RACE ONCOLOGY

ASX Announcement

Phase 2 Trial of Bisantrene for AML Meets Predetermined Efficacy Criteria

- Phase 1b/2 trial of RC110 bisantrene in relapsed or refractory acute myeloid leukaemia was successfully concluded by the investigators at the Sheba Medical Centre, Israel
- In patients with highly advanced disease, 40% showed a response to bisantrene combination treatment (5 complete responses and 1 partial response), surpassing the trial's predefined efficacy goal of at least 3 complete responses
- Findings strongly support Race's intention to initiate a new Phase 1/2 investigator-sponsored AML trial using RC220 bisantrene.

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30 July 2024 – 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 successfully concluded having achieved its primary endpoint for efficacy. 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 investigating intravenous Bis/Clo/Flu (bisantrene, clofarabine, fludarabine) in cohorts of adult patients with R/R AML using a Simon's 2-stage design: a Phase 1b lead-in dose escalation stage to establish the maximum tolerated dose (MTD) or recommended Phase 2 dose (RP2D) of Bis/Clo/Flu and a Phase 2 expansion stage 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 schema using a 3 + 3 design. Cohort 1 to enrol three patients who will receive the Bis/Clo/Flu regimen for four consecutive days. If no dose limiting toxicities (DLTs) occur in the first three patients by day 30 of their first cycle of treatment, then the dose escalation for Cohort 2 occurs.

Phase 2, Expansion (Efficacy Stage)

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

Study Results

As previously disclosed (ASX Announcement: 6 November 2023), six of the 15 evaluable patients (40%) in the Phase 2 efficacy stage responded to the Bis/Clo/Flu treatment (five complete responses, one partial response), with three of the clinical responders having active extramedullary disease. Five of the six treatment-responsive patients were able to be bridged to a potentially curative stem cell transplant within

one to three months of treatment. Of the five stem-cell transplanted patients, three have since died; one from graft-versus-host disease, one from relapse four months after transplant, and one from infection after two years. The patient complete response rate exceeded 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). It is expected that the final study outcomes will be published in a high impact peer-reviewed international journal later in 2024. This trial's clinical data builds on a prior Phase 2 RC110 bisantrene monotherapy clinical study in patients with R/R AML[1] and together they are highly supportive of future AML clinical studies using bisantrene.

The investigator's intention was to enrol two more participants in the trial, but due to the prevailing security situation in Israel and the achievement of the prespecified efficacy endpoint, it was determined by the researchers to conclude the study.

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 5 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 bisantrene's efficacy in treating patients with AML and has stimulated further clinician interest in taking the drug forward in new AML trials.*

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

Race has plans to support a new Phase 1/2 investigator-sponsored AML clinical study using RC220 bisantrene and will provide an update as soon as all relevant contracts are concluded.

References

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

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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 chemotherapeutic. 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 is investigating the effect of bisantrene on the m6A RNA pathway, following independent research published by the City of Hope identifying bisantrene as a potent inhibitor of FTO (Fat mass and obesity-associated protein). Dysregulation of the m^6A RNA pathway has been described in numerous peer reviewed studies to be a driver of a diverse range of cancers.

Race Oncology has collaborated with Astex, City of Hope, 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 https://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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