

## **ASX Announcement**

### **H1 2023 Preclinical and Clinical Programs Update**

**07 July 2023** – Race Oncology Limited (“Race”) wishes to share an update on its preclinical and clinical programs, following significant progress in Australia and Internationally through 2023.

#### ***Chemistry Manufacturing and Controls (CMC)***

##### **RC220 Proprietary Bisantrene Formulation**

Manufacturing of RC220, Race’s new intravenous (IV) formulation of bisantrene which is suitable for administration into a peripheral vein, (ASX Announcement: 28 September 2022 and 28 April 2023) is progressing well with an engineering batch completed in May. RC220 material from the engineering batch will be provided to Race in Q3 2023 for upcoming Good Laboratory Practice (GLP) safety pharmacology and toxicology studies as required by regulatory bodies to conduct clinical trials. A new European Contract Development and Manufacturing Organisation (CDMO) has been selected for GMP manufacturing production of RC220 at a scale and quality suitable to service all Phase I/II Australian, US and specifically European clinical trials.

##### **GMP Manufacturing of Bisantrene Active Pharmaceutical Ingredient (API)**

To support the new RC220 formulation, a substantial, value-building project has been delivered by Race’s active pharmaceutical ingredient (API = bisantrene) manufacturer, Laurus Laboratories (ASX Announcement: 21 April 2022). Laurus has optimised the process chemistry and delivered in excess of the minimum contracted amount of bisantrene dihydrochloride API material to GMP standard. This secures sufficient drug to adequately supply projected preclinical and clinical programs.

##### **Transition from RC110 to RC220 formulation**

Given that Race will focus its future development activities on the peripheral IV administered bisantrene formulation RC220, the Company has chosen at this point to cease manufacturing RC110 which clinically requires central venous access, due to its tendency to precipitate in and, therefore, damage the smaller peripheral veins. This migration to RC220 provides clear therapeutic advantage related to the combined ease and safety of peripheral IV administration. Furthermore, RC220 affords robust new intellectual property (IP) protection.

##### **Commercial Advantages of RC220**

- RC220 offers a more patient-centric approach with enhanced clinical utility, due to its superior and simplified route of administration.

- Dosing peripherally enhances the potential to recruit patients to clinical trials. Peripheral IV dosing is increasingly the standard in breast cancer and other solid tumour settings.
- Race is advised that the RC220 formulation generates strong, novel, primary IP with associated secondary and tertiary claims, enhancing bisantrene's franchise value.

In summary, RC220 provides Race with an assured IP basis and increased flexibility for use, making this formulation the stronger choice for multi-centre clinical studies.

### ***Preclinical Programs***

#### **Cardioprotection**

The preclinical program with cardio-oncologist Dr Brian Jensen (University of North Carolina, USA) to study the molecular mechanisms that underpin bisantrene's cardioprotective properties (ASX announcement: 3 March 2023) is well underway and will be reported in Q3 2023. Together with in-house preclinical studies being completed at the University of Wollongong, Race is building a comprehensive understanding of bisantrene's cardioprotective properties, which we aim to publish in conference proceedings and/or peer-reviewed journals over the coming year.

#### ***In vitro safety pharmacology and toxicology studies***

To support Race's RC220 clinical programs, downstream regulatory submissions and partnering discussions, Race has drafted its protocol designs for Good Laboratory Practice (GLP)-compliant safety, pharmacology and toxicology studies. These will be executed under the guidance of internationally renowned pharmaceutical industry toxicologist and Race Interim CSO, Dr Tim Hammond. Finalisation of contracts and program scheduling is in progress with the studies to commence in Q3 2023 using the engineering batch of RC220.

#### **Profiling the activity of bisantrene in multiple cancer cells**

In studies commissioned at Oncolines (Netherlands), bisantrene has shown entirely broad and potent cell-killing activity across a variety of human cancer types/indications. These data have spurred additional mechanism-informed combination studies with select cancer drugs in priority indications. Results of this ongoing work will be disseminated via conference abstracts or peer-reviewed publications following IP review and associated protection.

### ***Clinical Programs***

#### **RI-002 – Phase 2 AML clinical trial at Chaim Sheba, Israel (investigator led study)**

Under the leadership of principal investigator Professor Arnon Nagler, and applying central venous administered bisantrene formulation RC110, this trial has recruited to plan. To date, 20 heavily pre-treated patients with relapsed and refractory AML have been enrolled, with only two further patients required to meet the first stage of the Simon two stage decision point.

Observations in this open label protocol have been compelling, with several patients being effectively bridged to allogenic stem cell transplant with curative intent.

Given the strategic intent of the Company to migrate from RC110 to RC220, and with the full endorsement of Professor Nagler, it has been agreed that the RI-002 protocol will recruit the final two patients and then proceed to report on outcomes over the coming months.

Race wishes to thank Professor Nagler, Chaim Sheba Medical Centre, the patients who joined the trial and their families for invaluable contributions to the RI-002 study. The Chaim Sheba investigational team is now working towards assembling the data for publication in a peer-reviewed journal followed by a report to the market on the study outcomes.

### **BISECT (RAC-006) Phase 1b/2a clinical trial of bisantrene in AML & MDS patients with extramedullary disease**

RAC-006 was designed to assess bisantrene in patients with AML, myelodysplastic syndromes (MDS) and chronic myelomonocytic leukaemia (CMML) presenting with extramedullary disease (EMD). As highlighted previously, the study has experienced significant recruitment challenges based on the rarity of EMD and the embedded approach to screening for EMD in the AML setting (28 April 2023 Quarterly Activity Report).

Given the above and after extensive consultation with local and international clinical advisors, a decision has been made to amend the RAC-006 protocol. Led by Drs. Rashford and Duggal, the Company will amend and re-submit the associated protocol to include a broader subset of AML patients who will first receive RC110 plus oral decitabine. Subsequent cohorts are planned to receive RC220 plus oral decitabine as RC220 production becomes available. The broadened criteria are expected to significantly enhance recruitment and potentially expand the commercial opportunity. The amended study design will be shared through the coming strategic update.

### **RAC-008 – Phase 1b/2 cardio-protection trial in breast cancer patients to be treated with doxorubicin and cyclophosphamide and who have two or more cardiovascular risk factors**

While awaiting institutional and regulatory approvals, further diligence has been performed on “Trial 1 Non-Interventional”, which was designed to assess cardiac damage and tumour response in breast cancer patients receiving doxorubicin plus cyclophosphamide (AC) therapy only, establishing an effective baseline for comparison purposes.

In agreement with the principal investigator, and consultation with international breast cancer specialists and cardio-oncologists, the Company has chosen to terminate this non-interventional AC therapy protocol and allocate related capital (AUD \$3m) to RC220 led programs. Upon review, our panel of advisors suggests that readily available datasets can be used for baseline and clinical comparisons. Importantly, we emphasise that the timeframe for the RC220 interventional breast cancer study is not impacted by this decision and the non-interventional trial would have provided no bisantrene-specific insights.

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The refocusing across clinical programs delivers value for Race shareholders as we comprehensively back our novel patent protected formulation, RC220, informed by data analysis and consultation with international experts. Further information on all program elements will be shared in the coming strategic update.

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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 bisantrene.

Bisantrene 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 bisantrene 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 bisantrene 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 bisantrene 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 bisantrene. Learn more at [www.raceoncology.com](http://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](http://www.automicgroup.com.au).*

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