

**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:** **3/80 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
Fabyolla El-Tahche	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. Poster has been finalised.
- Monthly screening logs collected from all sites for ongoing monitoring of patient screening.
- Trial Management Committee (TMC) formed.
- Latest TMC meeting occurred on 1 May 2012. Next TMC meeting scheduled for July 2012.

- The protocol working group met on numerous occasions to revise the eligibility criteria of the PAN1 study. The protocol was amended to allow locally advanced pancreatic cancer patients onto the PAN1 study.
- The timeline for the hENT1 result was also revised to allow patients to be randomised onto the study prior to the result, as long as the tissue for testing is available. 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 amendment was finalised and submitted to the CINSW ethics committee for review at the meeting on 29<sup>th</sup> May 2012. Feedback from ethics should be available soon.
- Three (3) patients have been randomised onto the PAN1 study to-date. Please refer to the table below for more information.
- Site initiation scheduled for Prince of Wales Hospital on 22<sup>nd</sup> June 2012.

**Site summary:**

Site Name	Activation Date	Recruitment
Canberra Hospital	22-Jul-2011	1
Tweed Hospital	27-Jul-2011	0
Royal Hobart	28-Jul-2011	1
Nambour	31-Aug-2011	0
Border Medical Oncology	22-Sep-2011	0
Geelong Hospital	27-Sep-2011	0
Townsville	27-Sep-2011	0
Royal North Shore	03-Nov-2011	0
Port Macquarie	23-Nov-2011	0
Flinders Medical Centre	12-Dec-2011	0
Royal Perth	17-Jan-2012	1
Prince of Wales	Initiation Scheduled: 22-Jun-2012	-
Austin	-	-
Calvary Mater	-	-
Queen Elizabeth	-	-
Christchurch Hospital	-	-
Auckland Hospital	-	-