RACURA ONCOLOGY

ASX Announcement

CPACS Trial Cleared to Escalate to Next RC220 Dose Level

- **Racura Oncology's Cardioprotection and Anticancer Synergy (CPACS) Phase 1 trial Safety Review Committee (SRC) has convened to review the patient safety and pharmacokinetic data**
- **SRC identified no treatment related safety concerns in the Cohort 1 patients, and the trial has been allowed to progress to the Cohort 2 designated dose level of 80mg/m^2 of RC220**
- **Patient screening is underway to enrol new patients in Australia, Hong Kong and South Korea**

15 May 2026

Racura Oncology Limited ("Racura") is pleased to announce that it has received clearance from the Safety Review Committee (SRC) to escalate the RC220 dose in the Phase 1 CPACS trial to the next designated dose level of 80mg/m^2. Clearance follows confirmation by the SRC that RC220 showed an acceptable safety profile, with no dose limiting toxicities or safety concerns identified during the safety observation period for the first three Cohort 1 patients dosed at 40mg/m^2. Promisingly, all patients on trial are alive despite their advanced metastatic tumour status at the time of enrolment.

Racura Oncology CEO and Managing Director, Dr Daniel Tillett commented: *"I am extremely proud of the Racura team and our clinical collaborators for reaching this important milestone. The safety seen to date with RC220 in advanced cancer patients, including the absence of dose limiting toxicities even when combined with a standard of care doxorubicin dose, is highly encouraging. Finally, we wish to thank the patients and their families for their courage and generosity shown by participating in the CPACS trial."*

The study SRC reviewed all safety and pharmacokinetic data from Cohort 1 patients with advanced metastatic solid tumours. The patients were treated with RC220 alone at 40mg/m^2 dose, followed by up to six combination cycles of RC220 at 40mg/m^2 and doxorubicin at the standard of care dose of 60mg/m^2.

Screening of new eligible patients for enrolment in Cohort 2 (80mg/m^2 RC220 dose level) is currently underway using an updated trial protocol which includes an initial lead-in safety monotherapy cycle of doxorubicin prior to the administration of RC220. This protocol update enables an assessment of the anthracycline cardioprotective potential of RC220 using a blood-based molecular test (ASX Announcement: 11 February 2026). Cohort 1 patients who are still receiving ongoing treatment will be transitioned to the updated trial protocol for all future treatment cycles.

Q&A

What is a Safety Review Committee and why is it important in clinical trials?

A Safety Review Committee (SRC) is composed of a panel of clinicians and trial experts that oversee patient safety during the conduct of a clinical trial. The SRC members objectively review the accumulated clinical data on a regular basis, usually at a dedicated meeting to determine whether and how a study should proceed. For the CPACS trial, the SRC committee reviews adverse events, laboratory findings, dose-limiting toxicities, pharmacokinetic data, and other relevant patient observations to determine if the dose of RC220 can be increased.

While an independent Safety Review Committee is not strictly mandated by regulation for Phase 1 dose-escalation studies, regulatory guidance strongly encourages robust safety oversight procedures.[1,2,3]

References

1. USA FDA: 2026 Use of Data Monitoring Committees in Clinical Trials Guidance for Industry DRAFT GUIDANCE; https://www.fda.gov/media/176107/download
2. Australia NHMRC: https://www.nhmrc.gov.au/sites/default/files/documents/reports/data-safety-monitoring-boards.pdf
3. European Medicines Agency: Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products" (EMA/CHMP/SWP/28367/07 Rev. 1) https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-strategies-identify-and-mitigate-risks-first-human-and-early-clinical-trials-investigational-medicinal-products-revision-1_en.pdf

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About Racura Oncology

Racura Oncology (ASX: RAC) is a Phase 3 clinical-stage biopharmaceutical company with a mission to silence cancer.

Racura's lead asset, (E,E)-bisantrene, is a small molecule anticancer agent that primarily functions via G4-DNA & RNA binding, leading to potent silencing of the important cancer growth regulator MYC. (E,E)-bisantrene has demonstrated therapeutic activity in cancer patients with a well-characterised safety profile. Recent discoveries made by Racura have enabled composition of matter IP filings that provides for 20 years of patent protection over (E,E)-bisantrene.

Racura is advancing a proprietary formulation of (E,E)-bisantrene (RC220) to address the high unmet needs of patients across multiple oncology indications, with a Phase 3 clinical program in acute myeloid leukaemia (AML), a Phase 1a/b program in mutant epidermal growth factor receptor non-small cell lung cancer (EGFRm NSCLC), and a Phase 1a/b program in combination with the anthracycline doxorubicin, where we aim to deliver both cardioprotection and enhanced anticancer activity for solid tumour patients.

Racura has collaborated with Astex, Emory University, Purdue University, MD Anderson, Sheba City of Health, UNC School of Medicine, University of Wollongong, and University of Newcastle. Racura is actively exploring partnerships, licence agreements, or a commercial merger and acquisition to accelerate access to RC220 for patients with cancer across the world. Learn more at www.racuraoncology.com.

If you have any questions on this announcement, or any past Racura announcements, please visit our Interactive Announcements page.

Racura encourages all investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, at www.automicgroup.com.au.

Release authorised by

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