RACURA ONCOLOGY

ASX Announcement

First Patient Recruited to HARNESS-1 EGFRm Lung Cancer Trial

- **First patient recruited by Monash Health to the HARNESS-1 Phase 1 trial of RC220 in EGFR non-small cell lung cancer patients being treated with osimertinib**
- **Trial aims to address the significant unmet medical need of preventing or delaying resistance to standard of care EGFR-mutant tyrosine kinase inhibitors such as osimertinib**
- **Four additional clinical trial sites expected to be activated on the trial in the coming months**

31 March 2026

Racura Oncology Limited ("Racura") is pleased to announce that the first patient has been recruited to its Phase 1 HARNESS-1 clinical trial. The HARNESS-1 trial will assess the safety, tolerability and pharmacokinetics (PK) of RC220 (E,E-bisantrene) in combination with the standard of care tyrosine kinase inhibitor (TKI) osimertinib (Tagrisso®; AstraZeneca) in patients with non-small cell lung cancer (NSCLC) who have activating epidermal growth factor receptor mutations (EGFRm). The first participant has been consented onto the trial by Principal Investigator Associate Professor Surein Arulananda and his team at Monash Health (Clayton, Victoria).

Racura Oncology CEO and Managing Director, Dr Daniel Tillett commented: *"The enrolment of the first patient to the HARNESS-1 trial is a significant milestone for Racura. We are grateful to A/Prof Surein Arulananda and his clinical team at Monash Health for working diligently with us to activate the trial and recruit the study's first participant. We wish to thank all the patients and their families for their willingness to participate in our clinician trials."*

Principal Investigator, Associate Professor Surein Arulananda commented: *"Resistance to standard of care TKIs in NSCLC is a very significant issue. All patients with this devastating disease will face this issue which currently has no solution. This study is a very important one and will give us evidence related to the safety and efficacy of RC220 in this clinical area."*

HARNESS-1 trial overview

The HARNESS-1 trial is a multi-centre, Phase 1a/b study, using circulating tumour DNA (ctDNA) to screen and enrol EGFRm NSCLC patients receiving treatment with osimertinib. The trial will commence with a

ctDNA screening stage, followed by dose escalation of RC220 when patients have evidence of disease progression, where between 12 and 40 patients will receive intravenous (IV) infusion of RC220 on Day 1 of a 21-day cycle in combination with standard-of-care maintenance osimertinib therapy. This treatment stage will begin by enrolling participants into single-patient cohorts under an accelerated trial design (ATD), intended to balance the need for careful safety evaluation with the objective of reaching clinically active dose levels as quickly as possible. Once the ATD stage is complete, participants will be enrolled into a Bayesian Optimal Interval (BOIN) dose escalation study, using larger patient cohorts to identify the maximum tolerated dose (MTD) of RC220. Participants in the trial will continue to be treated with RC220 and osimertinib until they reach any of the following outcomes: successful control of disease or one year of treatment; disease progression; unacceptable toxicity; or withdrawal of consent.

Once the MTD of RC220 has been determined, all accumulated safety and PK data will be analysed before initiation of the double-blind, randomised dose expansion Phase 1b stage. In this stage, 40 participants will be randomised to one of two RC220 dose levels in combination with standard of care osimertinib. Patients will be monitored for safety and PK, together with a range of secondary and exploratory endpoints, including: progression-free survival (PFS), overall survival (OS); changes in levels of ctDNA; and changes in the cancer-specific mutations present in patients.

Q&A

Why is there such a wide range in the number of patients needed in the Phase 1a stage?

It is impossible to know how many patients will be needed in the Phase 1a stage of this study as the aim is to identify the optimal dose of RC220 in combination with osimertinib. The Bayesian design used in this trial allows the clinicians to “home in” on the best dose of RC220, but to achieve this outcome they may need to treat more patients. Identifying the best dose early will provide a greater probability of success in the dose expansion stage and future studies. This approach also helps satisfy the requirements of the US FDA’s Project Optimus which aims to better balance the efficacy and side effects of new cancer treatments.

Where can I find out more about this lung cancer trial?

Details of the HARNESS-1 trial, including open and recruiting sites, can be found on the Australian New Zealand Clinical Trial Registry (ACTRN12626000325303):

https://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=390394&isReview=true

Enquiries concerning participation in this trial can be directed via email to the Racura Oncology clinical team at trials@racuraoncology.com.

-ENDS-

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 Oncology 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 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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