ASX Announcement

Race Oncology Receives Human Ethics Approval for HARNESS-1 Phase 1a/b Lung Cancer Trial of RC220

- St Vincents Hospital (Melbourne) Human Research Ethics Committee has approved the HARNESS-1 Phase 1a/b trial of RC220 in combination with osimertinib in adult non-small cell lung cancer patients with activating driver mutations in the epidermal growth factor receptor
- Ethics approval allows the lead clinical site, Monash Health, to commence enrolling patients for the trial, subject to final institutional approval and site activation, in late Q4 2025 / early Q1 2026
- Four additional clinical trial sites expected to be activated in the coming months.

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26 November 2025 – Race Oncology Limited ("Race") is pleased to announce it has received human ethics approval from the St Vincents Hospital Melbourne Human Research Ethics Committee (HREC) to initiate a Phase 1a/b clinical trial assessing the safety, tolerability and pharmacokinetics (PK) of RC220 (E,E-bisantrene, RCDS1) with osimertinib (Tagrisso®; AstraZenica), in patients with non-small cell lung cancer (NSCLC) that have activating epidermal growth factor receptor mutations (EGFRm). This approval allows Monash Health (Clayton, Victoria), under the supervision of the Principal Investigator, Dr Surein Arulananda, to commence enrolling patients for the trial with the support of Beyond Drug Development. Patient enrolment is subject to final institutional approval and site activation by Monash Health, expected late Q4 2025 to early Q1 2026.

The trial is a multi-centre, Phase 1a/b study, using circulating tumour DNA (ctDNA) to screen and enrol EGFRm NSCLC patients receiving treatment with osimertnib. Phase 1a will commence with a ctDNA screening stage followed by dose escalation of RC220, 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 osimertinib. This Bayesian study will commence with three, single-patient cohorts before transitioning to larger number of patient cohorts to identify the maximum tolerated dose (MTD) of RC220. Patients in the trial will continue to be treated with RC220 and osimertanib until they reach any of the following outcomes: successful control of disease; 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 Phase1b stage (dose expansion). In the Phase 1b stage, 40 patients will be randomised to one of two treatment dose levels. 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.

Race Oncology Principal Scientist, Dr. Rodney Cusack commented*: "The mechanism of action of (E,E)-bisantrene as a G-quadruplex binder promises to address key pathways of resistance identified in EGFR mutated NSCLC. This human ethics approval now enables Race to open a clinical trial in patients with EGFR mutated NSCLC and who have progressed or who are at risk of progressing while on treatment, setting the drug up to make a significant impact in this patient population."*

Race Oncology CEO and Managing Director, Dr Daniel Tillett commented: *"Obtaining human ethics approval for this second study of RC220 is another major achievement for Race. In this trial we aim to address the significant unmet medical need for better treatments for patients who develop resistance to third-generation EGFRm NSCLC tyrosine kinase inhibitors. I wish to thank the St Vincents Hospital Melbourne HREC, the St Vincents Research Valet Service, and the entire Race and Beyond Drug Development teams for their efforts and dedication."*

-ENDS-

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 greater probability of success in the Phase 1b 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 trial, including open and recruiting sites, will be provided via the public trial registry: https://anzctr.org.au/ prior to site activation and recruitment of the first patient. Details of the trial will also be available on the Race Oncology website as soon as the trial is open for patient enrolment.

Enquiries concerning this trial can be directed via email to Race Oncology at trials@raceoncology.com.

About Beyond Drug Development

Beyond is a dedicated early-phase CRO focused primarily on advancing innovative products from small to medium biotechnology and pharmaceutical companies worldwide. As an Australian privately owned company, Beyond provides flexible and nimble solutions to match the needs of their clients, whether it is a stand-alone activity or a full suite of services.

Beyond's expert support staff average 20 years' experience in early phase product development, including preclinical consulting and regulatory expertise, guiding clients through product development post-discovery into the successful conduct of clinical trials in the Australia/New Zealand region and "Beyond".

About Race Oncology (ASX: RAC)

Race Oncology (ASX: RAC) is an ASX-listed Phase 3 clinical biopharmaceutical company with a dedicated mission to be at the heart of cancer care.

Race's lead asset, RCDS1 (E,E-bisantrene), is a small molecule anticancer agent that primarily functions via G4-DNA & RNA binding, leading to potent inhibition of the important cancer growth regulator MYC. RCDS1 has demonstrated therapeutic activity in cancer patients with a well characterised safety profile. Recent discoveries made by Race have enabled composition of matter IP filings that provide for 20 years of patent protection over RCDS1.

Race is advancing a proprietary formulation of RCDS1 (RC220) to address the high unmet needs of patients across multiple oncology indications, with Phase 3 clinical programs in acute myeloid leukaemia (AML), 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.

Race Oncology has collaborated with Astex, MD Anderson, Sheba City of Health, UNC School of Medicine, University of Wollongong and University of Newcastle, and 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.raceoncology.com.

If you have any questions on this announcement or any past Race Oncology announcements, please go to the Interactive Announcements page in our Investor Hub announcements.raceoncology.com

Race 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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