RACE ONCOLOGY

ASX Announcement

RC220 Peripheral Infusion Safety Confirmed in Preclinical Models

- Preclinical models acceptable by regulatory authorities demonstrate that the RC220 formulation of bisantrene avoids drug precipitation in peripheral veins and associated phlebitis
- Data supports the use of RC220 in human clinical trials where peripheral infusions are indicated
- RC220 provides significant IP value and increased convenience for both patients and clinicians

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17 October 2023 – Race Oncology Limited ("Race") is pleased to announce that it has successfully completed a series of preclinical animal and laboratory studies showing that Race's novel bisantrene formulation, RC220 (ASX Announcement: 28 September 2022), prevents drug precipitation (crystallisation) and phlebitis (vein inflammation or damage) when infused into peripheral veins. These studies, performed at Pharmaron (CA, USA) and by Race scientists based at the University of Wollongong (Australia), used *in vivo* (animal) and *in vitro* (laboratory) models accepted by regulators for assessing intravenous infusion (IV) safety.

Current administration of bisantrene (i.e., RC110) requires the use of an invasive central venous catheter (also known as a central or main line, which is inserted near or into the patient's heart) and must be performed in a hospital setting. While this approach is common practice for the delivery of chemotherapy drugs in patients with haematological (blood) cancers, it is not standard practice for solid tumours, such as breast cancer, where peripheral IV infusions (i.e., into an arm or leg vein) in an outpatient setting are typically preferred by both the patient and treating oncologist.

Peripheral IV administration can provide a better quality of life for patients with less risk and lifestyle disruption as it enables treatments to occur outside of a major hospital, or sometimes at home. The ability to precisely match the specific drug dose required for each patient is also simpler using a peripheral IV infusion than with other delivery options, such as fixed-size oral dosing. This is particularly important in chemotherapy, where imprecise dosing can have serious, life-threatening consequences.

The data from these studies will be used in future regulatory applications and patent filings and support the use of peripheral IV infusions of RC220 in clinical trials. As with RC110, RC220 can also be infused via a central line where clinically indicated, providing treatment flexibility.

Executive Director, Dr Pete Smith commented: *"Given the creativity, hard work and capital we have invested into RC220, it is gratifying to see the formulation perform as designed, preventing bisantrene peripheral vein precipitation and phlebitis in industry standard preclinical models expected by regulators. This is a key step on our path to bringing a superior version of bisantrene to the clinic for the benefit of a much larger number of patients with solid tumours and the clinicians who treat them. With RC220 also comes additional, robust intellectual property that adds significant commercial value to Race."*

Q&A

How confident is Race that RC220 will be able to be used for peripheral infusion in humans?

Highly. In early historical trials where bisantrene was infused into the peripheral veins of patients, drug precipitation problems were observed due to the lower solubility of bisantrene at pH 7 or higher (neutral to alkaline). Bisantrene dihydrochloride solution can precipitate (crystalise) when the pH rises above pH 6 if the concentration is high. Since the blood of mammals (animals and humans) is close to pH 7.4, peripheral infusion of early formulations resulted in a rapid, local precipitation of bisantrene in the vein, causing serious phlebitis and blockage. While the precipitation problem is overcome by using a central line infusion (where high blood flow dilutes the bisantrene before it can precipitate), it is riskier and less convenient for patients and clinicians than peripheral IV infusions.

The pH-dependent precipitation of bisantrene is comparable in both human and animal blood. This gives us high confidence that if the RC220 formulation doesn't precipitate when infused into an animal's peripheral vein, it won't precipitate when infused into a human's peripheral vein.

Has the patent for RC220 been filed?

Not yet. Race aims to maximise the value of all IP. Since patents have a limited 20-year life from the filing date, delaying submission until the composition of RC220 must be disclosed to regulatory authorities maximises the lifetime and commercial value of the RC220 formulation patent.

What is the commercial significance of these data?

Peripheral IV formulations have significant commercial advantages. As central line administration requires highly skilled healthcare personnel, simpler peripheral IV formulations are attractive in resource constrained healthcare environments. Secondly, it is likely that we will be able to administer bisantrene more rapidly, minimising occupancy of expensive oncology infusion chairs and providing patients with a less invasive treatment experience. Thirdly, peripheral IV administration would support bisantrene use in indications where central lines are rarely used. The more cancer indications where bisantrene is used, the higher the commercial value.

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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 anti-cancer plus cardio-protection 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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