

ASX Announcement

December 2022 Preclinical & Clinical Programs Update

23 December 2022 – Race Oncology Limited (“Race”) wishes to share an update on our clinical and preclinical programs, which were committed to in the Expected News sections of the June and September 2022 Quarterly Activity Reports (ASX Announcements: 22 July 2022 and 27 October 2022). Race has continued to make significant preclinical and clinical progress in Australia and internationally in 2022. A brief update on the progress of these programs is provided below.

Preclinical Programs

As outlined at the 2022 Annual General Meeting (ASX Announcement: 24 November 2022), the development and transfer to manufacturing of the new peripheral Zantrene formulation RC220 (ASX Announcement: 28 September 2022) provides Race with an opportunity to explore the preclinical programs in greater depth and breadth. This formulation advance has altered the current program timelines as the scope of the preclinical projects has expanded to be able to leverage earlier, lower cost work ahead of final indication selection and clinical trial commencement.

Cardioprotection

Additional preclinical studies are underway in cell culture and animal models exploring both the mechanism of action and optimal therapeutic usage of Zantrene as a cardioprotective agent. Positive advances have been made and it is hoped a progress update can be released in H1 CY2023, however precise timelines are difficult to estimate as this project involves complex and novel scientific research.

Breast Cancer

Cell and animal studies exploring the optimal combination of Zantrene with the standard of care drugs doxorubicin and cyclophosphamide were begun in H2 2022. While results to date are very promising, completion of these studies has been delayed by the acute sensitivity of the standard cancer mouse models to doxorubicin which has required the use of complex and time-consuming alternative cancer models. Further updates on this program are expected in H1 CY2023.

The current cardioprotection and breast cancer preclinical studies are designed to provide additional supportive data and their completion is not required for the initiation of any announced clinical trials.

Kidney Cancer

In H2 CY2022, dose ranging studies of Zantrene and a kinase inhibitor were performed in a rat model of clear cell renal cell carcinoma (kidney cancer). The results of these studies were promising and enable the design of further animal studies exploring the optimal

combination and dose of Zantrene with kinase inhibitors as a treatment for kidney cancer. Further updates on this program are expected in H1 CY2023.

Multiple Myeloma

Zantrene was found to protect heart muscle cells from the known cardiotoxic multiple myeloma drug carfilzomib (Kyprolis[®]) (ASX Announcement: 8 December 2021). In CY2022, both dose ranging and cardioprotection studies were initiated in mouse models of multiple myeloma and cardioprotection. The absence of a well-characterised rodent model of carfilzomib-induced cardiac damage has required the investment of significant time and effort into mouse model development and characterisation. Excellent progress has been made on this project, but an accurate completion timeline cannot be provided at this time.

Acute Myeloid Leukemia (AML)

A human derived mouse model of AML study was undertaken during H2 CY2022 exploring the optimal combination of decitabine and Zantrene as a low toxicity treatment for AML. Reporting on this project has been delayed as the mice treated with the optimal Zantrene and decitabine dose have controlled the growth of the cancer to such an extent that the mice have lived far longer than expected. The results of this study will be reported in Q1 CY2023.

Other

Preclinical programs are underway exploring the potential utility of Zantrene as an anti-cancer agent across more than 100 cancer types. Early data from these programs suggests Zantrene may have broad utility across a wide range of cancer types. Progress updates on this program are expected over the first half of CY2023.

Clinical Programs

Phase 2 R/R AML Combination Trial

The clinical Phase 2 expansion stage of Zantrene in combination with fludarabine and clofarabine to treat relapsed/refractory (R/R) Acute Myeloid Leukaemia is progressing to expectation and is continuing to recruit patients. This trial completed the Phase 1b dose escalation stage with 3 of the 6 patients successfully bridged to a stem cell transplant (ASX Announcement: 27 May 2022).

The study is being led by Professor Arnon Nagler of the Chaim Sheba Medical Center, Israel, who previously conducted the Phase 2 single agent Zantrene R/R AML trial, where a 40% clinical response was observed (ASX announcement: 16 June 2020). Race will update investors on the progress of this trial upon completion of the first stage of the Simon 2-stage analysis in 2023 (ASX Announcement: 22 June 2021).

Phase 1/2 EMD AML Trial

Progress on our Australian extramedullary AML-focused trial (RAC-006) is advancing with the support of the Contract Research Organisation (CRO), Parexel. To date three patients have been screened for EMD AML, however, no patient has been identified who is eligible for treatment in either stratum of this trial. An additional two AML patients are expected to be screened for EMD in the coming weeks.

As outlined at the Race 2022 Annual General Meeting, a number of factors including limited trial site capacity for new trials, COVID-19 disruptions, competition for limited clinical resources, and screening of AML patients for EMD by ^{18}F -DGD-PET not being standard of care, have all contributed to a slower than expected patient recruitment rate. In response, Race intends to modify the design of the trial in Q1 2023 to improve recruitment and commence expansion to additional sites in Australia and Europe.

FTO Biomarker

Race initiated two FTO-focused biomarker development projects in late 2021 in collaboration with Dr Dan Dominissini of the Chaim Sheba Medical Center, Israel (ASX Announcement: 27 October 2021) and Prof. Murray Cairns of the University of Newcastle (ASX Announcement: 3 November 2021). These are complex and long-term projects with significant intellectual property potential. While good progress has been made to date, Race is not in a position to update the market on details without compromising valuable IP. An update on this program will be provided at the appropriate point in time.

Race thanks all shareholders and interested investors for their support throughout 2022. We look forward to updating the market in 2023 as further material progress is made on our Three Pillar strategy.

-ENDS-

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.

Release authorised by:

Phil Lynch, CEO/MD on behalf
of the Race Board of Directors
phillip.lynch@raceoncology.com

Media contact:

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