

ASX Announcement

Breast Cancer Clinical Trial Program Initiated

- Clinical research organisation, George Clinical, appointed to progress Race's Phase I/II breast cancer trial program.
- Master Service Agreement will deliver a scoped and costed clinical proposal in 13 weeks.

26 November 2020 - Race Oncology (ASX: RAC) is pleased to announce that it has appointed the clinical research organisation (CRO), George Clinical, to scope and cost a proof-of-concept Phase I/II breast cancer clinical trial of Bisantrene in combination with cyclophosphamide. This program will enable the Race Oncology Board to make a fully informed and costed decision on this important clinical pathway before expending significant shareholder funds.

Bisantrene was the subject of a series of Phase II and III clinical trials in the USA in advanced breast cancer patients in the late 1980s and early 1990s. The Phase III trial showed that Bisantrene had the same efficacy as the standard of care treatment, doxorubicin, but caused significantly less damage to the patient's heart¹. Recent preclinical data from Race and the University of Newcastle's Hunter Medical Research Institute has shown that Bisantrene has additive cytotoxicity when paired with cyclophosphamide, similar to doxorubicin or epirubicin (ASX Release: 24 November 2020).

The first stage of the signed Master Service Agreement (MSA) between Race Oncology and George Clinical has the following key deliverables:

- Establish, support and manage an Australian Clinical Advisory Board (CAB) of Key Opinion Leaders (KOL) in breast cancer clinical research.
- Select suitable Principle Investigators.
- Select qualified trial sites.
- Develop a full clinical protocol under the supervision of the CAB.
- Statistical analysis to ensure a robust trial design.
- Detailed trial costs and timelines.
- Report on the practicability of the trial and any possible regulatory hurdles.

The MSA will start immediately with an estimated completion time of 13 weeks.

Race's CEO, Phillip Lynch commented, *"George Clinical has over 20 years' experience in providing clinical trial services and management. Their highly capable team has the clinical and regulatory experience to ensure our breast cancer clinical trial plans are fully optimised to drive patient and commercial value."*

James Cheong, CEO George Clinical, said, *"George Clinical is very pleased to collaborate with Australian biotech, Race Oncology in their upcoming breast cancer study. We will leverage our unique value proposition that combines scientific expertise with operational excellence and our strength in oncology clinical trials to ensure a successful delivery of this important project."*

1. Cowan, J.D. et al. *Randomized trial of doxorubicin, Bisantrene, and mitoxantrone in advanced breast cancer: a Southwest Oncology Group study*. Journal of the National Cancer Institute, 1991, 83(15), 1077–1084.



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About Race Oncology (RAC: ASX)

Race Oncology (RAC) is a drug development biotech with a Phase II/III cancer drug called bisantrene. RAC has compelling clinical data for Bisantrene in acute myeloid leukaemia (AML) as well as breast and ovarian cancer. RAC is pursuing an exciting '5-Path' clinical development strategy that involves parallel US and Australian clinical trials in AML, breast and ovarian cancer.

About George Clinical

George Clinical is a leading global clinical research organization founded in Asia-Pacific driven by scientific expertise and operational excellence. With 20 years of experience and more than 260 people managing 38 geographical locations throughout the Asia-Pacific region, USA, and Europe, George Clinical provides the full range of clinical trial services to biopharmaceutical, medical device, and diagnostic customers, for all trial phases, registration and post-marketing trials.

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