

ASX Announcement

First Australian Clinical Site for RC220 Phase 1 Solid Tumour Trial Opens for Patient Enrolment

- Lead Australian trial site, Southside Cancer Care Centre (Miranda) is activated to begin patient enrolment for the Phase 1 trial of RC220 in advanced solid tumours
- Study will provide human safety and pharmacokinetic data, identify the maximum tolerated combined dose of RC220 and doxorubicin, and provide initial clinical data on the cardioprotective, anticancer and m⁶A RNA activities of RC220.

3 April 2025 – Race Oncology Limited (“Race”) is pleased to announce the site activation of Southside Cancer Care Centre (Miranda, NSW) after receiving governance approval enabling the commencement of patient enrolment for its Phase 1 clinical trial of RC220 in combination with doxorubicin in advanced solid tumours patients. This follows the receipt of human ethics approval (ASX Announcement: 14 March 2025), undertaking site initiation (ASX Announcement: 27 March 2025), and completion of all documentation.

The Phase 1 trial will be open label and conducted across multiple sites in Australia, Hong Kong and South Korea. The trial will use ascending doses of RC220 in up to 33 patients to determine the safety, tolerability, pharmacokinetics, maximum tolerated combined dose (MTCD) in combination with doxorubicin, and effects on a range of clinical biomarkers including m⁶A RNA.

After an interim analysis of the data, the optimal dosage of RC220 in combination with doxorubicin will be assessed in an additional 20 patients for further safety, tolerability, and preliminary cardioprotective and anticancer efficacy signals. The Phase 1 trial will use a Bayesian design enabling greater trial flexibility and speed than traditional approaches.

A recent meta-analysis of single agent doxorubicin treatment undertaken by Race Oncology has identified an anticancer response rate to doxorubicin of up to 35% in a wide range of advance and metastatic solid tumour cancers including breast cancer, small cell lung cancer, ovarian cancer, bladder cancer, liver cancer, endometrial cancer, upper gastrointestinal cancer, thyroid cancer, non-small cell lung cancer, and prostate cancer (ASX Announcement: 17 March 2025). Preclinical studies by Race Oncology have identified enhancement of the cancer killing activity of doxorubicin by the active anticancer agent in RC220 in 85% of 143 diverse cancer cell lines screened (ASX Announcement: 21 September 2023).

Timing of first patient enrolment is subject to patient suitability and their interest in participating in the trial.

Race Chief Executive Officer, Dr Daniel Tillett comments: *“I am proud of the hard work and dedication from the Race clinical team, George Clinical and CCF in reaching this point. I look forward to soon treating the first patient with RC220 and beginning the process of advancing RC220 as a potential new treatment able to improve cancer therapy while protecting patients from the serious side effects of cancer treatment.”*

Cancer Care Foundation, Chair & CEO, Dr Tony Noun, said: *“Thank you to our Director of Clinical Trials, Dr Mahmood Alam, and to all of the team working to bring this project to fruition. It is another positive step in exploring the potential for RC220.”*

-ENDS

Q&A

What is required for a cancer patient to enter the trial?

Patients who are under the care of the clinical trial study doctors at recruiting trial sites can discuss their interest in participation and potential eligibility with their treating doctor.

Patients being treated outside of the recruiting trial sites should discuss their interest in the trial with their treating oncologist for potential referral to the trial study doctor of one of the recruiting trial sites.

All patients will need to understand the trial requirements and provide informed consent to participate. They will then be reviewed and assessed by the study doctor and clinical trial team to determine whether the trial is suitable for them and whether they meet all the eligibility criteria to be enrolled on the trial.

Where can I find out more information about the RC220 trial?

The details of the trial, including open and recruiting sites, are outlined and available on the public clinical trial registry: <https://clinicaltrials.gov/study/NCT06815575>. Further information is also available on the Race Oncology website.

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

About Cancer Care Foundation & Cancer Care Associates

Cancer Care Foundation is committed to supporting access to the highest quality cancer care options for all our patients. Our clinical trials program encompasses the cutting edge of research for a wide range of tumour streams and stages of cancer.

The CCA Group operates several cancer treatment clinics in Australia including the Riverina Cancer Care Centre (Wagga Wagga), Southside Cancer Care Centre (Miranda), and Northern Beaches Cancer Care Centre (Frenchs Forest), Cancer Care Griffith, Cancer Care Wollongong, Cancer Care MacArthur, Cancer Care Noosa, with three more well-established centres joining the group, imminently, and a further two centres expected to commence operations later this year.

Southside Cancer Care Centre commenced operations in July 2014. The Southside facility delivers chemotherapy services and is a significant contributor to the rapid growth-oriented Sutherland Shire. Housing the CCA Group headquarters, the Southside Cancer Care Centre is based in purpose-built, modern healthcare premises, within a healthcare precinct servicing the Sutherland Shire.

About George Clinical

George Clinical is a globally recognised clinical research organisation (CRO) with over 20 years of experience designing and managing clinical trials. With a robust presence across Asia-Pacific, the United States, Europe, and beyond, George Clinical is known for delivering operational excellence supported by deep scientific expertise. George Clinical provides expert guidance, underscoring its commitment to advancing medical research through innovative, patient-focused approaches.

About Race Oncology (ASX: RAC)

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

Race's lead asset, bisantrene, is a small molecule anticancer drug. Bisantrene has a rich and unique clinical history with demonstrated therapeutic benefits in both adult and paediatric patients, a well characterised safety profile, and compelling clinical data demonstrating an anticancer effect with less cardiotoxicity compared to anthracyclines such as doxorubicin.

Race is advancing a reformulated bisantrene (RC220) to address the high unmet needs of patients across multiple oncology indications, with a clinical focus on anthracycline combinations, where we hope to deliver cardioprotection and enhanced anticancer activity in solid tumours. Race is also exploring RC220 as a low-intensity treatment for acute myeloid leukaemia.

Race is investigating the effect of RC220 on the m⁶A RNA pathway, following independent research published by the City of Hope identifying bisantrene as a potent inhibitor of FTO (Fat mass and obesity-associated protein). Dysregulation of the m⁶A RNA pathway has been described in numerous peer reviewed studies as a driver of a diverse range of cancers.

Race Oncology has collaborated with Astex, City of Hope, 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 <https://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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