ANZUP 1802

ANZUP Cancer Trials Group Limited

UNICAB Trial News

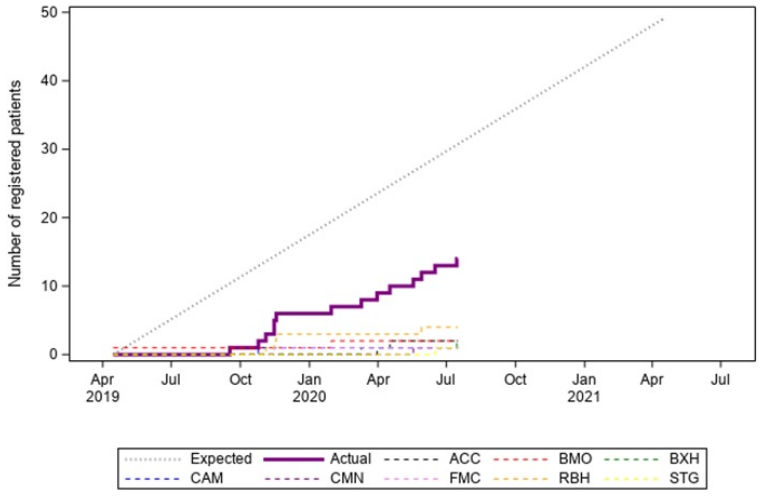
www.anzup.org.au

Welcome to the second issue of the UNICAB newsletter!

The study is currently open at 10 of 11 sites across Victoria, NSW, QLD and SA, and has recruited 14 of 48 patients to date. We are excited that ANZUP's first tele-trial site for UNICAB at Goulburn Valley Health in Shepparton is almost ready to launch.

Whilst COVID-19 has added complexity and challenges for trial sites and for trial patients, it is encouraging to see trials like UNICAB continue to recruit and offer new treatments for people with kidney cancer. ANZUP would like to express great appreciation of all your continued dedication and hard work to the study and ongoing patient care.

Study sites and accrual as of 16 July 2020



Site No.	Current Active Sites	# Patients Registered @16 July 2020
Enrolment Target: 48 patients		
1	Adelaide Cancer Centre SA	2
2	Border Medical Oncology NSW	2
3	Box Hill Hospital VIC	2
4	Campbelltown Hospital NSW	1
5	Calvary Mater Newcastle NSW	1
6	Flinders Medical Centre SA	1
7	Monash Medical Centre VIC	0
8	Macquarie University Hospital NSW	0
9	Royal Brisbane Hospital QLD	4
10	St George Hospital NSW	1
	TOTAL:	**14**

STUDY MILESTONES TO DATE:

- Protocol V1.1 dated 06 Feb 2019 is currently active at all the sites
- Protocol V1.2 06 Feb 2020 has been submitted to Monash HREC for approval
- The study is currently open at 10 sites across Victoria, NSW, QLD and SA
- Plan to open first tele-trial site at Goulburn Valley Health, Shepparton as Satellite and Border Medical Oncology Research Unit as primary site

UNICAB is a collaboration between ANZUP and BaCT

BaCT Centre for Biostatistics and Clinical Trials

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

IPSEN Innovation for patient care

STUDY CHAIR – Dr David Pook

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 completed via the study database (Viedoc).

Central review of following documents is mandatory prior to registration:

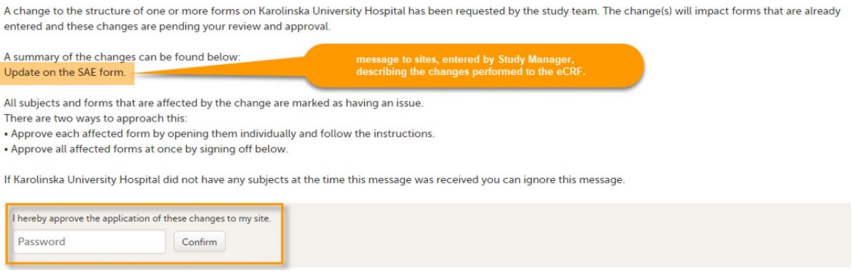
- ✓ Diagnostic Histopathology Report*
- ✓ Baseline CT Report

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

Data Management:

- ✓ Recently, minor changes have been made to certain forms in the study database (Viedoc). Sites are required to accept the forms pending upgrade. The forms affected by the upgrade are marked with an issue flag like this:

Site's study coordinator can batch approve all affected forms at once by typing in your password and clicking CONFIRM in the upgrade message panel:



- ✓ 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

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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
- ✓ 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

SDMC meeting timeline:

- The next Safety Data Monitoring Committee Meeting is planned for 12 August 2020
- Sites are requested to enter the data and address data queries generated by the system and/or raised by data Management in preparation for this SDMC meeting

Due to COVID-19, IPSEN has kindly agreed to cover the cost of shipping the trial drug cabozantinib to UNICAB trial patients. Sites will be able to send cabozantinib using their preferred shipping method to patients as required until November 2020.
If you have further questions, please contact UNICAB Clinical Trials Project Manager, Nisha Rana.

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Update your member details now!

Need to update your contact details or subscription preferences?

Update your member details now at **www.anzup.org.au/member/updateprofile.aspx** to stay up to date on all the latest ANZUP news and events.

UNICAB key contacts

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