ANZUP 1802

UNICAB Trial News

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Welcome to the fourth issue of the UNICAB newsletter!

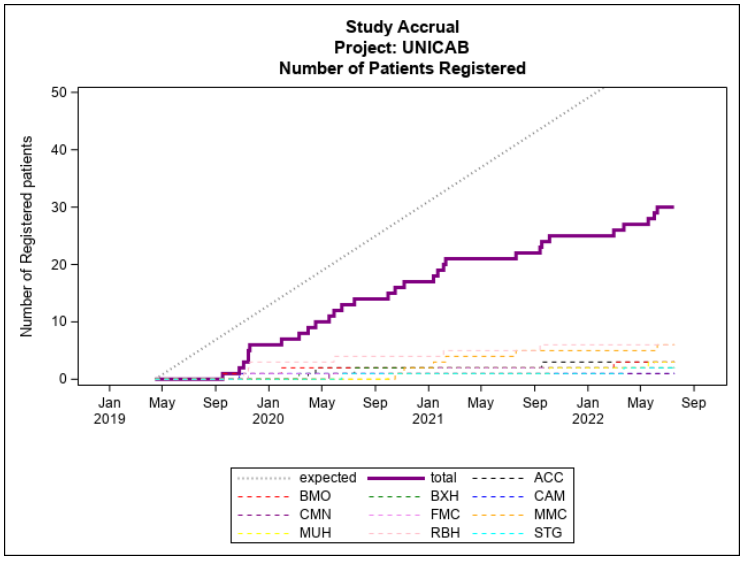
The study is currently open at 11 of 11 sites (including the tele trial site) across Victoria, NSW, QLD and SA, and has recruited 30 of 48 patients to date. We would like to congratulate and thank ANZUP's first tele trial site Goulburn Valley Health for recruiting 2 patients to the study thus far.

The study is nearing the end of recruitment and we are encouraging all PIs to enrol any eligible patients they are considering for the study as soon as possible.

With the challenge of the COVID-19 pandemic affecting UNICAB site teams and patients, ANZUP would like to express great appreciation of all your dedication and hard work to continue the study and keep caring for patients with nccRCC.

David Pook, UNICAB Study Chair.

Study sites & accrual as of 18 July 2022



RECRUITING SITES

Site No.	Current Active Sites	# Patients Registered as of 18 July 2022
Enrolment Target: 48 patients		
1	Adelaide Cancer Centre SA	3
2	Border Medical Oncology NSW	1
	Goulbourn Valley Health NSW	2
3	Box Hill Hospital VIC	2
4	Campbelltown Hospital NSW	1
5	Calvary Mater Newcastle NSW	1
6	Flinders Medical Centre VA	3
7	Monash Medical Centre VIC	6
8	Macquarie University Hospital NSW	3
9	Royal Brisbane Hospital QILD	6
10	St George Hospital NSW	2
	TOTAL:	**30**

STUDY MILESTONES TO DATE:

- Protocol V1.2 dated 06 Feb 2020 is currently active at all the sites
- The study is currently open at 11 sites across Victoria, NSW, QLD and SA

Main eligibility criteria

- ✓ Patients with non-clear cell renal cell carcinoma who have progressed following immunotherapy or who are unsuitable for treatment with immunotherapy will receive cabozantinib.
- ✓ At least 1 target lesion according to RECIST v1.1
- ✓ Patients with untreated brain or leptomeningeal metastases or current clinical or radiological progression of known brain metastases or requirement for steroid therapy for brain metastases to be excluded
- ✓ Patients must not have received prior targeted therapy or chemotherapy, but may have received previous checkpoint immunotherapy, for example, via the UNISoN trial (NCT03177239)

Registration Procedure highlights:

Registration of patients to the UNICAB study is to be completed via the study database (Viedoc). And a reminder to register patients prior to starting Cycle 1 Day 1.

Central review of following documents is mandatory prior to registration:

- ✓ Diagnostic Histopathology Report*
- ✓ Baseline CT Report

**Note: Previously enrolled UNISoN patients will not require review of their histology reports prior to registration.*

Data Management:

- ✓ Ensure de-identified source documents are sent to BaCT Within 5 business days of visit or report availability
- ✓ Please make sure all patients' reports are DE-IDENTIFIED and UNICAB patient registration number is visible on each page.
- ✓ Please ensure study visit data and data queries are entered and attended to in a timely manner.

Important Protocol Reminders:

- ✓ Both oral and IV contrast is required for CT scans. In the event of known allergy to contrast, non-contrast CT of chest and an MRI abdomen/pelvis may be performed as an alternative. Method of tumour assessment should be consistent throughout all visits.
- ✓ CT Brain to be performed at screening, subsequent brain scans as clinically indicated.

Important Protocol Reminders, cont…..

- ✓ Whole Body Bone Scans (WBBS) are only required for patients with known bone metastasis.
- ✓ Tumour assessments will occur in every 8 weeks (± 1 week) from cycle 1 day 1. If a tumour assessment has to be performed early or late, subsequent tumour assessments should be conducted according to the original schedule based on the date of first dose of cabozantinib administered on Cycle 1 Day 1.
- ✓ Patients will receive 12 cycles of treatment until disease progression or unacceptable toxicity. Following completion of 12 cycles of cabozantinib, patients receiving clinical benefit may be eligible to receive Ipsen supplied cabozantinib. Please refer to the UNICAB Compassionate supply_ Supply Process_V2.0 05NOV2020 document and ensure supply is requested early so that patients can receive an uninterrupted supply of cabozantinib.

SDMC meeting timeline:

A SDMC was held on the 24 June 2022. The next Safety Data Monitoring Committee Meeting is TBC.

Data cut-off date: TBC

Sites are requested to enter the data as per the data cut-off date and prioritise the query resolution and source the documents requested by UNICAB data management in preparation of upcoming SDMC meeting.

UNICAB is a collaboration between ANZUP and BaCT

We thank IPSEN for their ongoing product & funding support for UNICAB

STUDY CHAIR – A/Prof. David Pook

UNICAB key contacts

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