

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

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

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

Open Date: 22nd July 2011

Accrual: 4/80 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.
- 12 sites are activated to date.
- The CTC is currently reviewing new potential sites for the study and are performing feasibility assessments to determine suitability for PAN1.
- Original Protocol approved by Cancer Institute NSW Ethics Committee on 25-Jan-2011.
- PAN1 AGITG Annual Scientific Meeting (ASM) presentation at the 2010 and 2011 ASMs.
- PAN1 Trials In Progress Abstract submitted to ASCO 2012 and was accepted. Poster was finalised and presented at ASCO.
- Trial Management Committee (TMC) formed. Latest TMC meeting occurred on 24 July 2012. Next TMC meeting scheduled for Aug-2012.
- Monthly screening logs collected from all sites for ongoing monitoring of patient screening. Providing ongoing guidance and direction in the screening of any potential, eligible patients.
- 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 amendment will also address the non-recruitment issues.
- The protocol amendment was finalised and submitted to the Cancer Institute NSW ethics committee and was approved on 6 June 2012. The approved Protocol Amendment 1 documents have been sent to each active site for submission to either their local ethics committee or research governance office. To-date, it has been approved in NSW, TAS and WA. CTC will provide ongoing follow-up and assistance to the sites to ensure prompt approval occurs.
- Four (4) patients have been randomised onto the PAN1 study to-date. Please refer to the table below for more information. Prince of Wales Hospital was activated on 29th June 2012 and randomised their first patient on 6-Jul-2012. Two patients ‘In Screening’ at Port Macquarie Hospital are still awaiting histological confirmation of disease.

Site summary:

Site Name	Activation Date	Recruited	Screened	In Screening
Canberra Hospital	22-Jul-2011	1	19	0
Tweed Hospital	27-Jul-2011	0	10	0
Royal Hobart	28-Jul-2011	1	6	0
Nambour	31-Aug-2011	0	7	0
Border Medical Oncology	22-Sep-2011	0	6	0
Geelong Hospital	27-Sep-2011	0	5	0
Townsville	27-Sep-2011	0	14	0
Royal North Shore	03-Nov-2011	0	0	0
Port Macquarie	23-Nov-2011	0	4	2
Flinders Medical Centre	12-Dec-2011	0	0	0
Royal Perth	17-Jan-2012	1	2	0
Prince of Wales	29-Jun-2012	1	1	0
TOTAL:	12	4	74	2

