RACE ONCOLOGY

ASX Announcement

RC220 Engineering Batch Meets Manufacturing Quality Specifications

- A Certificate of Testing has been issued for the first engineering batch of the RC220 bisantrene formulation, clearing its use in GLP toxicology studies
- Confirms that RC220 can meet the manufacturing quality specifications required of IV drug products
- Major milestone to support the progression of RC220 into first human clinical trials

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09 November 2023 – Race Oncology Limited ("Race") is pleased to announce that a Certificate of Testing (CoT) has been issued by Societal CDMO (San Diego, USA) for the first engineering batch of Race's proprietary bisantrene formulation, RC220, confirming that the drug product meets manufacturing quality specifications. The CoT clears RC220 for use in Good Laboratory Practice (GLP) toxicology and safety pharmacology studies (ASX Announcement: 5 October 2023) and significantly de-risks the RC220 current Good Manufacturing Practice (cGMP) campaign underway at Ardena (ASX Announcement: 12 July 2023).

Societal CDMO was contracted to produce RC220; Race's innovative bisantrene formulation 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 under the supervision of Senior Scientist Dr Benjamin Buckley and his team, located at the University of Wollongong (ASX Announcement: 9 November 2021).

An engineering batch (EB; non-GMP) of more than 1,500 vials of RC220 was manufactured. The issued CoT confirms RC220 meets the manufacturing quality specifications required for IV drug products. Adherence to quality standards is a strict requirement for evaluating new IV drug products in GLP toxicology studies. Confirming that RC220 can be manufactured to the specified quality standards provides very high confidence that the production of cGMP RC220 currently in progress at Ardena will be able to meet the stringent specifications necessary for use in human clinical trials.

Executive Director, Dr Pete Smith commented: *"Bringing a new IV drug product like RC220 to the clinic is a complex undertaking that requires successful progress through multiple checkpoints. The recent data confirming that RC220 satisfied all manufacturing quality specifications when produced at scale for the first time represents an incredibly important milestone, as it strongly supports our ability to produce GMP material suitable for human clinical use."*

Q&A

What is an engineering batch and what relevance does it have to the manufacturing of RC220 for human use?

The process of creating a new sterile injectable drug product like RC220 is complex and demanding. The first stage involves experimentation via lab-based R&D to identify feasible formulations. Guided by the preliminary experimental findings, further lab-scale tests on prototype formulations are undertaken to support that candidate formulations could be produced at scale in a cGMP manufacturing facility. Once suitable lab-scale prototypes have been identified, batches of the formulation are produced at gradually increasing scale, ultimately ending in the production of a full-scale engineering batch. If the engineering-scale production is successful, as indicated by tests showing adherence to the quality specifications, the developed methods can then be used to manufacture cGMP drug products of the highest quality, meeting all requirements for use in humans.

cGMP batches of a drug product are produced at a similar scale using the methods developed for the engineering batch. The primary difference between an engineering batch and a cGMP batch intended for use in humans is the level of quality control auditing at each step in the process and higher cost.

What testing has been done on the RC220 formulation engineering batch?

A wide range of tests are performed to accurately determine 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.

-ENDS-

About Race Oncology (ASX: RAC)

Race Oncology (ASX: RAC) is an ASX-listed clinical stage, global biotechnology company with a dedicated mission to be at the heart of cancer care.

Race's lead asset, bisantrene, is a small molecule anthracene chemotherapeutic. Bisantrene has a unique and rich clinical history with demonstrated therapeutic benefits in both adult and paediatric patients, a well characterised safety profile, and compelling clinical data demonstrating an anti-cancer effect and less cardiotoxicity than other comparable agents.

Race is developing bisantrene to address the high unmet need of patients across multiple oncology indications, with an initial focus on metastatic breast cancer (lead indication) and acute myeloid leukaemia (AML) exploring anticancer plus cardioprotection in synergy with known standards of care.

As part of its clinical and preclinical programs, Race is investigating the effect of bisantrene on the m^6A RNA pathway, following independent research 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 is in collaboration with City of Hope, MD Anderson, Sheba City of Health and UNC School of Medicine, 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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