ASX Announcement

Race Develops Improved IV Formulation of Zantrene

- **Race researchers have developed an improved & novel formulation of Zantrene that enables peripheral intravenous (IV) delivery, expanding potential market**
- **Societal (San Diego, USA) has been contracted to manufacture the new GMP drug product formulation with expected delivery date of late Q2 CY 2023**
- **This new Zantrene IV formulation (codename RC220) provides Race with additional IP patent protection for Zantrene, valid to 2043.**

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28 September 2022 – Race Oncology Limited ("Race") is pleased to announce that Race researchers, led by Dr Benjamin Buckley in collaboration with the University of Wollongong (ASX Announcement: 8 November 2021), have developed a new formulation of Zantrene that enables peripheral (arm or leg vein) intravenous (IV) delivery to patients. This novel and improved formulation (codename RC220) provides clinicians with an easier to use alternative to the current central line formulation of Zantrene. This formulation has greater market potential and is particularly well suited to solid tumour patients.

Clinical Significance

Administration of Zantrene has until now required the use of an invasive central venous catheter (central or main line) that must be performed in a hospital setting. While this is common practice for the delivery of chemotherapy drugs in patients with leukaemias, it is not optimal for patients with solid tumours (such as breast cancer, melanoma, lung cancer, kidney cancer, etc) where peripheral IV infusion in an outpatient setting is often preferred by both the patient and treating oncologist.

Peripheral IV administration can provide a better quality of life for patients with less pain and lifestyle disruption as it enables patients to be treated outside of a major hospital or within their own homes. The ability to precisely match the required drug dose to the patient's need is also simpler using an IV formulation than with other delivery options, such as fixed size oral dosing. In addition, for uses where low and continuous dosing are desirable (such as inhibiting an enzyme like FTO), a peripheral IV formulation can be a better option.

Commercial Significance

Peripheral IV formulations have significant commercial advantage. As central line administration requires highly skilled healthcare personnel, simpler peripheral IV formulations are attractive in resource constrained healthcare environments. An additional commercial benefit of the new peripheral IV formulation is the ability to deliver Zantrene more rapidly to the patient, minimising occupancy of expensive oncology infusion chairs and providing the patient with a better treatment experience.

A more immediate impact of the RC220 IV formulation is improved patient recruitment potential for future clinical trials. Only a minority of solid tumour patients are willing to participate in clinical trials that require central line infusions. In a competitive oncology trial environment where the patient has many suitable trials to choose between, comfort and quality of life are important non-clinical factors that strongly influence patient choice of trial enrolment.

Next Steps

Race has signed a contract with Societal (San Diego, California, USA) to produce the new RC220 IV formulation to the FDA current Good Manufacturing Practice (cGMP) standard that is required for use in clinical trials. Societal are already familiar with Zantrene as they are the manufacturer of the current central line formulation. The final RC220 drug product is expected to be delivered by late Q2 2023 at a contracted cost of US$611,900.

A new international patent will be submitted in early Q2 2023. Advice from Race's patent attorneys is that the RC220 formulation is both novel and inventive and it should secure international patent protection. Delaying patent submission for as long as possible maximises the effective on-patent life of RC220 and hence its future commercial value.

Collaborative activities are continuing at the University of Wollongong and other sites to develop additional formulations of Zantrene that can be delivered orally and/or less frequently (i.e. longer acting formulations). Race will update investors on the progress of these new formulation activities when completed.

Race CSO Dr Daniel Tillett said: *"The development of the RC220 IV formulation is a major advance for Race. The chemical properties of Zantrene make developing a peripheral formulation highly complex and challenging. I am extremely proud of the Race team and our collaborators in developing the new RC220 formulation and believe this is a pivotal step in bringing the promise of Zantrene to clinical and commercial reality."*

Race CMO Dr David Fuller said: *"The availability of a peripherally administered formulation of Zantrene is a major step forward and will allow Race to more effectively explore multiple opportunities in the solid tumour and cardioprotection space."*

RACE ONCOLOGY

Q & A

What clinical problem does the new RC220 IV Zantrene formulation solve?

Zantrene is very insoluble in the blood. It was discovered early in clinical development that if Zantrene is infused via a peripheral vein it will crystallise and block the flow of blood through the vein. This problem was solved by using a central line catheter to slowly infuse into a large blood vessel near the heart (aorta) over 2 hours, where the high flow of blood diluted the Zantrene before it had a chance to crystallise. While this approach works, it is not ideal for many patients and clinicians.

The new RC220 formulation is able to keep Zantrene from crystallising in the blood even when it is infused into a smaller peripheral arm or leg vein. The RC220 formulation also allows Zantrene to be infused faster improving the patient's treatment experience.

What does this formulation breakthrough mean for Race shareholders?

The RC220 formulation is important for three reasons:

1. It expands the potential market size for Zantrene by making it easier to use in clinical practice, especially with non-leukaemia cancers. The value of any new drug is a function of the market size, the share that can be captured, and the drug price.

2. It makes it easier to recruit patients into our clinical trials, which will reduce the cost and time to complete these trials.

3. It provides valuable and protectable IP that effectively resets the patent clock on Zantrene. This 'improved formulation' approach is widely used in the pharmaceutical industry to protect drugs that have reached the end of life of their original patents. A good example of this in oncology was the development of Abraxane®, a protein bound formulation of paclitaxel (Taxol). This formulation avoided some of the side effects caused by the original Cremophor EL-based formulation. The developers of Abraxane, Abraxis BioScience, were acquired by Celgene in 2009 for US$2.9 billion, 10 times the annual sales of Abraxane at the time[1]. An old drug with an improved formulation can be highly valuable.

1. https://www.reuters.com/article/us-abraxis-takeover-celgene-idUSTRE65T1Z120100630

Why does it take so long to manufacture the new RC220 IV formulation?

The current Good Manufacturing Process for IV drug products is complex with many quality assurance and quality control (QA/QC) steps. New IV drugs must meet very strict controls over the quality, purity, and sterility of the formulation. Once this lengthy process is complete, the stability of the formulated drug in storage needs to be determined. All of these steps involve extensive documentation and cannot be rushed.

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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 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 two clinical trials in Acute Myeloid Leukaemia (AML).

Race is pursuing outsized commercial returns for shareholders via its 'Three Pillar' strategy.

Learn more at https://www.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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