RACE ONCOLOGY

ASX Announcement

# Ethics approval received for RC220 Phase 1 Solid Tumour Trial

- Bellberry Human Research Ethics Committee (HREC) approves Race's Phase 1 trial of RC220 in combination with doxorubicin in adult solid tumour patients
- Approval allows the lead clinical site, Southside Cancer Care Centre, to commence enrolling patients for the trial, subject to institutional approval and site activation in March 2025, with up to nine other sites to follow.

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**14 March 2025** – Race Oncology Limited ('Race'), in collaboration with the Cancer Care Foundation, is pleased to announce that it has received approval from Bellberry HREC to initiate a Phase 1 clinical trial to assess the safety, tolerability and pharmacokinetics (PK) of RC220 bisantrene alone and in combination with doxorubicin, in patients with solid tumours (ASX announcement: 4 December 2024). This approval allows the Cancer Care Foundation's lead site, Southside Cancer Care Centre (Miranda, NSW), under the supervision of the Principal Investigator, Dr Mahmood Alam, to commence enrolling patients for the trial, subject to institutional approval and site activation in March 2025.

The trial is an open-label, multi-centre, Phase 1 study and will be conducted in two stages. Stage 1 will commence with a dose escalation of RC220, where up to 33 patients will be enrolled and receive intravenous (IV) infusion of RC220 alone on Day 1 before progressing to a combination treatment, where patients will receive IV RC220 followed by IV doxorubicin on a 21-day cycle. Dose escalation will use a Bayesian design until the maximum tolerated combined dose (MTCD) is reached. Patients in the trial will continue to be treated until they reach either successful control of disease; disease progression; unacceptable toxicity; or withdrawal of consent.

Once the MTCD has been determined, all accumulated safety and PK data will be analysed before initiation of Stage 2. This expansion stage will recruit patients with solid tumours who have not previously been treated with doxorubicin or other anthracyclines. Patients will receive the optimal dosage of RC220 in combination with doxorubicin to confirm the safety of the combination and study a range of exploratory endpoints, including cardioprotection, anticancer, anti-aging and other clinical biomarkers, such as the effects of RC220 on the $m^6A$ RNA regulatory system.

Race Chief Executive Officer & Managing Director, Dr. Daniel Tillett commented: *"Receiving human ethics approval for the first RC220 trial is a significant milestone for Race, in line with our vision to improve cancer patient treatment by developing new cardioprotective therapies with anticancer benefits. I wish to thank the Bellberry HREC and the entire Race and George Clinical teams for all their efforts, which enabled us to reach this critical milestone."*

Race Chief Medical Officer, Dr. Michelle Rashford commented: "*This first approval is an important landmark for Race as it is an independent review of our protocol as well as our preclinical work and allows us to recruit additional sites to the trial. We are close to patients receiving RC220 for the first time. I would like to thank Dr. Alam and his team for their work in achieving this approval.*"

Cancer Care Foundation Founder, Chair & CEO, Dr. Tony Noun said: "*Congratulations to Race, to our Clinical Trial Director, Dr Alam, and our Cancer Care Foundation Team for helping to get us to this important milestone. Another step in our quest to improve outcomes for cancer patients."*

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Q&A

## What are the next steps for this trial?

Institutional approval and activation of the lead site by George Clinical to enable recruitment of the first patient. Approval of the ethics package has enabled us to submit the trial data package to the corresponding ethics and regulatory authorities in Hong Kong and South Korea.

## Will 33 patients need to be treated in Stage 1 of the trial?

**It is highly unlikely.** The trial uses a Bayesian statistical design to improve efficiency and speed, but this design choice means that the total number of patients required needs to be flexible. We expect that the final number of patients treated in Stage 1 of the trial will most likely be in the range of 12 to 18.

## Why is a dose escalation stage necessary if bisantrene has been used in more than a thousand patients?

While we have a good understanding of what the ideal dose will be from the hundreds of patients treated with bisantrene over the years, because RC220 is a new formulation of bisantrene, regulators such as the TGA, EMA or FDA require that we treat a new formulation as a "first-in-human" drug that has only ever been tested on animals. All first-in-human drugs are required to undergo a human dose escalation stage, even if the active drug substance in the formulation is very well understood in the clinic.

## How long will it take to activate the other trial sites?

Race expects that most Australian sites will be activated by George Clinical in Q1 or Q2 CY2025. As Hong Kong and South Korean sites have a longer regulatory review process, activation is expected in Q3 2025.

## 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 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.

-ENDS-

## 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, and Cancer Care Noosa.

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 chemotherapeutic. 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 bisantrene on the $m^6A$ 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 $m^6A$ RNA pathway has been described in numerous peer reviewed studies as a driver of a diverse range of cancers.

Race 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 bisantrene 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 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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