

ASX Announcement

Bellberry Ethics Approval Enables Activation of Additional HARNESS-1 Lung Cancer Trial Sites

- Bellberry Human Research Ethics Committee (HREC) has approved the HARNESS-1 trial
- Approval enables additional Australian clinical trial sites to be activated on HARNESS-1 study
- Chris O'Brien Lifehouse and Austin Health to progress to start-up upon governance approval

3 July 2026

Racura Oncology Limited ("Racura" or the "Company") is pleased to announce that Bellberry Human Research Ethics Committee (HREC) has approved the Company's HARNESS-1 lung cancer clinical trial, enabling additional Australian clinical trial sites to participate. This approval follows the earlier approval granted by St Vincents Hospital (Melbourne) HREC for the lead clinical trial site, Monash Health (ASX Announcement: 26 November 2025).

HARNESS-1 is evaluating the safety, tolerability and pharmacokinetics (PK) of RC220 (E,E-bisantrene) in combination with osimertinib (Tagrisso®, AstraZeneca) in patients with non-small cell lung cancer (NSCLC) harbouring activating epidermal growth factor receptor mutations (EGFRm). Bellberry ethics approval applies to Australian private hospital sites and eligible public hospital sites outside Victoria.¹

Chris O'Brien Lifehouse will now progress to governance and start-up activities. St Vincents Hospital (Melbourne) HREC has also approved the inclusion of Austin Health (Victoria), which will similarly proceed with governance and start-up activities. Additional Australian sites are expected to be added to the study in the coming months as further governance approvals are received.

Racura Oncology Principal Scientist, Dr. Rodney Cusack commented: "This additional HREC approval is another important milestone for the HARNESS-1 clinical program. Chris O'Brien Lifehouse and Austin Health are highly regarded cancer care centres with the clinical expertise and patient access needed to support the study. With these approvals secured, we look forward to activating both sites and advancing enrolment as we continue evaluating RC220 in combination with osimertinib."

HARNESS-1 Trial Overview

HARNESS-1 is a multi-centre Phase 1a/b clinical study in patients with EGFR-mutant non-small cell lung cancer who are receiving osimertinib. The observational (screening) stage of the study uses circulating

tumour DNA (ctDNA), a blood-based marker of cancer activity and growth, to help identify and enrol patients eligible for the treatment stage of the study.

The first treatment stage of the study will test increasing doses of RC220, given by intravenous infusion on Day 1 of each 21-day cycle, in combination with standard-of-care maintenance osimertinib. This stage is designed to carefully assess safety while efficiently identifying an appropriate dose for further study. Between 12 and 40 patients are expected to participate in this dose-escalation stage.

After the recommended dose has been established and reviewed against available safety and PK data, the study will move into a double-blind, randomised Phase 1b expansion stage. In this stage, 40 patients will receive one of two RC220 dose levels in combination with osimertinib. Patients will be monitored for safety, PK and early signals of clinical activity, including progression-free survival, overall survival, changes in ctDNA levels and changes in cancer-specific mutations.

HARNESS-1 Trial Information

The details of the HARNESS-1 trial, including open and recruiting sites, are provided on the Australian and New Zealand public clinical trial registry: www.anzctr.org.au, with the trial code ACTRN12626000325303.

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

References

1. [Early Phase Clinical Trials HREC Scheme frequently asked questions](#) | Office for Health and Medical Research, accessed 17th June 2026

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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 provide 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 or 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 Oncology 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.

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