RACURA ONCOLOGY

ASX Announcement

Racura Successfully Demonstrates Pharmacokinetic Equivalence of RC110 & RC220

- **A nonclinical pharmacokinetic bridging study has found that RC220 and the earlier RC110 formulation of (E,E)-bisantrene deliver equivalent systemic drug exposure**
- **Ratios of peak and total drug exposure of (E,E)-bisantrene fell within the pre-specified equivalence range of 0.80–1.25, meeting regulatory standards for formulation equivalence**
- **These nonclinical data support the use of the established RC110 clinical dataset and established dosing levels in the clinical development of RC220, including the Phase 2b/3 EMILI trial**

17 November 2026

Racura Oncology Ltd ("Racura" or the "Company") is pleased to announce the results of a Good Laboratory Practice (GLP) nonclinical pharmacokinetic (PK) bridging study comparing RC220, the Company's proprietary formulation of (E,E)-bisantrene, with RC110, the earlier Racura formulation used in two investigator-sponsored Phase 2 clinical trials in relapsed or refractory (returned or treatment-resistant) acute myeloid leukaemia (R/R AML). The study found RC220 and RC110 produced equivalent systemic exposure to (E,E)-bisantrene.

Pharmacokinetics describes how the body processes a drug over time, including the concentration it reaches in the bloodstream and how long it remains before being cleared. A PK bridging study tests whether two formulations of the same active drug produce the same drug exposure, so that clinical experience gained with one formulation can inform the development of the other.

Racura CEO and MD, Dr Daniel Tillett, commented: *"This nonclinical study was designed to answer a critical question for our RC220 clinical programs: does RC220 deliver the same drug exposure as RC110? The results of this GLP PK study show the two formulations delivered equivalent exposure to (E,E)-bisantrene. The findings provide an important bridge to the clinical experience with RC110, which produced a 40% response rate in two separate Phase 2 trials in heavily pre-treated AML patients. This bridging study supports our plans to evaluate RC220 in patients with AML in the Phase 2b/3 EMILI trial as well as our HARNESS and CPACS clinical programs. I wish to thank the Racura team and our study partners for the careful execution of this important work."*

Nonclinical Bridging PK Study Design & Results

RC110 and RC220 contain the same active ingredient, (E,E)-bisantrene, and differ only in their formulation excipients (non-drug ingredients). RC220 was developed to allow bisantrene to be given through a peripheral vein in the arm or leg, rather than requiring the use of a central line (a catheter placed in a large vein near the heart).

The nonclinical bridging study in six animals used a crossover design, in which each animal received intravenous infusions of both RC110 and RC220 in random order, separated by a drug-free washout period, and so served as its own control. Frequent blood sampling was used to measure plasma (E,E)-bisantrene concentrations over time.

Equivalence was assessed using the standard regulatory approach for comparing drug formulations, which is the ratio of average RC220 to RC110 exposure (the geometric mean ratio, GMR, where 1.00 means identical exposure) and its 90% confidence interval (CI), against a pre-specified range of 0.80–1.25.[1,2] Across three consecutive days of dosing, the 90% CIs for both peak plasma concentration (C_{max}) and total exposure (area under the concentration–time curve, AUC) fell within this range on every day (Figure 1), with GMRs ranging from 0.971 to 1.057.

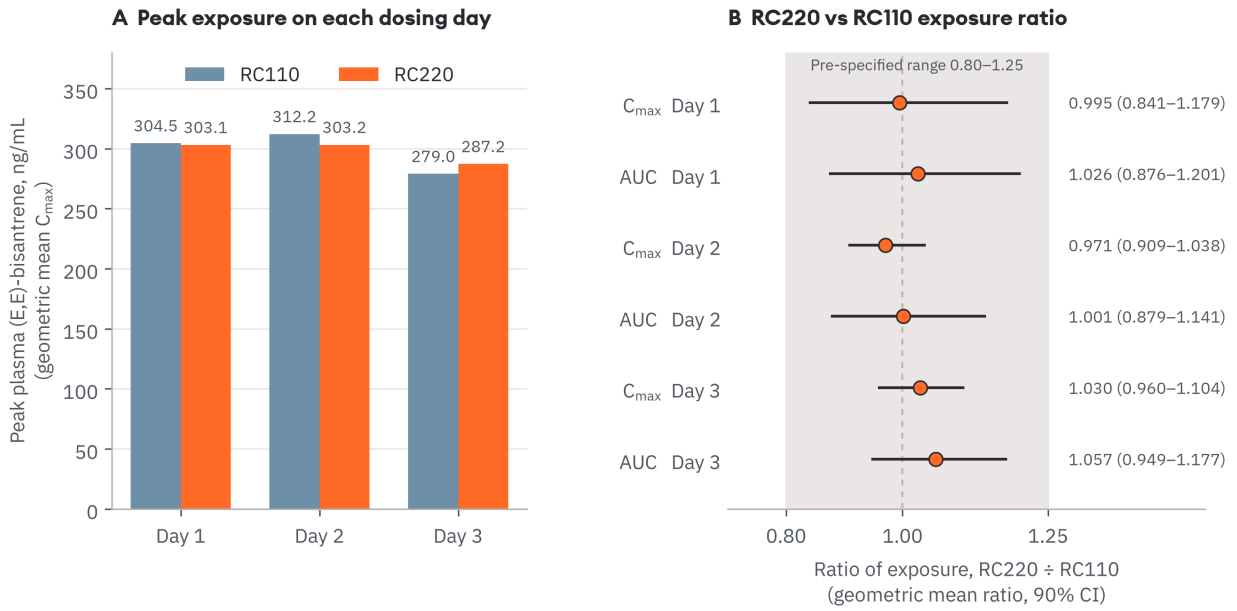


Figure 1. RC220 and RC110 deliver equivalent exposure to (E,E)-bisantrene with repeat daily dosing. (A) Geometric mean peak plasma concentration (C_{max}) of (E,E)-bisantrene after each of three once-daily 1 mg/kg intravenous doses (30-minute infusion) of RC110 or RC220 in male Beagle dogs (n = 6, two-period crossover with a five-day washout). (B) Ratio of RC220 to RC110 exposure (geometric mean ratio with 90% confidence interval) for C_{max} and AUC on each dosing day. The shaded band is the pre-specified equivalence range of 0.80–1.25; a ratio of 1.00 indicates identical exposure.

Significance for Racura's RC220 Clinical Programs

RC110 was used in two investigator-sponsored clinical trials in R/R AML conducted at the Sheba Medical Center, Israel. In a Phase 2 trial, RC110 given alone produced an overall response rate (complete or partial responses) of 40% in 10 patients (ASX Announcement: 16 June 2020).[3] In a Phase 1b/2 trial, RC110 combined with fludarabine and clofarabine produced a response in 6 of 15 evaluable patients (ASX Announcement: 4 August 2025).[4] These clinical results underpin Racura's plan to advance RC220 in AML through the Phase 2b/3 EMILI trial (ASX Announcement: 17 November 2025).

Both AML trials gave RC110 as a daily infusion over multiple consecutive days. These nonclinical PK equivalence data, together with the identical active ingredient in the two products, support applying the RC110 clinical experience to the future development of RC220.

References

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3. Canaani J, Danylesko I, Shemtov N, Zlotnick M, Lozinsky K, Benjamini O, et al. A phase II study of bisantrene in patients with relapsed/refractory acute myeloid leukemia. Eur J Haematol. 2021;106(2):260-6. doi:10.1111/ejh.13544
4. Danylesko I, Shimoni A, Avigdor A, Kedmi M, Amitai I, Shem-Tov N, et al. Bisantrene in combination with fludarabine and clofarabine as salvage therapy for adult patients with refractory or relapsed acute myeloid leukaemia (AML)—an open-label, phase I/II study. Br J Haematol. 2025;207(4):1425-34. doi:10.1111/bjh.70035

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Q&A

Why are PK bridging studies undertaken when a drug is reformulated?

When a drug is reformulated with different inactive ingredients, evidence is needed that the new product delivers the same exposure to the active drug before experience with the older formulation can be relied on. Showing equivalent exposure in a human or GLP animal study supports using earlier clinical experience to guide the development of a new formulation, such as RC220.

How does this study impact Racura's other RC220 trials?

RC220 is already being administered to patients through a peripheral vein in both the Phase 1 CPACS trial in solid tumours and the Phase 1 HARNESS trial in lung cancer. While the results of this bridging study are not essential for the running of these solid tumour trials, they may help accelerate the dose escalation stage or support earlier progression to later-stage trials.

What does a ratio "within 0.80–1.25" mean in an equivalence study?

The 90% confidence interval shows the range in which the true ratio of RC220 to RC110 exposure is likely to sit. Regulators such as the FDA or EMA treat two formulations as equivalent when the whole of this interval lies between 0.80 and 1.25, meaning the exposure differs by no more than 20% in either direction.[1,2] In this study, every interval for repeat daily dosing met this standard.

Why were dogs used, and why repeat daily dosing?

Dogs are a standard species for nonclinical PK and safety studies, and the dog was one of the two species used in the GLP toxicology program for RC220 (ASX Announcement: 26 June 2024). Repeat daily dosing was examined because RC110 was given daily over several consecutive days in the earlier AML trials, and the same approach is planned for RC220. No dog was harmed in this PK study, as the RC220 and RC110 doses used were well below the level that causes harm.

Does this mean RC220 is certain to work in AML patients?

No. This nonclinical study measured how much drug reached the bloodstream in dogs, not its anticancer activity in patients. While this study supports using the RC110 AML clinical data and dose experience to guide the development of RC220, the safety and efficacy of RC220 will need to be established in AML.

What happens next?

Racura will use these results to support regulatory submissions for AML and other clinical indications.

About Racura Oncology

Racura Oncology (ASX: RAC) is a late-stage clinical 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 inhibition of c-MYC gene expression, a key cancer gene dysregulated in up to 70% of all cancers. 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 2b/3 trial in acute myeloid leukaemia, the HARNESS Phase 1 trial in combination with osimertinib for EGFRm NSCLC, and the CPACS Phase 1 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 Cancer Center, Sheba Medical Center, University of North Carolina School of Medicine, University of Wollongong, and 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.

If you have any questions on this announcement, or any past Racura Oncology announcements, please visit the Company's 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.

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