ANZUP 1602

ANZUP Cancer Trials Group Limited

UNISoN Trial News

www.anzup.org.au

Welcome to the fifth UNISoN newsletter

Thank you again to the teams across all 19 participating sites for all your hard work and support in recruiting patients to this study.

As of Friday 2 August, we are down to our last 3 patient registrations into Part 1 of the study. You have recruited 83 (~97%) patients into Part 1, with 31 of these patients transitioning to Part 2 of the study. The speed of recruitment far exceeds our projections and expectations, and it humbles us that we have been able to offer an opportunity to people with an unmet treatment need in the non-clear cell renal cell carcinoma landscape.

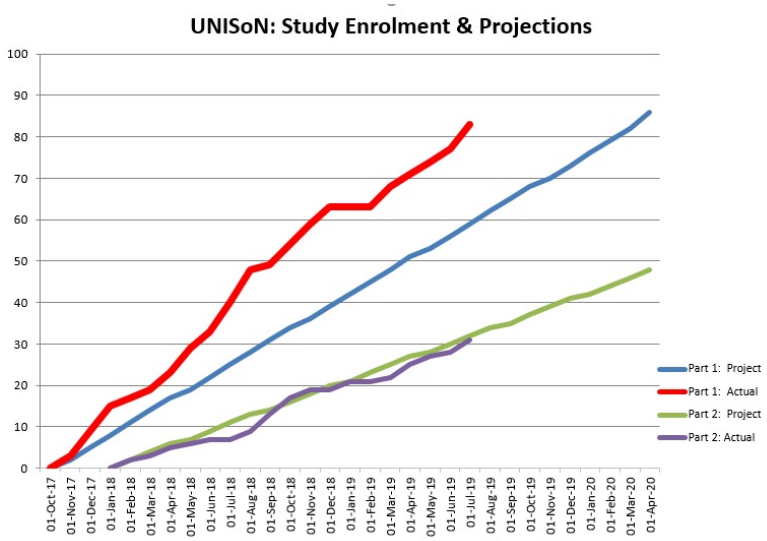
Patient spots in our trial

As stated above, we are down to our last 3 patient registrations into Part 1 of the study. A reminder to please contact the UNISoN Clinical Trial Manager as soon as you identify a potential patient and **PRIOR** to offering a PICF to a patient, in order to confirm that there are 'slots' remaining.

We have no capacity to recruit more than our allocated number of patients. Therefore, to avoid disappointment and frustration we advise that you please do not offer a PICF to any further patients until you have email confirmation from the BaCT Coordinating Centre that a trial slot is available.

A reminder to also inform the UNISoN Clinical Trial Manager promptly at each of the following instances:

a) When the patient signs consent and their proposed treatment start-date
b) If the potential patient declines consent (so they can be removed from the screening list and the position be made available to others)
c) If the patient fails screening post-consent and is no longer considered for the study (again, so they can be removed from the screening list and the position be made available to others)



UNISoN is a collaboration between ANZUP and BaCT

BaCT Centre for Biostatistics and Clinical Trials

Current Recruitment

All participating sites have enrolled at least one patient, with Ballarat Oncology & Haematology Services enrolling their very first patient, on the last day of July 2019.

Ian Davis and the team at Box Hill Hospital continue to serve a large part of Victoria, with 14 patients enrolled to date. Royal Brisbane Hospital also continues to be working hard, enrolling 11 patients, as well as Flinders Medical Centre, Westmead Hospital, Monash Health and Northern Cancer Institute continuing to see numerous patients.

The national reach of the study has been illustrated with all sites having screened and enrolled patients.

On-study treatment

A reminder that on-study treatment is capped at either:

a) A maximum of 12 months of treatment in Part 1 alone; or
b) A maximum of 12 months of treatment in both Part 1 and Part 2 combined

Treatment after the 12-month mark is considered post-study access and patients must meet the criteria outlined in Section 8.1 of the protocol to receive further access to treatment.

UNISoN Post-Study Access to Nivolumab

Since the first patients completing Part 1 of the study from late 2018, we are now facing the undreamed-of situation where patients who may still be deriving clinical benefit with Nivolumab, decide with you, their treating physician, that they may wish to continue further treatment.

The UNISoN protocol allows for a continuation of Nivolumab beyond 12 months under the following conditions (Section 8.1):

Clinicians may wish to continue study treatment for participants who experience an ongoing complete response, partial response or stable disease and who are still deriving investigator assessed clinical benefit after 12 months of treatment with nivolumab (in either Part 1 or Part 2 of the trial).

After discussion with the Coordinating Principal Investigator, participants treated with 12 months of nivolumab may be permitted to continue treatment with nivolumab as long as they meet all of the following criteria:

1. *Investigator-assessed clinical benefit*
2. *No evidence of progressive disease (by RECIST 1.1)*
3. *Continue to meet all other study protocol eligibility criteria (participants who have experienced a complete response or who otherwise do not have measurable disease are permitted)*
4. *Tolerance of study drug*
5. *Stable ECOG performance status (0-1)*

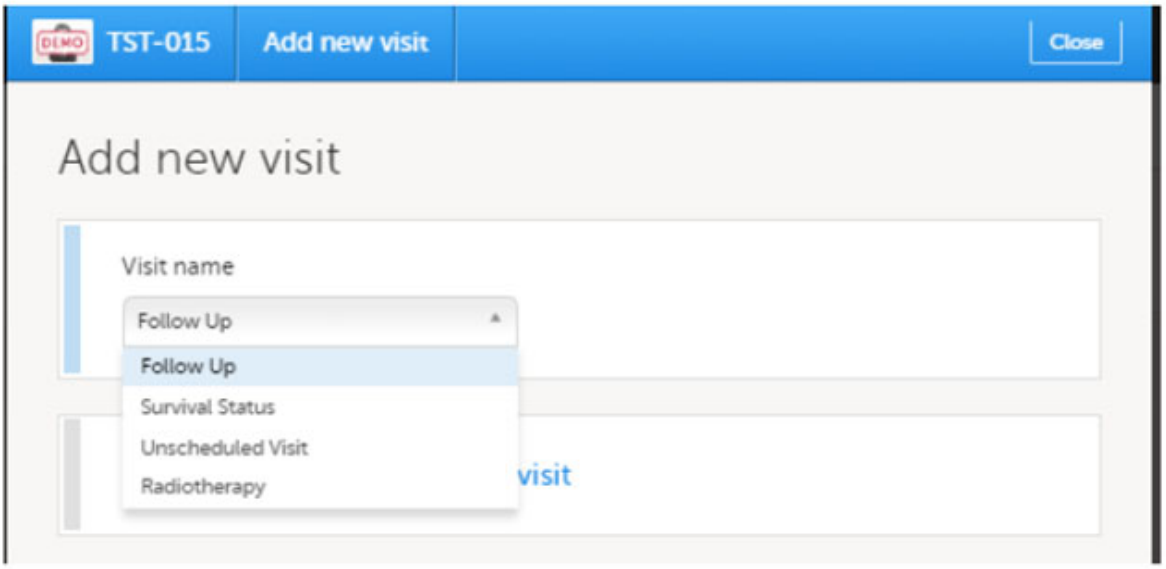
Our supporters at BMS have agreed to support continued treatment for these patients, with the following stipulations:

a) Ensuring all data up until the End of Treatment visit has been entered, cleaned and signed off by the site PI.
b) As per Section 8.1 of the protocol, the patient will be considered to have concluded their participation in the treatment phase and will have entered the follow-up phase of the study. This means that we will not be capturing treatment administration or protocol defined data points on these patients in Viedoc, other than what is captured during Follow-Up visits.
c) Ordering and shipping of Nivolumab for these patients to occurs via the same process that is currently in place for ordering drug (i.e. via the BMS/Bracket IWRS system)
d) Prior to continuing treatment, evidence has been provided confirming an absence of progressive disease (by RECIST 1.1) – copies of the latest CT report/RECIST worksheet are mandatory requested for review please.
e) Maximum duration of treatment: We request that sites plan to treat patients for an additional 6 months at first, then discuss/re-evaluate each patient with the CPI and study team on a case by case basis.

Follow up schedule

As patients are entering the follow-up stage for the UNISoN study, a reminder as to which type follow-up visit should be initiated for patients. The UNISoN database allows for two types of follow-up visits to be initiated:

1. Follow-Up
2. Survival Status



As per protocol, once a patient ceases treatment, they enter follow-up visits after attending an End of Treatment visit. Therefore, the following visits should be initiated in the following instances:

- If a patient ceases treatment for any reason (other than Disease Progression), a **FOLLOW-UP** visit must be initiated; whereby the following assessments occur:

1. 3-monthly CT scans (tumour assessment)
2. Physical assessment
3. ECOG Performance Status
4. Documentation of New Anti-Cancer Therapies (if patients are continuing Nivolumab treatment, we ask that this is recorded within this CRF).

- If a patient ceases treatment for Disease Progression according to RECIST 1.1, a **SURVIVAL STATUS** visit must be initiated; whereby the following assessments are completed:

1. Survival Status
2. Documentation of New Anti-Cancer Therapies

Please refer to the UNISoN eCRF Completion Guidelines for detailed instructions regarding initiated Follow-Up visits, or alternatively, email **BaCT_Helpdesk@petermac.org** for further instruction.

Hot tips

These best practice tips will help you administer the protocol and avoid data queries and protocol

Tip #1: Please ensure that Screen Fails are not entered into Viedoc – please record screen fails using the UNISoN paper-based Screening Log. Only eligible patient should be registered into the UNISoN database.

Tip #2: We ask that data queries are addressed in a timely manner (within 5 business days) and corresponding source documents are appropriately de-identified and submitted to BaCT accordingly.

Tip #3: We ask that Form upgrades in Viedoc are also implemented in a timely manner to ensure that you are entering data on the latest version of the database or CRF. Guidance on how to batch implement form upgrades can be found on Page 5 of the UNISoN eCRF Completion Guidelines, or email **BaCT_Helpdesk@petermac.org** for further instruction.

Viedoc User Guide

PI Oversight of Data: As per Section 14.6 of the UNISoN protocol, Site Principal Investigators are required to confirm the accuracy of completed eCRFs by routinely logging into Viedoc (the UNISoN electronic data capture (EDC) system) and signing completed forms on a quarterly basis.

Outstanding Training: To date; there are still a number of site investigators yet to have completed the mandatory online Viedoc training. This training is required in order to gain access to the UNISoN database and ultimately, for oversight of your patient data.
Training reminders are being re-sent to site investigators every month via email. Please check your inboxes and click on the link provided to access the training module. Training only takes 15 minutes to complete. Once completed, you will be issued with a training certificate and required to complete a 1 page EDC User Policy and Authorisation form. Please return completed forms to **BaCT_Helpdesk@petermac.org** for processing.

Sign-Off of Patient Data: Investigators whom have already completed EDC training have been provided with a username and password. If you cannot locate your username or password, please contact **Laura Galletta**, UNISoN Clinical Trial Manager, to arrange for your username and password to be re-sent to you.

UNISoN key contacts

- **Clinical trial operations, BaCT E:** laura.galletta@petermac.org **T: +61 3 8559 7529**
- **Sponsor queries (e.g. site payments, contracts) E:** jaclyn.verghis@anzup.org.au **T: +61 2 8036 5271**
- **Coordinating PI: Craig Gedye E:** craig.gedye@newcastle.edu.au
- **Hunter Cancer Biobank E:** hcra-biobank@newcastle.edu.au **T: +61 2 4042 0313**
- **ANZUP ClinTrial Refer app available for download from iTunes and Google Play**