

ASX Announcement

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

- First Hong Kong trial site, Queen Mary Hospital is activated to begin patient enrolment for the Phase 1 trial of RC220 in advanced solid tumours
- The Phase 1 trial will determine safety, tolerability and pharmacokinetic data of RC220, plus the maximum tolerated combined dose of RC220 with doxorubicin.

2 September 2025 – Race Oncology Limited ('Race') is pleased to announce the site activation of Queen Mary Hospital in Hong Kong. Activation follows receipt of Department of Health approval, enabling the commencement of patient enrolment in Hong Kong for its Phase 1 clinical trial of RC220 in combination with doxorubicin in advanced solid tumour patients. Screening of patients has begun at the Queen Mary Hospital with treatment of the first Hong Kong patient expected this month.

Additionally, the Prince of Wales Hospital (also in Hong Kong) has received both ethics approval as well regulatory approval from the Hong Kong Department of Health during August. Site activation for Prince of Wales Hospital is scheduled to occur in the coming weeks, allowing for the commencement of patient recruitment at the second Hong Kong site.

Trial progress in Australia is on track, with two patients treated with RC220 at the Southside Cancer Care Centre (Miranda, NSW). So far, 12 patients have been evaluated for inclusion by trial investigators and the Race clinical team. Due to the additional risks from doxorubicin in patients with advanced disease, recruitment is proceeding cautiously. Recruitment is expected to accelerate as additional sites are opened in Hong Kong and South Korea, which is expected to significantly increase the pool of eligible patients.

Race Chief Executive Officer, Dr Daniel Tillett said: *"Activating the first RC220 trial site in Hong Kong for our solid tumour study is a key milestone for Race Oncology. We appreciate the dedication of the investigators, clinical teams and patients participating in the trial. We look forward to the first patient being treated in Hong Kong."*

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. In Stage 1, escalating doses of RC220 will be administered to up to 33 patients alongside doxorubicin to evaluate safety, tolerability, pharmacokinetics, and to determine the maximum tolerated combined dose (MTCD) of RC220. The study will also assess the impact on various clinical biomarkers.

Following interim data analysis, the optimal dosage of RC220 in combination with doxorubicin will be evaluated in an additional cohort of 20 patients during Stage 2 to further examine safety, tolerability, and preliminary indications of cardioprotective and anticancer efficacy. The Phase 1 trial employs a Bayesian design, providing enhanced flexibility and efficiency compared to traditional methodologies.

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Q&A

Why has Race opened these trial sites in Hong Kong?

There are three major reasons.

1. **Strong interest in the trial from eminent clinical investigators.** Dr Loong and Dr Leung are highly experienced clinicians who recognise the need to address the serious issue of cardiotoxicity caused by anthracyclines like doxorubicin. The opportunity to participate in an innovative trial of a new cancer treatment that offers the potential to improve cancer treatment, while protecting the patient from doxorubicin cardiotoxicity, was compelling.
2. **Faster trial recruitment.** The more sites added, the sooner human data can be collected on the potential cardioprotection and enhanced anticancer activity of RC220 in combination with doxorubicin.
3. **Provides evidence of clinical safety and efficacy in regions outside of Australia.** Significant differences in clinical practice and patient populations exist around the world. Expanding the trial to Hong Kong allows Race to investigate safety and efficacy of RC220 in the commercially important East Asian pharmaceutical market. Hong Kong has a well-established healthcare system, strong research capabilities, and a regulatory environment that aligns with international standards.

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 at 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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