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ASX Announcement

Racura RC220 CPACS Trial Opens for Patient Enrolment in Korea

- **First Korean site, Ewha Womans University Seoul Hospital, has been opened to allow enrolment in the CPACS Phase 1 trial of RC220 and doxorubicin in patients with advanced solid tumours**
- **Second and third Korean sites, Severance Hospital and Samsung Medical Center, are scheduled to be activated and opened for patient enrolment on 4 and 8 September, respectively**
- **Opening of Korean sites for patient enrolment is expected to accelerate trial progress**

1 September 2026

Racura Oncology Ltd ("Racura" or the "Company") is pleased to announce the activation of Ewha Womans University Seoul Hospital (Ewha), Republic of Korea, as the first Korean site added to the Cardioprotection and Anticancer Synergy (CPACS) Phase 1 trial of RC220 in combination with doxorubicin in patients with advanced solid tumours.

Pre-screening of patients has begun at Ewha and Severance Hospital. Treatment of the first patient is expected soon, subject to the availability of an open treatment slot. Severance Hospital is scheduled to be activated to allow patient recruitment from 4 September and Samsung Medical Center from 8 September. The final Korean site, Asan Medical Center, has received all regulatory and governance approvals, with site activation awaiting execution of the study contract by the relevant institutional personnel.

All Korean CPACS trial sites are recognised world-class oncology centres with outstanding five-year patient survival outcomes. In 2026, Newsweek ranked Samsung Medical Center and Asan Medical Center as the third- and fourth-best oncology hospitals in the world, respectively, and ranked Severance Hospital as the 22nd-best oncology hospital.[1]

Activation of trial sites in Korea was protracted by the protocol changes required to support the blood-based biomarker of cardioprotection (ASX Announcement: 11 February 2026). These changes required resubmission of the modified CPACS trial protocol to the Republic of Korea Ministry of Food and Drug Safety (MFDS) for approval and to each trial site for independent Institutional Review Board (IRB) ethics and governance approvals.

Racura Oncology CEO/MD, Dr Daniel Tillett, said: *"Activating the CPACS trial sites in Korea is an important milestone for Racura. We appreciate the dedication and enthusiasm of these world-class investigators and*

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clinical teams participating in this trial. We look forward to enrolling and treating the first patient with RC220 in Korea in the near future."

1. https://rankings.newsweek.com/worlds-best-specialized-hospitals-2026/oncology

-ENDS-

Q&A

Why did the CPACS trial protocol need to be modified?

The protocol was amended so the new cardioprotection blood-based biomarker test could be used. This test is designed to measure each patient's baseline cellular damage after doxorubicin exposure alone compared with when RC220 is used in combination with doxorubicin (i.e. whether RC220 can protect normal cells from doxorubicin damage). To collect this baseline cell damage data, patients must first receive a cycle of doxorubicin on its own and have blood samples collected. The original trial protocol did not include a doxorubicin monotherapy cycle, so the protocol needed to be amended.

Adding a doxorubicin monotherapy cycle also improves patient safety. Many late-stage cancer patients are unable to safely tolerate doxorubicin, and this risk increases when doxorubicin is used in combination therapies. Because there is currently no reliable way to predict which patients can safely tolerate doxorubicin, trial investigators previously had to be careful to invite only patients they believed were physically able to tolerate the combination of RC220 and doxorubicin.

With the updated trial protocol, patients who can't tolerate doxorubicin are excluded from being exposed to the more intense combination of doxorubicin with RC220. This increases patient safety and avoids premature termination of the trial due to side effects caused by doxorubicin being attributed to RC220.

Why are some cancer patients not able to tolerate doxorubicin?

There is considerable variation from person to person in how rapidly they metabolise (break down) doxorubicin. The rate of metabolism can vary more than 10-fold from person to person depending on a range of factors, including their general health, organ function, and the metabolism genes the patient has inherited.[2]

At doxorubicin's standard-of-care dose of 60mg/m^2, some patients metabolise doxorubicin so rapidly that they experience no side effects, while others metabolise doxorubicin so slowly that they are exposed to very toxic levels of the drug and suffer serious side effects. Unfortunately, there are no tests that can accurately predict the rate of doxorubicin metabolism at the individual patient level. This means the only way to know if a patient can tolerate doxorubicin is to dose the patient with doxorubicin, assess the seriousness of any side effects, and then modify the doxorubicin dose level in future cycles. As a result, up to 40% of patients suffer Grade 3 or 4 side effects from standard-of-care doxorubicin-containing therapies.

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2. M.A. Rudek, A. Sparreboom, E.S. Garrett-Mayer, et al. *Factors affecting pharmacokinetic variability following doxorubicin and docetaxel-based therapy.* European Journal of Cancer 40 (2004) 1170–1178.

What would have happened to the CPACS trial if patients who are unable to tolerate doxorubicin were treated with the combination of RC220 and doxorubicin?

In the original CPACS trial design, the first time any patient was exposed to doxorubicin was when they were treated with the RC220 and doxorubicin combination (ASX Announcement: 25 November 2024). Since it is impossible to assign side effect causality with certainty to a particular drug when drugs are used in combination, any dose-limiting toxicities (i.e. Grade 3 or 4) caused by doxorubicin would also be attributed to RC220. Given the expected dose-limiting toxicity rate for doxorubicin is above the allowed rate in a dose-escalation trial (i.e. 33%), the trial could have failed even if RC220 was free of toxicity.

By including an upfront doxorubicin monocycle, patients who are unable to tolerate doxorubicin are not exposed to RC220. This prevents toxicities caused by doxorubicin from being incorrectly attributed to RC220 and avoids unnecessary confounding of the trial outcome.

What happens if patients are unable to tolerate 80mg/m^2 of RC220 with doxorubicin?

The dose-escalation stage of the CPACS trial ends, and the efficacy stage starts. The aim of all dose-escalation oncology studies is to identify the maximum dose of a drug that can be tolerated by patients. The CPACS trial has already established that 40mg/m^2 of RC220 with doxorubicin is safe (ASX Announcement: 15 May 2026). This dose level provided both cardioprotection and added anticancer activity in preclinical models, so this dose can be taken forward if 80mg/m^2 of RC220 proves to be toxic for patients.

Why has Racura opened these new CPACS trial sites in Korea?

There are three major reasons.

1. **Strong interest in the trial from eminent clinical investigators.** The highly experienced and world-class clinicians in Korea recognise the need to address the serious issue of cardiotoxicity caused by anthracyclines like doxorubicin. The opportunity to participate in an innovative trial of a new cancer treatment that offers the potential to improve cancer treatment, while reducing the risk to patients from doxorubicin cardiotoxicity, was compelling.
2. **Faster trial recruitment.** Adding more sites increases both the number of patients who can be recruited and the overall speed of recruitment.
3. **Provides evidence of clinical safety and efficacy in regions outside of Australia and Hong Kong.** Significant differences in clinical practice and patient populations exist around the world. Expanding the trial to Korea allows Racura to investigate the safety and efficacy of RC220 in the commercially important Korean pharmaceutical market.

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Why does patient enrolment in dose-escalation oncology trials take time?

Patient enrolment in early-stage oncology trials is deliberately careful because each patient must meet strict eligibility criteria, provide informed consent, complete screening assessments, and be reviewed by the clinical trial team at each stage of treatment. In the CPACS trial, patients need to be assessed for safety before doxorubicin monotherapy, after doxorubicin monotherapy, after RC220 monotherapy, and finally after the first cycle of the combination of RC220 and doxorubicin.

These four safety assessments and three treatment cycles take approximately five months to complete for each patient, reflecting the extensive safety assessments required when using doxorubicin in advanced cancer patients.

When is the first Korean patient expected to be treated?

Pre-screening has begun at Ewha and Severance Hospital with treatment of the first Korean patient expected soon. As with all early-stage oncology studies, patient enrolment remains subject to patient eligibility, completion of screening requirements, and the availability of an open treatment slot.

Does opening these Korean sites change the expected CPACS trial timeline?

The opening of additional sites in Korea is expected to improve recruitment capacity by increasing the number of clinicians and patients who can participate in the trial. The pace of enrolment will still depend on site readiness, patient screening, eligibility assessment, and the availability of treatment slots.

Why is Cohort 2 important for the CPACS trial?

Cohort 2 is important because it tests whether 80mg/m^2 of RC220 can be safely combined with doxorubicin. Preclinical data generated by Racura suggests that the cardioprotective and anticancer effects of RC220 increase with dose level. The aim of the dose-escalation process is to identify the highest RC220 dose that can be safely combined with doxorubicin in cancer patients.

Making the effort to identify the best dose to use in the clinic for any drug increases the probability that later efficacy studies will be successful. It is not uncommon for later trials of new treatments to fail because the optimal dose of the drug was not correctly identified.

What happens after CPACS Cohort 2 is completed?

After Cohort 2 is completed, the available safety and tolerability data will be collated and reviewed by the Safety Review Committee (SRC) to determine the next step. If 80mg/m^2 of RC220 is considered tolerable and safe, the trial will escalate to Cohort 3 and test the safety of RC220 at 160mg/m^2. Alternatively, if the dose-limiting toxicity rate exceeds the prespecified rate allowed by the trial protocol, the dose-escalation stage will end and the efficacy stage will begin using the highest tolerated dose of RC220 (i.e. 40mg/m^2), with the aim of collecting evidence of its anticancer and cardioprotective activity.

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When will investors be updated on the progress of the CPACS trial?

Investors will be updated once the SRC has reviewed all patient data from Cohort 2 and determined the next step of the trial (i.e. to proceed to Cohort 3 or end the dose-escalation stage).

What is required for a cancer patient to enrol in the CPACS trial?

Patients who are under the care of the clinical trial study doctors at recruiting trial sites can discuss their interest in participation and potential eligibility with their treating doctor.

Patients being treated outside the recruiting trial sites should discuss their interest in the trial with their treating oncologist and ask about potential referral to the trial study doctor at one of the recruiting trial sites.

All patients will need to understand the trial requirements and provide informed consent to participate. They will then be reviewed and assessed by the study doctor and clinical trial team to determine whether the trial is suitable for them and whether they meet all the eligibility criteria to be enrolled in the trial.

Where can I find out more information about the CPACS trial?

The details of the trial, including open and recruiting sites, are outlined and available on the public clinical trial registry: https://clinicaltrials.gov/study/NCT06815575. Further information is also available on the Racura Oncology website.

Enquiries can be directed via email to Racura Oncology at trials@racuraoncology.com.

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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 clinically derisked small-molecule anticancer agent that primarily acts by stabilising G4-DNA and RNA structures, driving potent silencing of c-MYC, a key cancer gene dysregulated in up to 70% of all cancers. (E,E)-bisantrene has shown therapeutic activity in cancer patients and has a well-characterised safety profile. Racura's discoveries have supported composition-of-matter IP filings that, if granted, could provide up to 20 years of patent protection for (E,E)-bisantrene.

Racura is advancing RC220, its proprietary formulation of (E,E)-bisantrene, to address significant unmet need across multiple MYC-driven oncology indications. The Company's clinical programs include the EMILI Phase 3 trial in acute myeloid leukaemia, the HARNESS Phase 1a/b trial in combination with osimertinib for EGFR-mutated non-small cell lung cancer, and the CPACS Phase 1a/b trial in combination with doxorubicin, where Racura aims to deliver both anthracycline cardioprotection and enhanced anticancer activity.

Racura has collaborated with Astex, Emory University, Purdue University, MD Anderson, Sheba Medical Center, UNC School of Medicine, the University of Wollongong, and the University of Newcastle. Racura is actively exploring partnerships, licence agreements, and potential commercial merger and acquisition opportunities to accelerate global patient access to RC220. Learn more at www.racuraoncology.com.

For questions about this announcement or previous Racura Oncology announcements, please visit our Interactive Announcements page.

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

Release authorised by

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