

ASX Announcement

Patient Enrolment Opened at Second Site for RC220 Phase 1 Solid Tumour Clinical Trial

- **Second clinical trial site, Central Coast Local Health District (Gosford and Wyong Hospitals) has been activated, enabling patient enrolment for the Phase 1 clinical trial of RC220 in advanced solid tumours**
- **Site activation follows the earlier activation of the lead Australian site, Southside Cancer Centre (Miranda)**
- **The 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.**

22 April 2025 - Race Oncology Limited ('Race') is pleased to announce the activation of the second site for patient enrolment for its Phase 1 clinical trial of RC220, in combination with doxorubicin, in patients with advanced solid tumours at the Central Coast Local Health District (Gosford and Wyong Hospitals). Site activation follows the receipt of human ethics approval (ASX Announcement: 31 March 2025), site initiation and completion of all the required documentation.

The open-label, Phase 1 trial will be conducted at multiple sites across Australia, Hong Kong and South Korea. Activation of Central Coast Local Health District follows the activation of the lead Australian trial site, Southside Cancer Centre in Miranda, NSW (ASX Announcement: 3 April 2025).

Race Chief Executive Officer, Dr Daniel Tillett commented: *"The activation of our second clinical site enables us to accelerate patient recruitment for the Phase 1 clinical trial, aiding the collection of critical safety, tolerability and pharmacokinetics data. We're grateful for the collaboration with our clinical partners and remain committed to advancing the clinical development of RC220."*

Race's Phase 1 trial will use ascending doses of RC220 in up to 33 patients in Stage 1 to determine its safety, tolerability, pharmacokinetics, maximum tolerated dose in combination with doxorubicin (MTCD), 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 in Stage 2 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 overall response rates to doxorubicin of up to 35% in a wide range of advanced 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 bisantrene in 85% of 143 cancer cell lines screened (ASX Announcement: 21 September 2023).

Q&A

What is required for a cancer patient to enrol in the trial at Gosford or Wyong?

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 Phase 1 Solid Tumour 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 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 bisantrene 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 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 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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