

ASX Announcement

Human Ethics Approvals Received for Phase 1 RC220 Trial at Two Hong Kong Hospitals

- Prince of Wales Hospital & Queen Mary Hospital in Hong Kong have received Human Research Ethics Committee (HREC) approval to participate in Race's Phase 1 clinical trial of RC220 in combination with doxorubicin
- Ethics approvals allows both hospitals to enrol patients, subject to formal approval from the Hong Kong Department of Health (DoH) and site activations.

10 July 2025 – Race Oncology Limited ('Race') is pleased to announce HREC approvals have been received from the Institutional Review Board of The University of Hong Kong to commence its Phase 1 clinical trial of RC220 in combination with doxorubicin (RAC-010) at the Prince of Wales and Queen Mary Hospitals (Hong Kong). Formal DoH approval has been received for the Queen Mary Hospital and is expected for the Prince of Wales Hospital in the coming weeks. Site activations will follow in late July/mid-August 2025 enabling patient recruitment to begin.

The RAC-010 clinical trial is designed to assess the safety, tolerability and pharmacokinetics (PK) of RC220 alone and in combination with doxorubicin, in patients with solid tumours.

Dr Herbert Loong, Principal Investigator at Prince of Wales Hospital, Hong Kong commented: *"Cancer patients being treated with cardiotoxic agents need the potential cardiac protection and added efficacy that RC220 may bring. We are extremely excited to be recruiting patients to this important trial."*

Dr Roland Ching-Yu Leung, Principal Investigator at Queen Mary Hospital, Hong Kong commented: *"This trial is a declaration that cardio-oncology cannot be overlooked. RC220 may be the agent that protects the heart against doxorubicin damage and adds efficacy. We are very excited."*

Race Vice President of Medical, Dr Simon Fisher commented: *"We are delighted to have received human ethics approval for our RC220 Phase 1 trial in Hong Kong with the support of two internationally recognised clinical investigators. I wish to thank both Dr Loong and Dr Leung for their support and enthusiasm in progressing RC220 and I look forward to our respective teams working together in the coming months."*

These approvals follow HREC approval for the Southside Cancer Centre (Miranda) (ASX Announcement: 14 March 2025) and Gosford and Wyong Hospitals (ASX Announcement: 31 March 2025). It is expected that additional HREC approvals will be received for up to four additional trial sites in South Korea over the coming months.

-ENDS-

Q&A

Why has Race opened two new trial sites in Hong Kong?

There are three major reasons.

1. **High 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 drug that offers the potential to improve doxorubicin 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 provides important and early clinical evidence of safety and efficacy 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 enter the trial?

Patients who are under the care of the clinical trial study doctors at the 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 if 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 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 agent. 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 and less cardiotoxicity over certain 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 Oncology has collaborated with Astex, 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.

Release authorised by:

Daniel Tillett, CEO
info@raceoncology.com

Media contact:

Jane Lowe +61 411 117 774
jane.lowe@irdepartment.com.au

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