

ASX Announcement

Phase II Bisantrene trial data published in *European Journal of Haematology*

- Phase II Bisantrene clinical trial data has been published in the prestigious peer-reviewed
 European Journal of Haematology
- The paper identifies a high response rate in patients with extramedullary AML and also refers to the role that Bisantrene may have in blocking Fat mass and obesity-associated protein (FTO)
- Investigators support additional studies with Bisantrene in high-risk AML patients

10 November 2020 – Race Oncology Limited (ASX: RAC) is pleased to report that the clinical data from the investigator initiated Phase II clinical trial of Bisantrene in relapsed and refractory Acute Myeloid Leukaemia (R/R AML), conducted at Israel's Sheba Medical Centre has been published.

This open label, single agent trial, led by Professor Arnon Nagler, studied patients (n=10) with relapsed or refractory Acute Myeloid Leukaemia (R/R AML) who on average had failed three prior lines of treatment. Bisantrene was found to be well tolerated, and after only a single course of treatment, an overall clinical response rate of 40% was observed (ASX Announcement: June 16 2020).

The paper, entitled "A phase II study of Bisantrene in patients with relapsed/refractory acute myeloid leukemia" by Canaani et al. concludes:

"...bisantrene induced clinical responses in 4 of 10 patients with R/R AML with acceptable toxicity. Bisantrene is somewhat similar to Thiotepa and Treosulfan in that an old drug that is being now revisited gaining a lot of interest especially due to better understanding of its intracellular mechanism of action blocking FTO, a recently discovered key factor in leukomogenesis. Further studies are needed to make evidence-based conclusions regarding the candidate role of bisantrene in AML therapeutics. While interventions targeting FLT3, IDH1, IDH2, and hedgehog signalling provide new hope, traditional cytotoxic chemotherapy retains a critical role in AML patient management. We speculate that bisantrene-based chemotherapy may have its greatest applicability to patients with extramedullary disease given the marked activity here observed with leukemia cutis, chloromas, and CNS disease. Our data reveal a particularly encouraging response in this high-risk population and support additional bisantrene clinical trials in R/R AML patients."

The paper, which has been accepted for publication and has undergone full peer review, is available via the following link:

doi.org/10.1111/ejh.13544

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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 with clinical trials to begin in 2020.

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