

ASX Announcement

Race Initiates Extramedullary AML Preclinical Study

- Race enters a collaborative preclinical research program with The University of Newcastle to support the use of Bisantrone in the treatment of extramedullary acute myeloid leukaemia (AML)
- Research designed to support the use of Bisantrone to treat this form of AML with substantial unmet clinical needs
- The work will aid the clinical progress of Bisantrone under Pillar 3 of Race's Three Pillar strategy

30th March 2021 – Race Oncology Limited (“Race”) is pleased to announce that it has entered into a new collaborative preclinical research program with The University of Newcastle. This work will be led by the eminent cancer researcher, Associate Professor Nikki Verrills, who successfully ran Race’s preclinical breast and ovarian program (ASX announcements: 24 November 2020, 23 February 2021, 9 March 2021).

The aim of this project is to support the clinical use of Bisantrone as a novel treatment for extramedullary AML, a difficult to treat form of AML, using an extramedullary mouse model developed by A/Prof Verrills’ team. Extramedullary AML occurs when the leukaemia spreads from the bone marrow and forms solid tumours in tissues such as the skin, breast, kidney, brain, or other organs¹. A 2020 prospective positron imaging trial identified that up to 22% of AML patients have extramedullary AML².

In a recent Sheba Medical Centre Phase II clinical trial conducted in relapsed and refractory (R/R) AML patients (ASX announcement: 16 June 2020), Bisantrone was observed to be highly effective in patients with extramedullary AML, with all patients with this subtype (4/4) showing a clinical response³. Patients with extramedullary AML currently have limited treatment choices with no approved, and very limited experimental treatment options⁴.

Race is pursuing Bisantrone therapies targeting AML, as part of its Three Pillar strategy (ASX announcement: 30 Nov 2020). This new program could lead to AML treatments with improved safety and efficacy for patients with extramedullary AML.

In addition, this study will be used to provide supportive data for a pivotal (Phase II/III) trial of Bisantrone in extramedullary AML patients with the aim of providing a rapid path to FDA approval for Bisantrone as an orphan drug under the 505(b)(2) track. Orphan drug designation provides for seven years post approval marketing exclusivity in the USA and potentially 10 years in the EU/UK, as well as other tax and regulatory benefits.

Chief Scientific Officer, Dr Daniel Tillett said: *“This is a key project for Race using Associate Professor Verrills’ extramedullary AML mouse model. Recent clinical evidence has identified Bisantrone as an effective treatment option for patients with the difficult-to-treat extramedullary*

form of AML. We believe that we have identified a low-risk pathway to rapid approval of Bisantrene via this indication that offers significant upside for Race in a crowded clinical space.”

This project is to start immediately with the pre-clinical results expected to be reported over the coming 12 months.

1. Solh, M., Solomon, S., Morris, L., Holland, K., & Bashey, A. (2016). Extramedullary acute myelogenous leukemia. *Blood Reviews*, 30(5), 333–339.
2. Stölzel, F., Lüer, T., Löck, S., Parmentier, S., Kuithan, F., Kramer, M., et al. (2020). The prevalence of extramedullary acute myeloid leukemia detected by 18FDG-PET/CT: final results from the prospective PETAML trial. *Haematologica*, 105(6), 1552–1558.
3. Canaani, J., Danylesko, I., Shemtov, N., Zlotnick, M., Lozinsky, K., Benjamini, O., et al. (2021). A phase II study of bisantrene in patients with relapsed/refractory acute myeloid leukemia. *European Journal of Haematology*, 106(2), 260–266.
4. Cunningham, I., Hamele Bena, D., Guo, Y., Shiomi, T., Papp, A. C., Chakravarti, B., et al. (2019). Extramedullary leukemia behaving as solid cancer: clinical, histologic, and genetic clues to chemoresistance in organ sites. *American Journal of Hematology*, 94(11), 1200–1207.

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About Associate Professor Nikki Verrills

Since completing her PhD in 2005 on chemotherapy resistance in childhood leukaemia, Associate Professor Verrills was awarded a Peter Doherty Postdoctoral Fellowship from the National Health and Medical Research Council in 2006. In the same year she was the inaugural recipient of a Hunter Medical Research Foundation grant for young cancer researchers. Since then she has established an innovative research lab at the University of Newcastle studying the differences between cancer cells that respond well to drug treatments and those that do not.

Prof Verrills is currently supported by a fellowship from the Australian Research Council and project funding from the National Health and Medical Research Council. She has published over 60 journal articles with an H-index of 24.

About Race Oncology (ASX: RAC)

Race Oncology is an ASX listed precision oncology company with a Phase II/III cancer drug called Bisantrene.

Bisantrene is a potent inhibitor of the Fat mass and obesity associated (FTO) protein. Over-expression of FTO has been shown to be the genetic driver of a diverse range of cancers. Race is exploring the use of Bisantrene as a new therapy for melanoma and clear cell renal cell carcinoma, which are both frequent FTO over-expressing cancers. The Company also has compelling clinical data for the use of Bisantrene as a chemotherapeutic agent with reduced



cardiotoxicity in Acute Myeloid Leukaemia (AML), breast and ovarian cancers and is investigating its use in these areas.

Race is pursuing outsized commercial returns for shareholders via its 'Three Pillar' strategy for the clinical development of Bisantrene.

See more at www.raceoncology.com.

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