ASX Announcement

RC220 cGMP Manufacturing Complete

- **Certificate of Analysis issued by Ardena for the first cGMP batch of bisantrene formulation RC220**
- **Confirms RC220 meets all cGMP specifications required for a human IV drug product**
- **Major milestone in the progress of RC220 for use in human clinical trials.**

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26 March 2024 – Race Oncology Limited ("Race") is pleased to announce that a Certificate of Analysis (CoA) has been issued for the first current Good Manufacturing Practice (cGMP) batch of Race's proprietary bisantrene formulation, RC220, confirming that the drug product meets the quality specifications required for human use. Ardena was contracted by Race to manufacture the cGMP RC220 drug product to ensure that it meets the exacting standards required by major global regulatory authorities for human clinical use, including the European Medicines Agency (EMA), the US Food & Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA) (ASX Announcement: 12 July 2023).

Race's innovative bisantrene formulation is designed to enable safe administration of bisantrene to patients via peripheral vein (arm or leg) intravenous (IV) infusions (ASX Announcement: 28 September 2022). The project built upon the successful R&D formulation work completed by Race's lab team at the University of Wollongong (ASX Announcement: 9 November 2021).

A cGMP batch of 2600 vials of RC220 was manufactured in this campaign. The issued CoA confirms that RC220 meets the manufacturing quality specifications required for IV drug products to be used in humans. Adherence to cGMP quality standards meets the requirements for evaluating new IV drug products in human Phase 1 & 2 clinical studies in Asia-Pacific, Europe and the USA.

CEO, Dr Daniel Tillett comments: *"Reaching this point in the development of bisantrene is a major milestone and accomplishment. The original developers of bisantrene, Lederle Laboratories, tried for nearly a decade to make a formulation of bisantrene that could be delivered via a peripheral vein without success. It is a testament to the dedication and skill of the Race team that we were able to accomplish what Lederle could not. I, along with the entire team at Race, are looking forward to completing the GLP toxicology testing of RC220 in the coming months and beginning the clinical program that will give patients access to bisantrene in a format that is both easier and safer to use."*

CMO, Dr Michelle Rashford comments: *"This is a major milestone to have reached and means we have manufactured RC220 to a standard suitable to start our Phase 1 clinical trial here in Australia."*

Q & A

How many vials of RC220 were manufactured?

2600, with 1799 available for patient use. This is enough drug vials to treat more than 150 patients and will satisfy the requirements of all planned human clinical trials over the next several years. Additional batches of cGMP RC220 will be manufactured as needed and at increasing scale to ensure that Race meets future clinical trial needs and can demonstrate to regulators and pharmaceutical partners that RC220 can be produced consistently at commercial scale.

What testing was done on the cGMP batch of RC220

A wide range of tests were conducted under cGMP standards to accurately measure the amount of bisantrene, impurity levels and the moisture content of drug product vials to ensure that the formulation contents adhere to narrow, prespecified limits. The vials are examined for appearance, the time to reconstitute the dry powder (i.e., how long it takes to dissolve a vial of RC220 upon the addition of water), and the pH of the solution. In addition, the vials are tested for sterility (i.e., no detectable bacteria) and for the absence of endotoxins (bacterial cell wall components), which can cause serious adverse reactions if injected into a patient.

What are the next steps in the development of RC220?

The final step required before RC220 can be used in human clinical trials is completion of GLP toxicology and safety pharmacology studies (ASX Announcement: 5 October 2023). These studies are progressing well and remain on track for completion in late Q2 CY2024.

How soon can human clinical trials start?

H2 2024. Significant progress has been made by Race's clinical team preparing the extensive documentation required to undertake a Phase 1 trial in Australia. Investors can expect to be updated on a regular basis on the progress of this work as each milestone is accomplished.

-ENDS-

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 m^6A RNA pathway has been described in numerous peer reviewed studies to be 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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