

ASX Announcement

Race Submits Human Ethics Application Package for RC220 Phase 1 Solid Tumour Trial

- Human ethics regulatory package submitted for Race's Phase 1 trial in solid tumour patients using RC220 bisantrene, with up to 10 additional sites to follow
- Will study RC220 in combination with doxorubicin in adult cancer patients
- First patient recruitment is expected to occur in Q1 2025.

5 December 2024 – Race Oncology Limited ('Race') is pleased to announce submission of the ethics and regulatory package to Bellberry Human Research Ethics Committee (HREC) for approval of a Phase 1 clinical trial of RC220 at the Australian lead site, Southside Cancer Care Centre (Miranda, NSW), under the supervision of Principal Investigator (PI), Dr Mahood Alam. Following approval, this site will be activated for patient recruitment and institutional approval, with first patient recruitment anticipated in Q1 2025.

In parallel, regulatory and institutional packages have been completed for submission to a second Australian site immediately following HREC approval of the trial, with both sites planned to be activated simultaneously. Regulatory and institutional packages are in advance preparation for multiple locations in Hong Kong and South Korea, with submissions anticipated in early Q1 2025. Additional site evaluation and recruitment is ongoing with the aim of achieving 10 active sites.

This open label, Phase 1 trial will be conducted in two stages (ASX announcement: 20 June 2024). Stage 1 will assess the safety and tolerability of ascending doses of RC220 alone, as well as in combination with standard-of-care (SOC) doses of doxorubicin (Adriamycin®) in patients with advanced solid tumours. The trial objectives of Stage 1 are to identify the maximum tolerated combination dose (MTCD), the pharmacokinetics of RC220, and the effects of RC220 on a range of exploratory clinical biomarkers, including m⁶A RNA and cardiovascular capacity. The trial will use a Bayesian statistical design for the dose escalation stage, a design that has proven faster and more efficient than the traditional (3+3) dose escalation approach.

An interim analysis of all data from Stage 1 will be performed after the last patient completes their first cycle of the combination treatment with the aim of identifying the optimal dose of RC220 in combination with doxorubicin. In Stage 2, RC220 will be used to treat patients with solid tumours who have not previously received doxorubicin or other anthracyclines using the optimal combination dose. Stage 2 will generate additional safety and tolerability data on the combination, cardioprotective (via VO₂peak measurements) and anticancer efficacy data, and the effects of RC220 on a range of biomarkers. Subject to HREC approval, Stage 2 is planned to commence while patients in Stage 1 continue treatment according to the study protocol.

This Phase 1 study will set the foundational clinical evidence from which to advance to larger Phase 2 multi-regions studies (USA, Europe and Asia) to advance the clinical development of RC220 as a potential cardioprotective anticancer agent aimed at improving the health outcomes of cancer patients treated with anthracyclines.

Race Chief Executive Officer & Managing Director, Dr Daniel Tillett commented: *"I wish to thank the entire Race team and especially the Race clinical team for their extraordinary effort to reach this point in the*

clinical development of RC220. I also wish to thank George Clinical, the Cancer Care Foundation, and Dr Mahmood Alam for their support and advice. RC220 offers the potential to help millions of cancer patients avoid the detrimental side effects and accelerated-aging anthracycline chemotherapy can cause while also improving cancer treatment outcomes for cancer patients."

Race Chief Medical Officer, Dr Michelle Rashford commented: *"This is a critical milestone for the team; selection and evaluation of an appropriate site and the start of the ethical review for this study. Once we have the approval for the lead site, the team will focus on advancing patient recruitment as efficiently as possible to commence the assessment of the cardioprotective benefits of RC220 for patients treated with anthracyclines. I thank the clinical team and George Clinical for their efforts to date."*

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About Cancer Care Foundation and Cancer Care Associates

The Cancer Care Foundation was established in 2018 as a not-for-profit charity dedicated to supporting cancer research, promoting cancer prevention, and enhancing quality of life for cancer patients and their carers by improving accessibility to cancer-related services. The Foundation together with Cancer Care Associates are committed to the provision of excellence in Cancer Care by providing world-class state-of-the-art facilities that deliver multidisciplinary care in a comfortable, serene, nurturing environment. Patient care is delivered by a team of highly skilled medical professionals who have a proven track record of innovation and clinical leadership, using the latest in technology and treatment protocols.

Cancer Care Associates operates several cancer treatment centres in Australia including the Riverina Cancer Care Centre (Wagga Wagga), Southside Cancer Care Centre (Miranda), Northern Beaches Cancer Care Centre (Frenchs Forest), Cancer Care Wollongong, Cancer Care Macarthur (Campbelltown), Cancer Care Griffith and the soon-to-be-opened facilities in Noosa, Caboolture, Brisbane, Taree and others.

Southside Cancer Care Centre (Miranda) commenced operations in July 2014. The Southside facility delivers chemotherapy services and is a significant contributor to the rapid growth-oriented Sutherland Shire. Southside Cancer Care Centre is housed in a purpose-built, modern healthcare premises, within a healthcare precinct servicing the Sutherland Shire.

About George Clinical

George Clinical is a globally recognized clinical research organization (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 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 anti-cancer 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/announcements>

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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