

PAN1: A randomised phase II study evaluating potential predictive biomarkers in the treatment of metastatic pancreatic cancer.

Overview: To prospectively evaluate hENT1 as a predictive marker of benefit from gemcitabine treatment in metastatic pancreatic cancer.

Study Chair: Dr Yu Jo Chua, Medical Oncologist, Canberra Hospital

Open Date: 22nd July 2011

Accrual: 1/80 patients

Trial Management Committee Members:

Yu Jo Chua	Canberra Hospital	ACT
Andrew Biankin	Garvan Institute of Medical Research	NSW
Chris Karapetis	Flinders Medical Centre	SA
Craig Underhill	Border Medical Oncology	VIC
Louise Nott	Royal Hobart	TAZ
David Goldstein	Prince of Wales Hospital	NSW
Michelle Cronk	Nambour Hospital	QLD
George Laking	Auckland Hospital	NZ
Val GebSKI	NHMRC CTC	NSW
Katrin Sjoquist	NHMRC CTC	NSW
Nicole Wong	NHMRC CTC	NSW

Study Progress:

- Received funding from the Avner Nahmani Pancreatic Cancer Research Fund.
- 20 sites are planned and 17 have been selected to date.
- 11 sites are activated to date.
- Protocol approved by Cancer Institute NSW Ethics Committee on 25/01/2011.
- Central pharmacy and oxaliplatin sourced for Australian and New Zealand sites.
- Biological testing process designed and contracts in place.
- PAN1 InForm database designed, tested and launched live at active, participating sites.
- Internal PAN1 processes and documentation in place for site use and direction.
- Providing ongoing guidance and direction in the screening of any potential, eligible patients.
- Focus on working with New Zealand sites for additional, supplementary funding to support the conduct of the study in New Zealand.
- PAN1 AGITG Annual Scientific Meeting (ASM) presentation at the 2010 and 2011 ASMs.
- PAN1 Trials In Progress Abstract submitted to ASCO 2012 and has been accepted.
- Monthly screening logs collected from all sites for ongoing monitoring of patient screening.
- Trial Management Committee (TMC) formed.
- Latest TMC meeting occurred on 21 February 2012 to discuss status of the trial and recruitment strategies. Next TMC meeting scheduled for 1 May 2012.
- The working group met on 13th March and 13th April to further discuss revising the eligibility criteria of the PAN1 study. It has been proposed that locally advanced pancreatic cancer patients be included on the PAN1 study, in addition to metastatic pancreatic cancer patients.
- It has also been proposed to amend the study protocol to allow patients to be randomised as long as tissue for testing is available and that the hENT1 status be removed from the stratification. hENT1 will still be assessed prospectively, but this will occur in batches during

the study and the results will be available before the patient outcomes are known, so that the effect of hENT1 can still be evaluated.

- These changes do represent significant modifications to the study design, but are important to preserve the overall aim of the trial, which remains to evaluate hENT1 and other potential predictive biomarkers in the treatment of pancreatic cancer.
- The protocol is currently being updated and the plan is to submit the amended protocol to HREC in May.
- First patient randomised onto the PAN1 study: Canberra Hospital randomised 1 patient on 17th April 2012.

Site summary:

Site Name	Activation Date	Recruitment
Canberra Hospital	22/07/2011	1
Tweed Hospital	27/07/2011	0
Royal Hobart	28/07/2011	0
Nambour	31/08/2011	0
Border Medical Oncology	22/09/2011	0
Geelong Hospital	27/09/2011	0
Townsville	27/09/2011	0
Royal North Shore	03/11/2011	0
Port Macquarie	23/11/2011	0
Flinders Medical Centre	12/12/2011	0
Royal Perth	17/01/2012	0
Christchurch Hospital	-	-
Auckland Hospital	-	-
Prince of Wales	-	-
Queen Elizabeth	-	-
Austin	-	-
Calvary Mater	-	-