## ASX Announcement

# Racura Treats First Patient in HARNESS-1 EGFRm Lung Cancer Trial

- **First patient has been treated in the HARNESS-1 Phase 1 RC220 lung cancer trial with no adverse events observed**
- **RC220 is being assessed alongside osimertinib in EGFR-mutant NSCLC, where osimertinib resistance is a major clinical challenge**
- **Additional clinical trial sites are expected to open in the coming months, supporting increased patient recruitment and study progress**

**25 June 2026**

Racura Oncology Limited ("Racura") is pleased to announce that the first patient has been treated with RC220 at 50mg/m$^2$ in the Phase 1 HARNESS-1 clinical trial. The treatment of the first patient marks the start of patient dosing in this important clinical program. The patient was treated by Principal Investigator Associate Professor Surein Arulananda and his team at Monash Health (Clayton, Victoria). No adverse events were observed during or after the RC220 infusion.

HARNESS-1 is evaluating whether RC220 (E,E-bisantrene) can be safely combined with the standard-of-care tyrosine kinase inhibitor (TKI) osimertinib (Tagrisso®; AstraZeneca) in patients with EGFR-mutant non-small cell lung cancer (NSCLC). Patients with this form of lung cancer can benefit from targeted TKI therapy, but resistance to TKI treatments remains a significant clinical challenge.

The study uses single-patient cohorts for the first three dose escalations (50mg/m$^2$, 100mg/m$^2$ and 150mg/m$^2$), before progressing to larger cohorts to identify the maximum tolerated dose (MTD) of RC220 in combination with osimertinib. This staged approach is designed to support careful dose escalation while generating early safety and pharmacokinetic (PK) data. Patients will continue treatment with RC220 and osimertinib until one year of treatment is completed, disease progression, unacceptable toxicity, withdrawal of consent, or another protocol-defined discontinuation criterion occurs.

Racura Oncology CEO/MD, Dr Daniel Tillett commented: *"Treating the first patient in HARNESS-1 is an important step in the clinical development of RC220 and reflects the progress being made across Racura's oncology pipeline. This trial is focused on a patient group where resistance to current targeted therapies remains a significant challenge. We are grateful to A/Prof Surein Arulananda and his team at Monash Health for their work in recruiting and treating the study's first participant, and we thank the patients and families supporting this clinical research."*

## HARNESS-1 Trial Overview

HARNESS-1 is a multi-centre Phase 1a/b clinical study in patients with EGFR-mutant NSCLC receiving osimertinib. The study includes an observational (screening) stage that uses circulating tumour DNA (ctDNA), a blood-based marker of cancer activity and growth, to help identify and enrol patients eligible for RC220 treatment.

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

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 dose expansion stage, 40 patients will receive one of two RC220 dose levels in combination with osimertinib. Patients will be monitored for safety, PK and clinical activity measures, 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.

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## About Racura Oncology

Racura Oncology (ASX: RAC) is a clinical-stage biopharmaceutical company developing new approaches to treat cancer.

Racura's lead asset, (E,E)-bisantrene, is a small molecule anticancer agent designed to silence cancer growth pathways through G4-DNA and RNA binding, including the cancer growth regulator MYC. (E,E)-bisantrene has demonstrated therapeutic activity in cancer patients and has a well-characterised safety profile. Recent Racura discoveries have enabled composition of matter IP filings that provide for 20 years of patent protection over (E,E)-bisantrene.

Racura is advancing RC220, a proprietary formulation of (E,E)-bisantrene, across multiple oncology indications. Its clinical programs include a Phase 3 program in acute myeloid leukaemia (AML), a Phase 1a/b program in EGFR-mutant NSCLC, and a Phase 1a/b program in combination with doxorubicin for solid tumour patients.

Racura has collaborated with leading research and clinical organisations including Astex, Emory University, Purdue University, MD Anderson, Sheba City of Health, UNC School of Medicine, University of Wollongong, and University of Newcastle. Racura is also exploring partnerships, licence agreements, and other commercial opportunities to support the development of RC220.

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.

Release authorised by

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