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ASX Announcement

Results of Phase 2 of RC110 Bisantrene for AML Published in the *British Journal of Haematology*

- Final results of the Phase 1b/2 trial of RC110 bisantrene in relapsed or refractory acute myeloid leukaemia conducted by investigators at the Sheba Medical Centre, Israel has been published in the *British Journal of Haematology*
- In patients with highly advanced disease, 40% showed a response to RC110 combination treatment (5 complete responses and 1 partial response), surpassing the trial's predefined efficacy goal of at least 3 complete responses
- One patient remains alive and disease free more than 2 years after treatment.

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4 August 2025 – Race Oncology Limited ("Race") is pleased to announce that the investigator-sponsored Phase 1b/2 trial of bisantrene in combination with clofarabine and fludarabine (Bis/Clo/Flu) in relapsed or refractory acute myeloid leukaemia (R/R AML) patients has been published in the prestigious peer-reviewed *British Journal of Haematology* under the title *"Bisantrene in combination with fludarabine and clofarabine as salvage therapy for adult patients with refractory or relapsed acute myeloid leukaemia (AML)—An open-label, phase I/II study"* (doi:10.1111/bjh.70035)[1].

The trial was conducted at the Chaim Sheba Medical Centre in Israel under the supervision of AML key opinion leader Professor Arnon Nagler (clinicaltrials.gov: NCT04989335).

Study Design

An open-label, Phase 1b/2 clinical trial to investigate the intravenous combination of Bis/Clo/Flu (bisantrene (250 mg/m2), clofarabine (60 mg/m2), fludarabine (10 mg/m2)) in adult patients with R/R AML where the Phase 1b lead-in dose escalation stage established the recommended Phase 2 dose (RP2D) of Bis/Clo/Flu and a Phase 2 expansion stage was to determine efficacy and confirm safety of the Bis/Clo/Flu regimen at the RP2D in up to 17 subjects (ASX Announcement: 22 June 2021).

Phase 1b, Dose-Escalation (Lead-in Stage)

A two-cohort dose escalation using a 3 + 3 design where Cohort 1 would test three patients with the Bis/Clo/Flu regimen for four consecutive days. If no dose limiting toxicities (DLTs) occurred in these patients by Day 30 of their first cycle of treatment, a dose escalation to a five-day schedule for Cohort 2 would occur.

Phase 2, Expansion (Efficacy Stage)

Up to 17 patients to be enrolled into a Phase 2 expansion efficacy cohort using a 2-stage Simon design with the first nine patients enrolled and treated with the recommended Phase 2 dose of Bis/Clo/Flu. If none of these patients responded according to the complete response criteria as outlined in the European Leukaemia Net guidelines, the study would be terminated for futility. If at least one patient shows a complete response, eight more patients would be enrolled and treated. If three or more patients treated in the efficacy stage demonstrated a complete response, the null hypothesis of no clinical benefit would be rejected.

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Study Results

As previously disclosed, six of the 15 evaluable patients (40%) in the Phase 2 efficacy stage clinically responded to the Bis/Clo/Flu treatment (five complete responses, one partial response), with three of the clinical responders having active extramedullary disease (ASX Announcement: 6 November 2023). Five of the six treatment-responsive patients were bridged to a potentially curative stem cell transplant within one to three months of receiving treatment. Of the five stem-cell transplanted patients, three have since died: one from graft-versus-host disease at Day 45 after transplant, one from disease relapse four months after transplant, and one from infection at Day 610 after treatment. One patient remains alive and free of disease more than 2 years after Bis/Clo/Flo treatment.

Importantly, the patient complete response rate met the trial's prespecified 2-stage Simon efficacy threshold of 3 or more complete responses.

The interim trial results were presented at the prestigious American Society of Hematology (ASH) 65th Annual Conference held on the 9-12 December 2023 (ASX Announcement: 13 December 2023). This trial's clinical data builds on a prior Phase 2 RC110 bisantrene monotherapy clinical study in patients with R/R AML[2] and together they are highly supportive of future AML clinical studies using bisantrene.

Race Oncology CEO, Dr Daniel Tillett, said: *"I would like to extend my sincere thanks to Professor Nagler and his dedicated team at the Chaim Sheba Medical Centre, who have spent the last 6 years meticulously investigating the utility of bisantrene for patients with relapsed / refractory Acute Myeloid Leukaemia. The Sheba team's dedication and commitment has added to the strong historical evidence of the efficacy of bisantrene in treating patients with AML.*

We extend our gratitude to all patients and their families whose participation make the development of new AML treatments such as bisantrene possible."

References

1. Danylesko, I. *et al.* Bisantrene in combination with fludarabine and clofarabine as salvage therapy for adult patients with refractory or relapsed acute myeloid leukaemia (AML)—An open-label, phase I/II study. *Br. J. Haematol.* (2025) doi:10.1111/bjh.70035.

2. Canaani, J. *et al.* A phase II study of bisantrene in patients with relapsed/refractory acute myeloid leukemia. *Eur. J. Haematol.* (2021) 106, 260–266.

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About Race Oncology (ASX: RAC)

Race Oncology (ASX: RAC) is an ASX-listed clinical stage biopharmaceutical company with a dedicated mission to be at the heart of cancer care.

Race's lead asset, bisantrene, is a small molecule anticancer agent. Bisantrene has a rich and unique clinical history with demonstrated therapeutic benefits in both adult and paediatric patients, a well characterised safety profile, and compelling clinical data demonstrating an anticancer effect and less cardiotoxicity over certain anthracyclines, such as doxorubicin.

Race is advancing a reformulated bisantrene (RC220) to address the high unmet needs of patients across multiple oncology indications, with a clinical focus on anthracycline combinations, where we hope to deliver cardioprotection and enhanced anticancer activity in solid tumours. Race is also exploring RC220 as a low intensity treatment for acute myeloid leukaemia.

Race Oncology has collaborated with Astex, MD Anderson, Sheba City of Health, UNC School of Medicine, University of Wollongong and University of Newcastle, 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 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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