RACE ONCOLOGY

ASX Announcement

Race Appoints George Clinical to Support a Phase 1a/1b Trial of RC220 Bisantrene in Solid Tumour Patients

- George Clinical International appointed to support the clinical development of RC220 bisantrene as a cardioprotective & anticancer treatment in solid tumour patients
- Phase 1a/1b trial is for cancer patients in Australia, Hong Kong & South Korea with advanced solid tumours where doxorubicin treatment is indicated
- Study will provide human safety and pharmacokinetic data, optimal dosing in combination with doxorubicin, plus initial human data on the cardioprotective, anticancer and m^6A RNA activity of RC220 bisantrene.

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20 June 2024 – Race Oncology Limited ('Race') is pleased to announce the appointment of the Contract Research Organisation (CRO), George Clinical International, to support the clinical development of RC220 bisantrene. George Clinical was selected after an extensive and rigorous selection process conducted by the Race Oncology clinical team.

George Clinical is a leading global CRO with over 20 years of operation, extensive trial experience globally and impressive track record of success conducting oncology trials at all phases in the United States, Europe, China, South-East Asia, New Zealand and Australia.

In addition to clinical trial expertise, George Clinical, brings access to a supplementary network of key opinion leading clinical oncologists with extensive expertise in the treatment of solid tumours with anthracyclines. These clinical experts will assist Race in the refinement and efficient execution of the proposed Phase I study of peripherally administered intravenous RC220 bisantrene in combination with a standard-of-care (SOC) regimen of doxorubicin (Adriamycin®) in patients with advanced solid tumours.

The Phase 1 trial will be conducted under an open label in two stages across multiple sites in Australia, Hong Kong and South Korea. The first Phase 1a stage will study ascending doses of RC220 bisantrene to determine safety, tolerability, pharmacokinetics, m^6A RNA effects, and the maximum tolerated dose alone and in combination with doxorubicin. In the second Phase 1b stage, the optimal dosage of RC220 bisantrene in combination with doxorubicin will be assessed for additional safety, tolerability, and preliminary cardioprotective and anticancer efficacy signals. The Phase 1 trial will use a Bayesian design allowing for greater trial flexibility and speed. The final trial protocol and commencement of the trial is subject to human ethics and institutional approvals.

Race has commenced engagement of George Clinical under a Start-Up Agreement (SUA) at a cost of $1,071,067. Additional payments will be made to George Clinical under a Master Service Agreement (MSA) throughout the study after completion of key milestones, with the total cost dependent on the number of recruited patients and other variables of trial execution. The current estimated CRO cost of the Phase 1 trial is $6 million based on the recruitment of 34 patients, with additional costs for drug supply, pharmacokinetics and biomarker analysis.

Race Chief Executive Officer, Dr Daniel Tillett comments: *"This agreement with George Clinical is a significant milestone for Race to bring RC220 bisantrene to the clinic to potentially protect patients from the heart damage caused by anthracyclines while improving the treatment of their cancer. I welcome the*

opportunity for Race to work with George Clinical and wish to thank the Race clinical team for their hard work and dedication in reaching this agreement."

Race Chief Medical Officer, Dr Michelle Rashford comments: *"This is a key foundational study to establish important safety and drug absorption kinetics for RC220 and provide appropriate doses for effective combination with doxorubicin to advance the development of RC220 for clinical cardiac benefit to patients treated with anthracyclines while providing improved outcomes. We are delighted George Clinical can support this significant step for Race and through the selection process their responsiveness and clinical insight has impressed us. I and the rest of Race clinical team look forward to working with George Clinical on this and future trials."*

Q&A

How long will this Phase 1a/1b trial take to complete?

This is difficult to answer as the trial uses a Bayesian statistical design. While efficient in terms of patient numbers and cost, Bayesian trial designs can be difficult to estimate accurate timelines as the number of patients needed is not fixed. Our current best estimate is the trial should complete recruitment during 2026.

Why test RC220 bisantrene in a range of cancer types?

The damage to the heart caused by anthracyclines like doxorubicin is independent of the cancer type. For example, the hearts of breast cancer patients are damaged in exactly the same way as lung cancer patients by doxorubicin so there is no ethical reason to limit recruitment to specific cancer types at this stage. In addition, recent preclinical data generated by Race has shown that bisantrene improves the cell killing of over 85% of human cancer cells treated with doxorubicin (ASX announcement: 21 September 2023), supporting the use of bisantrene across a range of cancer types.

The trial cost is now lower than the $11 million estimated last November. How have you managed to decrease the trial costs?

Clinical trial design efficiencies and careful CRO selection have enabled the Race clinical team to optimise the Phase 1a/1b trial such that the total cost of the trial is now expected to be well under $9m.

How can I learn more?

Race Chief Medical Officer Dr Michelle Rashford explains more in a video interview here:
https://announcements.raceoncology.com/link/WrA3by

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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 m^6A 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^6A 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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