

## ASX Announcement

### Successful & Safe Dosing of First Patient with RC220 in Phase 1 Solid Tumour Trial

- First patient safely dosed in Phase 1 clinical trial of RC220 in advanced solid tumour patients at lead Australian trial site, Southside Cancer Care
- This Phase 1 trial will determine safety, tolerability and pharmacokinetic data of RC220, plus the maximum tolerated combined dose of RC220 with doxorubicin
- Up to another 32 patients to be recruited across multiple sites in Australia, Hong Kong and South Korea in first stage of the trial.

**1 May 2025** – Race Oncology Limited ('Race') is pleased to announce the successful and safe dosing of the first patient with RC220 in its Phase 1 clinical trial in advanced solid tumours. The patient was treated by Prof Paul de Souza and his team at the study's lead trial site, Southside Cancer Care Centre, Miranda, NSW. No phlebitis (vein inflammation) or any other adverse events were reported.

**Race Chief Executive Officer, Dr Daniel Tillett said:** *"The safe dosing of the first patient in our solid tumour trial is a major milestone for Race Oncology and the beginning of an important program to assess the safety, tolerability and therapeutic potential of RC220. We are grateful to all the patients, investigators, and clinical teams who have made this trial possible. I would also like to thank our shareholders for their strong and loyal support that has enabled us to bring RC220 to patients in the clinic."*

First patient dosing follows the activation of Southside Cancer Care Centre in April 2025 (ASX Announcement: 3 April 2025). A second trial site at the Gosford & Wyong Hospitals (Central Coast Local Health District) has recently opened for patient enrolment (ASX Announcement: 22 April 2025).

Race's Phase 1 solid tumour clinical trial is open-label and will be conducted across multiple sites in Australia, Hong Kong and South Korea. Stage 1 of the trial will use ascending doses of RC220 to determine the safety, tolerability, pharmacokinetics and maximum tolerated combined dose (MTCDD) of RC220 in combination with doxorubicin in up to 33 patients. Effects on a range of clinical biomarkers including m<sup>6</sup>A RNA will also be examined.

After 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 previous approaches.

As the trial is open-label in nature, patient outcomes will be obtained soon after patients are treated. Race intends to announce progress updates on the trial on a regular basis, but not at the individual patient level.

A short video interview with Race's CEO on this announcement is available on the Race Investor Hub: <https://announcements.raceoncology.com/link/4PK7YP>

-ENDS-

## Q&A

What is known about the anticancer efficacy of bisantrene and doxorubicin in advanced solid tumours?

A recent review of single-agent doxorubicin treatment, undertaken by Race Oncology, has identified that the overall response rates to doxorubicin is 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).

Bisantrene, the active drug in RC220, has been investigated in more than 50 clinical trials where it was found to be efficacious in a range of solid and haematological cancers including breast, ovarian, kidney, lung and various leukaemias including acute myeloid leukaemia.

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).

What is required for a cancer patient to enrol in 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 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](mailto: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 m<sup>6</sup>A 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<sup>6</sup>A 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](http://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](http://www.automicgroup.com.au).*

**Release authorised by:**

Daniel Tillett, CEO  
[info@raceoncology.com](mailto:info@raceoncology.com)

**Media contact:**

Jane Lowe +61 411 117 774  
[jane.lowe@irdepartment.com.au](mailto:jane.lowe@irdepartment.com.au)

For personal use only