ANZUP Cancer Trials Group Limited

Phase 3 BEP Study News

www.anzup.org.au

Welcome to our Phase 3 BEP newsletter

Thank you for your ongoing participation and efforts to screen and recruit to this randomised clinical trial of first-line chemotherapy for intermediate and poor-risk metastatic germ cell tumours, which has now recruited 91 patients, achieving an important milestone of sufficient patients to trigger the first formal interim analysis by the IDSMC.

We are particularly grateful to our international collaborators in the UK and through COG, who have recruited 15 of the 19 patients recruited in the last 6 months.

We look forward to ongoing contribution from sites worldwide in this rare population.

A/Prof Peter Grimison, Study Chair

Site Accrual

Site	Activation Date	Participants to Date
Macquarie Cancer Clinical Trials	21/08/2014	1
Prince of Wales Hospital	19/02/2014	1
Concord Repatriation General Hospital	13/04/2014	1
Chris O'Brien Lifehouse	28/11/2014	8
Calvary Mater Newcastle Hospital	4/03/2014	2
Nepean Hospital	10/03/2014	4
Peter MacCallum Cancer Centre	15/05/2014	9
Box Hill Hospital	19/06/2014	1
Austin Health	11/06/2014	2
Border Medical Oncology	20/07/2015	1
Royal Brisbane and Women's Hospital	8/04/2014	2
Princess Alexandra Hospital	16/06/2014	6
Royal Adelaide Hospital	1/07/2014	3
Flinders Medical Centre	7/04/2015	1
Fiona Stanley Hospital	19/03/2014	4
Royal Hobart Hospital	16/06/2014	1
Auckland Hospital	12/12/2014	5
Christchurch Hospital	26/11/2014	1
Palmerston North Hospital	12/12/2014	1
Total		**55**

We are grateful to Cancer Australia for their financial support to conduct the study. Phase 3 BEP Study is being led by ANZUP Cancer Trials Group in collaboration with the NHMRC CTC.

Australian Government
Cancer Australia

NHMRC
Clinical Trials Centre

ANZUP Cancer Trials Group Limited

Study Updates

Australia and New Zealand

Study Accrual
Target Recruitment: 150 (stage 1)
No. patients screened (AU only): 155
No. patients randomised: 91
No. of sites activated and active: 26 (ANZ); 13 (UK); 20 (USA)

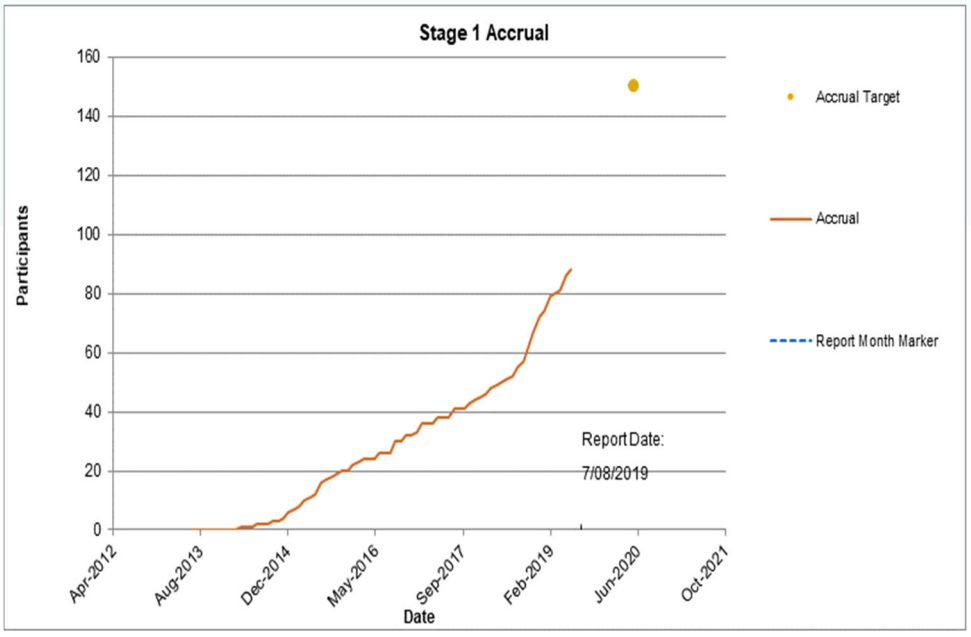
HREC submissions and approvals:

- Protocol amendment V4.1 was approved by SLHD RPAH HRECS 18 June 2019 and sent to all ANZ sites on 19 June 2019.
- The Ethics annual report was acknowledged by SLHD RPA HREC and sent out to all sites on 2 July 2019.

Please ensure you submit these documents to your local HREC/RGO per your local requirements and forward through approval to **p3bep@ctc.usyd.edu.au** when received.

International collaborations

The Cambridge Clinical Trial Centre (CCTC UK) team led by Dr Danish Mazhar have initiated 12 sites and recruited 22 patients since study activation in May 2017. Children's Oncology Group (COG USA) led by Dr Farzana Pashankar now have 86 active sites with IRB approval. Since activation 14 patients have been recruited across US sites.



Extra Information

Follow up visit "Months"

Follow up visits are 3 monthly, from 9 – 24 months from randomisation (i.e. at 9, 12, 15, 18, 21, 24), then 6 monthly from 24 – 60 months from randomisation (i.e. at 30, 36, 42, 48, 54, 60) and then annually thereafter until the study closes.

- All visits should be forecast from date of randomisation. If a follow up visit is missed, or the visit was delayed the next schedule visit should be scheduled from the date of randomisation.
- Follow up 'months' are calculated based on the days in a year, one month = 365 days/12 (this equates to roughly 30.5 days).
- There is a - / + 1 month window either side of the calculated visit date to perform the follow up visit.

Welcome

To new ANZUP fellow Shalini Subramaniam and new trial coordinator Amy Zhong, who have joined the P3 BEP team to work with ANZUP fellow Dr Alison Zhang, translational fellow Dr Sonia Yip, and project manager Kate Ford.

Study data

The stage 1 interim analysis for P3BEP is due to begin in early August 2019. In order to facilitate this analysis, please promptly enter data and respond to data queries in InForm within 2 weeks of queries being raised.

Translational research

Sample collection

Blood and tissue from consenting P3 BEP participants will be collected for translational research studies.

Blood for translational research (optional) is collected at Baseline.

Process blood samples within 60 minutes of phlebotomy

Make a copy of the completed blood collection form, email to p3bep@ctc.usyd.edu.au

Store samples in their original snap-lock kit bag with the blood collection form – place in the large biopouch in freezer at -70°C or below.

- Enter all translational research blood collections into InForm database.
- Complete and email all blood collection forms to p3bep@ctc.usyd.edu.au

Our current focus is on:

- Opening additional adult sites in the USA through the NCTN framework
- Data cleaning for the first formal interim analysis, scheduled for Q3-4 2019 when there is data available for the primary endpoint on the first 75 patients.

Phase 3 BEP key contacts

- **Clinical trial operations E: p3bep@ctc.usyd.edu.au T: +61 2 9562 5000**
- **Sponsor queries (e.g. site payments, contracts) E: p3bep@ctc.usyd.edu.au T: +61 2 9562 5000**
- **Coordinating PI: A/Prof Peter Grimison E: peter.grimison@lh.org.au**
- **Trial information: https://anzup.org.au/content.asp?page=trials-p3bep**
- **ANZUP ClinTrial Refer app** available for download from **iTunes** and **Google Play**