

UNICAB Trial News

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Welcome to the third issue of the UNICAB newsletter!

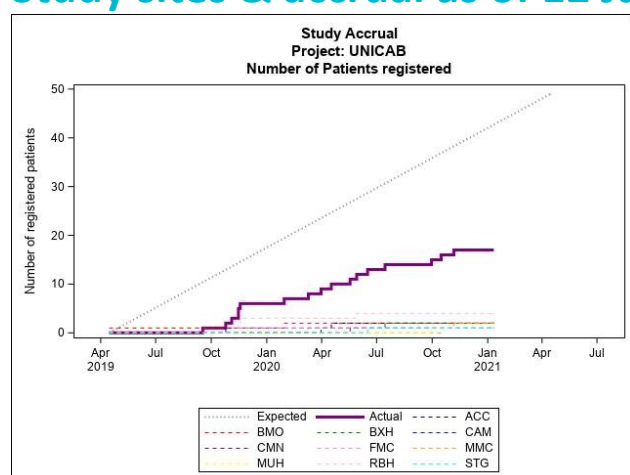
The study is currently open at 10 of 11 sites across VIC, NSW, QLD and SA, and has recruited 18 of 48 patients to date. We are also delighted to announce that Goulburn Valley Health in Shepparton has been added as a tele-trial site under the supervision of Border Medical Oncology Research Unit and is ready to recruit. This is ANZUP's first tele-trial and we look forward to ever expanding the availability of our trials to rural and regional patients.

In the midst of these most challenging times, with policies and practices changing at a rapid rate in response to the pandemic, we would like to express our deep appreciation to all site PI's and trial staff for their dedication and commitment to ensuring the safety and wellbeing of patients and staff remains paramount.

I wish you all a very healthy and happy new year ahead!

David Pook, UNICAB Study Chair.

Study sites & accrual as of 12 Jan 2021



STUDY MILESTONES TO DATE:

- Protocol V1.2 dated 06 Feb 2020 is currently active at all the sites
- The study is currently open at 10 sites across VIC, NSW, QLD and SA
- Goulburn Valley Health, Shepparton has been opened as first tele-trial site under the supervision of Border Medical Oncology Research Unit

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



Site No.	Current Active Sites	# Patients Registered as of 12 January 2021
<i>Enrolment Target: 48 patients</i>		
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 VA	1
7	Monash Medical Centre VIC	3
8	Macquarie University Hospital NSW	1
9	Royal Brisbane Hospital QLD	4
10	St George Hospital NSW	1
TOTAL:		18

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).

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.

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.

Important Protocol Reminders, cont.....

- ✓ 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 UNICAB Compassionate supply_ Supply Process_V2.0 05NOV2020 document.

SDMC meeting timeline:

The next Safety Data Monitoring Committee meeting has been planned on 15 February 2021.
Data cut-off date: 15 January 2021.

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

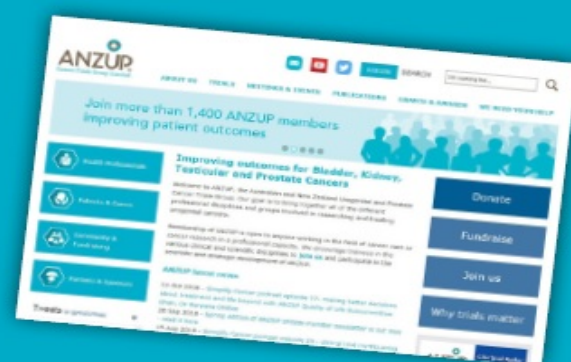
IPSEN shipping costs

Australia's response to the coronavirus outbreak so far has been among the most successful in the world. We are very grateful to Ipsen for agreeing to cover the costs of shipping the study drug (cabozatinib) to the patients' home particularly in those early months. As of November 2020, IPSEN is no longer able to deliver study drug to the trial participant's home. With this in mind, please send all related invoices, to Deepti Pandey, Clinical Trial Project Manager at BaCT for processing and reimbursement. Once again we acknowledge and thank Ipsen for providing this invaluable support to UNICAB and in particular the trial participants.

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UNICAB key contacts

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