eligibility criteria:

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

Exclusion Criteria:
- Progressive disease within 6 months of completion of curatively intended systemic treatment for locoregionally advanced disease
- On steroids
- CNS metastases
- Auto-immune disease
- Prior PD-1 inhibitor

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: Sarah Healy
P: 9496 9918
Pg: 1503
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<thead>
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<th>Head and Neck</th>
</tr>
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<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>
<tr>
<td>Key eligibility criteria:</td>
<td>Inclusion Criteria:</td>
</tr>
<tr>
<td></td>
<td>• Stage III (excluding T1-2N1) or Stage IV (excluding T4, N3 and M1) if smoking history &lt; 10 pack/years. If &gt;10 pack/years, nodal disease must be N0-N2a.</td>
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<td>• P16+</td>
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<td>• Clinical measurable disease (ie not adjuvant treatment)</td>
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<td>• Previously untreated</td>
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<td></td>
<td>• ECOG 0-1</td>
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<tr>
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<td>• Subject has adequate bone marrow, renal, and hepatic function</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria:</td>
</tr>
<tr>
<td></td>
<td>• Peripheral neuropathy G2</td>
</tr>
<tr>
<td></td>
<td>• Tinnitus G2</td>
</tr>
<tr>
<td></td>
<td>• Hearing loss G2</td>
</tr>
<tr>
<td></td>
<td>• Interstitial lung disease</td>
</tr>
<tr>
<td>Contact:</td>
<td>A/Prof Hui Gan (0448 048 266) or Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: <a href="mailto:anis.hamid@austin.org.au">anis.hamid@austin.org.au</a>)</td>
</tr>
<tr>
<td>To refer patient:</td>
<td>To minimise delays, please fax a referral to the 03-9457-6698 with:</td>
</tr>
<tr>
<td></td>
<td>• Patient contact information</td>
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<td></td>
<td>• Referrer’s contact details and provider number</td>
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<tr>
<td></td>
<td>• Brief clinical history</td>
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<tr>
<td></td>
<td>• Whether the patient has been discussed with a particular trials personnel already</td>
</tr>
<tr>
<td>Principal Investigator:</td>
<td>A/Prof Hui Gan</td>
</tr>
<tr>
<td></td>
<td>After hours contact:</td>
</tr>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Trish Jenkins</td>
</tr>
<tr>
<td></td>
<td>P: 9496 4301</td>
</tr>
<tr>
<td>Tumour Type:</td>
<td>Head and Neck</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Protocol &amp; Title:</td>
<td><strong>Eagle (D4193C00002):</strong> 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)</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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) |
| 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 |
| Primary study Co-ordinator: | Lotus Wannarath |

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Liver

**Tumour Type:** Advanced Hepatocellular Carcinoma

**Protocol & Title:** CA209-459-002: A Randomized, Multi-center Phase III Study of Nivolumab versus Sorafenib as First-Line Treatment in Patients with Advanced Hepatocellular Carcinoma (CheckMate 459: CHECKpoint pathway and nivolumAb clinical Trial Evaluation 459)

**Study Synopsis:** A Randomized, Multi-center Phase III Study of Nivolumab versus Sorafenib as First-Line Treatment in Patients with Advanced Hepatocellular Carcinoma

### Key eligibility criteria:

#### Inclusion Criteria:

- Histologic confirmation of hepatocellular carcinoma.
- No prior systemic treatment
- Not eligible or progressed with loco-regional therapy (completed 4 weeks prior)
- RECIST 1.1 measurable disease (of previously untreated lesions)
- Child Pugh A
- ECOG 0-1
- Resolved/chronic HBV or active/resolved HCV
- Adequate organ function

#### Exclusion Criteria:

- Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC
- Prior liver transplant
- History of hepatic decompensation such as hepatic encephalopathy, ascites, evidence of portal hypertension with bleeding esophageal or gastric varices within the past 6 months
- Autoimmune diseases requiring systemic treatment
- >10mg steroid use/day
- Active systemic infection including coinfection of Hep C & Hep B or Hep D & Hep B.
- Known HIV
- Known cardiac disease (IHD within last 6 months, >G2 valvular disease, arrhythmias requiring treatment (B blockers & Digoxin allowed)
- Prior bleeding or thromboembolic event (requiring anti platelet or anti coagulation)

### Contact:

A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@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 Niall Tebbutt

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

### Primary study Co-ordinator:

Elizabeth Cooch

**P:** 9496 3576

**Pg:** 1101
# Lung (NSCLC)

<table>
<thead>
<tr>
<th><strong>Tumour Type:</strong></th>
<th>Lung</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>BLOOM (D6030C00001):</strong> A Phase I, Open-label, Multicentre Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-Tumour Activity of AZD3759 or AZD9291 in Patients with EGFR Mutation Positive Advanced NSCLC</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>This is a Phase 1 open label trial of AZD9291 or AZD3759 (a novel EGFR TKI) in patients with proven leptomeningeal (LM) and/or brain metastases (BM). There are separate cohorts for LM and BM patients. Australia is part of the expansion phase of the trial (not the dose-finding cohorts).</td>
</tr>
</tbody>
</table>

## Key eligibility criteria:

### Inclusion Criteria:
- Histologically or cytologically confirmed diagnosis of NSCLC with single activating EGFR mutations (L858R or Exon19Del).
- In Part B- LM expansion, patients who have progressed following previous EGFR TKI treatment must have stable extracranial disease.
- For patients with LM (both Part A and Part B):
  - Confirmed diagnosis of LM by positive CSF cytology.
  - At least one site of CNS LM disease that can be assessed by MRI
- ECOG performance status 0-1 with BM and 0-2 with LM

### Exclusion Criteria:
- Other trial medication within 30 days, surgery and or wide field RT within 4 weeks, chemotherapy within 14 days or EGFR TKI within 8 days
- Known intracranial haemorrhage
- Known ILD
- Other standard exclusion criteria

### 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:
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 Tom John

## Primary study Co-ordinator:
Rajani Iywan

After hours contact: via Austin switch: 9496 5000

**P:** 9496 3544

**Pg:** 3544
**Melanoma**

<table>
<thead>
<tr>
<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>

### Key eligibility criteria:

**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 Coordinator:** N/A

---

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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 antiviral 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)

To refer patient: To minimise delays, please fax a referral to the 03-9457-6698 with:
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- Referrer’s contact details and provider number
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- 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: Noel Micallef
P: 9496 3081
Pg: 6741

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<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Melanoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>Amgen 20110266: Talimogene Laherparepvec (T-VEC) Neoadjuvant Treatment Plus Surgery Versus Surgery Alone for Resectable, Stage IIIB to IVM1a Melanoma</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Key eligibility criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inclusion Criteria:</strong></td>
</tr>
<tr>
<td>• Histologically confirmed diagnosis of stage IIIB, IIIC, and IVM1a melanoma and eligible for complete surgical resection</td>
</tr>
<tr>
<td>• Men and women, &gt; 18 years of age.</td>
</tr>
<tr>
<td>• Prior systemic treatments must have been completed ≥ 3 months</td>
</tr>
<tr>
<td>• Candidates for intralesional treatment, with at least one injectable lesion ≥ 10mm</td>
</tr>
<tr>
<td>• Have measurable disease with at least one lesion ≥ 10mm</td>
</tr>
<tr>
<td>• ECOG 0-1</td>
</tr>
<tr>
<td>• Adequate organ function</td>
</tr>
<tr>
<td>• Serum LDH level ≤ 1.0 upper limit of normal (ULN) within 28 days prior to randomization</td>
</tr>
<tr>
<td><strong>Exclusion Criteria:</strong></td>
</tr>
<tr>
<td>• Primary ocular or mucosal melanoma</td>
</tr>
<tr>
<td>• Other known additional malignancy within 3 years, except for treated non-melanoma skin cancer</td>
</tr>
<tr>
<td>• History of autoimmune disorders or immunosuppressive treatments</td>
</tr>
<tr>
<td>• Known HIV positivity, Hepatitis B or Hepatitis C</td>
</tr>
<tr>
<td>• Active herpetic skin lesions or prior complications of HSV-1 infection</td>
</tr>
<tr>
<td>• Requires intermittent or chronic systemic (intravenous or oral) treatment with an antiviral drug (e.g., acyclovir), other than intermittent topical use</td>
</tr>
<tr>
<td>• Prior treatment with T-VEC or other tumour vaccine</td>
</tr>
<tr>
<td>• 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</td>
</tr>
</tbody>
</table>

| Contact: | (Fellow; P: 9496 9933; or Pager: 9496 5000 then page 5264) |
|--------------------------|
| To refer patient: | To minimise delays, please fax a referral to the 03-9457-6698 with: |
| • Patient contact information |
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| • Brief clinical history |
| • Whether the patient has been discussed with a particular trials personnel already |

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Mr David Gyorki</th>
<th>After hours contact:</th>
<th>via Austin switch: 9496 5000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Noel Micallef</td>
<td>P: 9496 3081</td>
<td>Pg: 6741</td>
</tr>
</tbody>
</table>

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Pancreatic Tumour Type: Metastatic Pancreatic Cancer

Protocol & Title: CL-SBP-101-01: A PHASE 1A/1B STUDY OF SBP-101 IN PREVIOUSLY TREATED SUBJECTS WITH LOCALLY ADVANCED OR METASTATIC Pancreatic Ductal Adenocarcinoma

Study Synopsis: A Phase 1a/1b Study of SBP-101 in Previously Treated Subjects with Locally Advanced or Metastatic Pancreatic Ductal Adenocarcinoma

Key eligibility criteria:

Inclusion criteria:
1. Histologically/cytologically confirmed locally advanced or metastatic pancreatic ductal adenocarcinoma.
2. ECOG Performance Status 0 or 1.
3. Failed or were intolerant to at least 1 prior systemic therapy including: gemcitabine, abraxane or FOLFIRINOX. If used in neoadjuvant or adjuvant setting – has to be >6 months
4. Adult, age ≥ 18 years, male or female
5. Adequate bone marrow, hepatic, renal and coagulation function

Exclusion criteria:
1. Evidence of severe or uncontrolled systemic disease.
2. Presence of islet-cell or pancreatic neuroendocrine tumor or mixed adenocarcinoma-neuroendocrine carcinoma
3. Have symptomatic central nervous system (CNS) malignancy or metastasis.
4. Hb A1C > 8.0%
5. Presence of known active bacterial, fungal, or viral infection requiring systemic therapy, viral hepatitis, human immunodeficiency virus (HIV). 7. Lung disease (pulmonary fibrosis, pulmonary hypersensitivity reaction), AMI in last 12 months of NYHA Class 3/4
6. Maldigestion/malabsorption syndrome pre-dating the diagnosis of pancreatic cancer
7. Known, existing coagulopathy or receiving anticoagulants
8. Major surgery within 4 weeks of the start of study treatment, without complete recovery

Contact: A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@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 Niall Tebbutt
After hours contact: via Austin switch: 9496 5000

Primary study Co-ordinator: Brie Jelbart
P: 9496 3297
Pg: 1769
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Advanced Pancreatic Adenocarcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol &amp; Title:</strong></td>
<td><strong>YOSEMITE:</strong> A Phase 3 RCT: Gemcitabine, Abraxane +/- Demcizumab as 1st line treatment in metastatic pancreatic cancer.</td>
</tr>
<tr>
<td><strong>Study Synopsis:</strong></td>
<td>A 3-Arm Phase 2 Double-Blind Randomized Study of Gemcitabine, Abraxane® Plus Placebo versus Gemcitabine, Abraxane® plus 1 or 2 Truncated Courses of Demcizumab in Subjects with 1st-Line Metastatic Pancreatic Ductal Adenocarcinoma</td>
</tr>
</tbody>
</table>
| **Key eligibility criteria:** | **Inclusion Criteria:**
1. Subjects must have cytologically or histologically confirmed metastatic pancreatic ductal adenocarcinoma. Prior chemotherapy and/or radiotherapy either in the adjuvant or neoadjuvant setting or for metastatic disease is not allowed.
2. Age >21 years
3. ECOG performance status 0 or 1
4. Measurable disease per RECIST v1.1

**Exclusion Criteria:**
1. Subjects with a neuroendocrine tumor of the pancreas, an acinar tumor of the pancreas or a pancreatic tumor with mixed histologies.
2. Subjects receiving heparin, warfarin, factor Xa inhibitors or other similar anticoagulants. Note: Subjects may be receiving low-dose aspirin and/or non-steroidal anti-inflammatory agents.
3. Any cardiac conditions:
   - Heart failure
   - Cardiac ischemia (current medications, AMI in last 6m or current symptoms
   - Pulmonary hypertension
   - Received a total cumulative dose of ≥400 mg/m2 doxorubicin
   - Grade ≥2 ventricular arrhythmia

| **Contact:** | A/Prof Niall Tebbutt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@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 Niall Tebbutt |
| **Primary study Co-ordinator:** | Catherine Johnston |
| **After hours contact:** | via Austin switch: 9496 5000 |
| **P:** | 9496 3038 |
| **Pg:** | 3038 |

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<table>
<thead>
<tr>
<th><strong>Tumour Type:</strong></th>
<th>Pancreatic</th>
</tr>
</thead>
<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:** | (Fellow; P: 9496 9933) or Pager: 94965000 then page 5264 |
| **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 Niall Tebbutt |
| **After hours contact:** | via Austin switch: 9496 5000 |
| **Primary study Co-ordinator:** | Brie Jelbart |
| **P:** | 9496 3297 |
| **Pg:** | 1769 |
## 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 – specific tumour cohorts only</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  
- **Specific tumour cohorts – contact Study Team for more information**  |
|  | **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 Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au) |
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- Brief clinical history  
- Whether the patient has been discussed with a particular trials personnel already |

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<th>Principal Investigator:</th>
<th>A/Prof Hui Gan</th>
</tr>
</thead>
<tbody>
<tr>
<td>After hours contact:</td>
<td>via Austin switch: 9496 5000</td>
</tr>
<tr>
<td>Primary study Co-ordinator:</td>
<td>Jaren Caine</td>
</tr>
<tr>
<td>P: 9496 3906</td>
<td>Pg: 1755</td>
</tr>
</tbody>
</table>

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**Tumour Type:** Metastatic Squamous Cell Carcinoma

**Protocol & Title:** 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

**Study Synopsis:** 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.

**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.
- 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 (Fellow; P:9496 9933; or Pager: 9496 5000 then page 5264)

**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

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

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

**P:** 9496 3084

**Pg:** 3084

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:
**Solid Tumours**

### Protocol & Title:
**CMD-2015-001**: A Phase 1 Dose-Finding and Pharmacokinetic Study of DpC, Administered Orally to Patients with Advanced Solid Tumors

### Study Synopsis:
Multicenter, open-label, phase 1 study of DpC administered orally to patients with advanced solid tumors.

### Key eligibility criteria:

**Inclusion Criteria:**
- Be ≥ 18 years of age
- ECOG 0-1
- Have histologically or cytologically confirmed diagnosis of advanced of metastatic solid organ tumour for which standard therapy either does not exist or has proven ineffective, intolerable or unacceptable for the patient.
- Have measurable disease as defined by RECIST 1.1
- Demonstrate adequate organ function, ejection fraction >50%
- >3 weeks since last anti tumour treatment
- CRPC – testosterone adequately suppressed
- Stable bone targeting agents for >4 weeks

**Exclusion Criteria:**
- Can swallow tablets
- >G1 toxicities from prior treatment
- Known CNS malignancy/involvement
- Prior malignancies
- Atrial fibrillation/enlargement on echo
- History of haemoglobinopathy of current chelation therapy
- Current use of anticoagulants at therapeutic doses
- Breast feeding or ineffective contraception use while on study

### Contact:
A/Prof Andrew Weickhardt (9496 5763) or trials fellow Alysson Wann (9496 5000 pager 3990 or alysson.wann@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 Andrew Weickhardt

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

### Primary study Co-ordinator:
Lucy Demeo

### P: 9496 9916

### Pg: 1733
<table>
<thead>
<tr>
<th>Tumour Type:</th>
<th>Solid Tumours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol &amp; Title:</td>
<td>GO29674: A Phase IB open-label study of the safety and pharmacokinetics of MOXR0916 and MPDL3280A (atezolizumab) in patients with advanced/metastatic solid tumours</td>
</tr>
<tr>
<td>Study Synopsis:</td>
<td>This is a Phase IB dose-escalation study designed to evaluate dual checkpoint blockade with MOXR9016 (anti-OX40) and atezolizumab (MPDL3280A; anti-PDL1) for advanced solid cancers</td>
</tr>
<tr>
<td>Key eligibility criteria:</td>
<td></td>
</tr>
<tr>
<td>Inclusion Criteria:</td>
<td>ECOG 0-1, life expectancy &gt;12w</td>
</tr>
<tr>
<td></td>
<td>Adequate end organ function</td>
</tr>
<tr>
<td></td>
<td>Histologically proven advanced cancers progressed beyond standard therapy</td>
</tr>
<tr>
<td></td>
<td>Tumour tissue available for PD-L1 evaluation (&gt;15 unstained slides)</td>
</tr>
<tr>
<td></td>
<td>Treatment based on PD-L1 IHC positivity/negativity – please contact Study Team for more information.</td>
</tr>
<tr>
<td></td>
<td>Measurable disease by RECIST v1.1</td>
</tr>
<tr>
<td></td>
<td>Some cohorts require on-trial serial biopsy</td>
</tr>
<tr>
<td>Exclusion Criteria:</td>
<td>Significant cardiovascular, liver or other co-morbid disease</td>
</tr>
<tr>
<td></td>
<td>Anti-cancer therapy (incl radiotherapy) within 3 weeks, or TKIs within 1 week</td>
</tr>
<tr>
<td></td>
<td>Eligibility based on prior cancer treatment is complex. Specifically, PD-1 inhibitor pre-treated are permitted in particular cohorts.</td>
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<tr>
<td></td>
<td>Untreated/active CNS metastases</td>
</tr>
<tr>
<td></td>
<td>Uncontrolled pain, pleural/pericardial effusions or ascites</td>
</tr>
<tr>
<td></td>
<td>Autoimmune diseases (with noted exceptions)</td>
</tr>
<tr>
<td>Contact:</td>
<td>A/Prof Jonathan Cebon or Dr Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: <a href="mailto:anis.hamid@austin.org.au">anis.hamid@austin.org.au</a>)</td>
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<tr>
<td>After hours contact:</td>
<td>via Austin switch: 9496 5000</td>
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<tr>
<td>Primary study Co-ordinator:</td>
<td>Noel Micallef</td>
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<tr>
<td>P:</td>
<td>9496 6741</td>
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<tr>
<td>Pg:</td>
<td>3081</td>
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<tr>
<td>Key eligibility criteria:</td>
<td>Inclusion Criteria:</td>
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<td></td>
<td>• Measurable disease by RECIST v1.1</td>
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<td></td>
<td>• The study will be open to specific tumour cohorts – please contact Study Team for more information</td>
</tr>
</tbody>
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<th>Exclusion Criteria:</th>
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<td>• Autoimmune diseases (with noted exceptions)</td>
</tr>
<tr>
<td></td>
<td>• Concurrent immunosuppressive medication (e.g. prednisolone &gt;10mg/d)</td>
</tr>
<tr>
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<td>• Active or unstable CNS metastases</td>
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<td>• Significant cardiovascular, liver or other co-morbid disease</td>
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<tr>
<td></td>
<td>• Anti-cancer therapy (incl radiotherapy) within 4 weeks</td>
</tr>
<tr>
<td></td>
<td>• Unresolved AEs from prior treatments &gt;Grade 1 (CTCAE)</td>
</tr>
</tbody>
</table>

| Contact: | A/Prof Hui Gan (9496 9925) or Dr Anis Hamid (Fellow; P:9496 9929; or Pager: 94965000 then page 3248; or E: anis.hamid@austin.org.au) |

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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>Claire Healy</td>
</tr>
<tr>
<td></td>
<td>P: 9496 9912</td>
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Tumour Type: Solid Tumours

Protocol & Title: INCSHR 1210-101: A Phase I study to evaluate safety and tolerability of INCSHR01210 (PD-1 inhibitor) in patients with advanced solid tumours

Study Synopsis: This is a Phase I dose-escalation study designed to evaluate safety of INCSHR01210 (PD-1 inhibitor) for advanced solid cancers

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# Thyroid

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

<table>
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<tr>
<th>Protocol &amp; Title:</th>
<th>EXAMINER: A Randomized, Double Blind Study Comparing Cabozantinib (XL184) at 60mg daily compared to 140mg daily in Progressive Medullary Thyroid Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Synopsis:</td>
<td>This is a study comparing the efficacy of Cabozantinib between the approved dose (140mg/d) versus an alternate dose level.</td>
</tr>
</tbody>
</table>

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<th>Key eligibility criteria:</th>
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<tr>
<td><strong>Inclusion Criteria:</strong></td>
</tr>
<tr>
<td>• Subject has a histologically proven MTC.</td>
</tr>
<tr>
<td>• Availability of tissue for RET M198T mutation (negative prognostic marker) testing, either archival or fresh</td>
</tr>
<tr>
<td>• Subject has a ECOG Performance Status (KPS) of 0-1</td>
</tr>
<tr>
<td>• Subject has adequate bone marrow, renal, and hepatic function</td>
</tr>
<tr>
<td>• Subject has documented Progressive Disease by RECIST 1.1 compared to a scan within the last 14 months</td>
</tr>
<tr>
<td>• Patients with brain metastases are allowed so long as adequately treated and not on anti-coagulation</td>
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<th><strong>Exclusion Criteria:</strong></th>
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<tbody>
<tr>
<td>• Prior treatment with another agent or modality within 28 days</td>
</tr>
<tr>
<td>• Use of anticoagulation except low dose aspirin and LMWH that has been on a stable dose for 12 weeks</td>
</tr>
</tbody>
</table>

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<tr>
<th>Contact:</th>
<th>A/Prof Hui Gan (0448 048 266) or (Fellow; P:9496 9929; or Pager: 94965000 then page 3248)</th>
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<tr>
<td>Primary study Co-ordinator:</td>
<td>Jenni Flynn</td>
</tr>
<tr>
<td></td>
<td>P: 9496 3651</td>
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