ANZUP Cancer Trials Group Limited

WOMBAT Trial News

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Welcome to the second WOMBAT newsletter

Thank you for your continued invaluable contribution and support of the WOMBAT (ANZUP 2201) trial. We are pleased to announce that we currently have 10 sites collaborating to this trial.

Study Chair: Professor Anthony Joshua

"We continue to be inspired by the commitment of our participants and site teams as we explore the potential of bipolar androgen therapy to enhance both the effectiveness of darolutamide and the quality of life for those receiving it. Thank you for your ongoing contributions. Please contact myself or the team if you have any concerns or questions."

Study Update

We're excited to be working toward our goal of enrolling 69 patients in the WOMBAT study! Every enrolment brings us one step closer, and your ongoing commitment is making a real impact. Below is the current enrolment breakdown. A huge thank you and congratulations to all involved for your dedication and hard work in reaching this milestone. Let's keep the momentum going!

Site	Principal Investigator	In Screening	Screen Failures	On Treatment
Cabrini Health	David Pook	0	2	**6**
Eastern Health-Box Hill Hospital	Angelyn Anton	0	0	**1**
GenesisCare North Shore	Laurence Krieger	0	0	**0**
Grampians Health Ballarat	Sharad Sharma	0	1	**1**
ICON Cancer Centre (Chermside)	Jeff Goh	0	0	**1**
Royal Adelaide Hospital	Hsiang Tan	0	2	**3**
St Vincent's Hospital Sydney	Anthony Joshua	0	0	**1**
Sydney Adventist Hospital	Gavin Marx	0	0	**1**
The Border Cancer Hospital	Kay Xu	0	0	**1**
Totals		**0**	**5**	**15**

Working Out M0 Bipolar Androgen Therapy (WOMBAT) - ANZUP 2201

It is a single-arm phase II trial to determine the utility of the addition of bipolar androgen therapy to intermittent darolutamide upon PSA progression on darolutamide alone for M0CRPC as measured by metastasis free survival (time from commencing BAT to evidence of metastasis or death) and to determine if this treatment is worthy of further study.

A huge thank you to all WOMBAT site staff for your ongoing hard work in getting this important study opened at your hospital. WOMBAT is a collaboration between ANZUP and TGI. This investigator initiated ANZUP study has been supported financially by Bayer. ANZUP is supported by the Australian Government through Cancer Australia.

ANZUP Annual Scientific Meeting (ASM)

ANZUP's recent ASM was a great opportunity to meet some of WOMBAT's site staff and hold a Study Coordinator Session. Discussions highlighted the importance of this study and the various recruitment strategies to ensure WOMBAT's profile is maintained within each site.

The following suggestions were made:

- Communication is key to keeping WOMBAT on the agenda at every site. All oncologists on-site should be made aware of the study, and WOMBAT participation is considered as an option for any patient with PSA progression on Darolutamide.
- Promote WOMBAT at MDT meetings and include study information in any internal trial updates or newsletters. Study slides are available from TGI if required.
- Principal Investigators are encouraged to utilise their referral networks to seek potential patients for the study. If you have any useful strategies or comments on cross-referral that have worked at your site, we would love to hear them.
- Please share these newsletters with colleagues in and outside your site.
- ANZCTR and Clinical Trials.gov are useful resources for study reference, including active WOMBAT sites and contact numbers.
- Flag patients currently on Darolutamide treatment on your hospital's EMR. If/when PSA progression occurs, the patient's treating oncologist will be aware that WOMBAT may be a potential treatment option

New Protocol amendment (version 3) Clarifications:

We're excited to share that a protocol and PICF amendment will be submitted very soon. You'll be notified once HREC approval is received and it's ready for submission to your RGO.

These updates reflect thoughtful feedback from our recruiting sites, who highlighted challenges with tight sample collection windows. In response, we've introduced more flexibility to support smoother scheduling and improve feasibility.

While some timing windows remain narrow due to scientific and logistical requirements, we hope these changes will ease the burden for participants who generously give their time to support this important research.

We've also clarified wording in Section 6 to better align with the Schedule of Assessments.

If you have any questions, please don't hesitate to reach out and our team will be in touch soon to discuss how this may affect your site.

Key changes:

- Darolutamide interruption prior to C1D1 and during treatment cycles.
    - *A minimum 24-hour gap is required between the dosing of darolutamide and Testosterone at each cycle, including prior to cycle 1*. Concurrent darolutamide will be taken at a dose of 600mg BD on days *29-55 of each cycle*.
- Windows of timing of Testosterone dosing
    - *Testosterone dosing alone will occur on day 1 of each cycle (+3 days). Dosing of IMP should occur on Day 1 but is acceptable to Day 4 if needed to accommodate scheduling issues*
- Inclusion/Exclusion criteria clarifications
- Windows of timing of other study assessments

Protocol Paper - A gentle reminder that we're looking forward to receiving your feedback on the protocol paper by 25th September.

WOMBAT (ANZUP 2201) Central Team

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- **Sponsor queries (payments, contracts, lab kit re-supply), ANZUP:** trials@anzup.org.au **or** Antoinette.Fontela@ANZUP.org.au
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NOTE: If in doubt, please reach out to the contacts outlines above.