

ASX Announcement

Race Receives Human Ethics Approval for Observational Cardioprotection Breast Cancer Trial

- Human ethics approval received for the initial observational stage of a planned interventional Phase 1/2b cardioprotection clinical program using Zantrene
- Research institutional governance submission is expected soon and will enable enrolment of the first study patient
- This observation trial is the first step in advancing the cardioprotection opportunity for Zantrene in the clinic.

1 February 2023 – Race Oncology Limited (“Race”) is pleased to announce it has received human ethics approval from the Hunter New England Human Research Ethics Committee (NSW, Australia) for the observational stage of a planned Phase 1/2b clinical trial of Zantrene® (bisantrene dihydrochloride) in breast cancer patients, to be treated with doxorubicin and cyclophosphamide and who have two or more cardiovascular risk factors. Details of the trial design and purposes have been previously described (ASX Announcement: 9 December 2022).

Before patients can be enrolled and treated Race must first submit and then receive research institutional governance (site budget and contracting) approval. Submission is expected to take place in the coming weeks. Governance approval is typically received within 4 to 8 weeks of submission.

The study will recruit and monitor up to 50 patients being treated for breast cancer using the standard of care (SoC) regimen of doxorubicin (Adriamycin®) and cyclophosphamide – referred to as “AC chemotherapy”. The aim of this study is to identify the rate and level of heart damage caused by AC chemotherapy, using modern advanced cardiac imaging and biochemical methods. In addition, the anti-cancer efficacy of AC chemotherapy will be monitored using a liquid biopsy (DNA) approach.

The data from this study will be directional for the design of a subsequent Phase 1/2b interventional trial that may help patients to avoid the permanent heart damage that can be caused by AC chemotherapy as well as potentially improving anti-cancer outcomes. These human trials are fully funded from capital raised in December 2021 (ASX Announcement: 21 December 2021).

Race CEO Mr Damian Clarke-Bruce commented, *“Cardioprotection for breast cancer is a significant unmet need, and our preclinical data suggests that Zantrene may help to address the therapeutic gap for patients whilst still delivering clinical efficacy. I look forward to the team progressing the clinical program and building more knowledge to enable further clarity on the potential commercial opportunity this program represents.”*

Race CSO Dr Daniel Tillett commented, *"This trial is Race's first step in advancing the cardioprotection opportunity for Zantrene in the clinic. Gaining high quality observational data to design our interventional Phase 1/2b trial of Zantrene in breast cancer is critical to the success of this program. We look forward to updating our investors on the progress of this trial."*

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About Race Oncology (ASX: RAC)

Race Oncology is an ASX listed precision oncology company with a Phase 2/3 cancer drug called Zantrene®.

Zantrene is a potent inhibitor of the Fatso/Fat mass and obesity associated (FTO) protein. Overexpression of FTO has been shown to be the genetic driver of a diverse range of cancers. Race is exploring the use of Zantrene as a new therapy for melanoma and clear cell renal cell carcinoma, which are both frequent FTO over-expressing cancers.

In breakthrough preclinical research, Race has also discovered that Zantrene protects from anthracycline-induced heart damage, while in tandem acting with anthracyclines and proteasome inhibitors to improve their ability to target cancer.

The Company also has compelling clinical data for Zantrene as a chemotherapeutic agent and is in multiple clinical trials in Acute Myeloid Leukaemia (AML).

Race is pursuing outsized commercial returns for shareholders via its 'Three Pillar' strategy for the clinical development of Zantrene. 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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