ASX Announcement

First Patient Dosed in Phase 1b/2 AML Trial at Chaim Sheba Medical Center, Israel

- **This Phase 1b/2 relapsed/refractory Acute Myeloid Leukaemia (R/R AML) trial will use Zantrene® (bisantrene dihydrochloride) in combination with fludarabine and clofarabine**
- **The treatment of the first patient in this trial is an important step in advancing Zantrene® to approval for use in adult R/R AML**
- **The study is being led by Professor Arnon Nagler of the Chaim Sheba Medical Center, Israel, who previously conducted the Phase 2 single agent Zantrene® R/R AML trial which demonstrated a 40% clinical response**

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09 August 2021 – Race Oncology Limited ("Race") is pleased to announce that the first patient has been dosed in the Phase 1b/2 trial in relapsed/refractory Acute Myeloid Leukaemia (ASX Announcement: 22 June 2021).

This investigator-led trial supervised by Professor Arnon Nagler will use Zantrene® (bisantrene dihydrochloride) in a novel three drug combination which has demonstrated compelling efficacy in pre-clinical studies (ASX Announcement: 10 May 2021). Prof Nagler was the Principal Investigator of the Phase 2 investigator-initiated trial where Zantrene was used as a single agent in R/R AML patients and reported an impressive 40% clinical response rate (ASX Announcement: 16 June 2020).

The trial will run in parallel with a separate Australian Phase 2 trial in patients with extramedullary AML (ASX Announcement: 2 June 2021).

Both trials are key components of Race's Three Pillar strategy.

Relapsed or Refractory Acute Myeloid Leukemia

Primary refractory or relapsed Acute Myeloid Leukemia is associated with poor prognosis and remains a serious therapeutic challenge. Primary refractory AML is defined by the absence of complete remission (CR), manifested by blast count of ≥5% in bone marrow after one or two cycles of intense induction chemotherapy.

Up to 30% of adults with newly diagnosed AML fail to achieve CR after two courses of intensive chemotherapy.

Even when CR is achieved through intense chemotherapy, approximately half of the younger and 80% of the older patients, relapse. In both clinical situations, refractory and/or relapsed AML, active disease remains a major therapeutic challenge despite recent advances in the clinic.

Clinical Trial Design

The trial is an open-label, Phase 1b/2 study of intravenous FluCloZan (Fludarabine, Clofarabine, Zantrene®) in cohorts of up to 12 adult patients with R/R AML with a Phase 1b dose escalation stage to establish the maximum tolerated dose (MTD) or recommended Phase 2 dose of the combined FluCloZan regimen, followed by a Phase 2 expansion stage to determine efficacy and confirm safety of FluCloZan at the recommended Phase 2 dose in up to 17 patients.

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

A two-cohort dose escalation schema using a standard 3 + 3 design will be employed.

Cohort 1 will enroll three patients to receive the FluCloZan regimen for four consecutive days. If no dose limiting toxicities (DLTs) have occurred in the first three patients by day 30 of their first cycle of treatment, then Cohort 2 will receive the treatment for five days (with the extra day representing dose escalation).

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, 9 patients will be enrolled and treated with the recommended Phase 2 dose of FluCloZan as determined in the Phase 1b part of the study. If there are no patient responses in the first nine subjects according to the response criteria outlined in the European Leukemia Net (ELN) guidelines, the study will be terminated for futility. If at least one patient shows a response, eight more patients will be enrolled and treated. If three or more of the patients treated in Stage 2 respond, the null hypothesis of treatment futility can be rejected.

Efficacy assessments will be based on bone marrow examination at a minimum of two time points on Day 21 and on Day 30. A further bone marrow examination may be performed on Day 42 at the investigator's discretion, based on patient's disease and performance status and/or on peripheral blood hematology results during the treatment course and between Day 21 to 42.

Treatment will be terminated upon any sign of progressive/recurrent disease and/or referral to pre-transplant conditioning therapy for (allogeneic) stem cell transplantation.

Patients who do not progress or experience any DLTs may receive a second course of treatment for the same duration as in their first cycle.

All patients will be actively followed-up every three months for a further 12 months following completion treatment for disease free survival (DFS) and overall survival (OS).

Indicative Costs and Timelines

The trial is expected to take 36 to 40 months to complete with full patient recruitment over approximately 18 months. Given the trial is open-label, Race expects that data will be reported at interim points throughout the trial.

Race will pay Chaim Sheba a total fee of USD $668,739 over the study's life. Payments will be made to Chaim Sheba upon reaching key milestones and the total trial cost will depend on the number of patients recruited and other operational variables.

Race CMO Dr David Fuller said: *"We are delighted to see the start of this important clinical project which uses a novel combination approach for relapsed or refractory Acute Myleoid Leukaemia. This study is also an important step in our journey towards approval of Zantrene® in this area of high unmet medical need."*

Race CEO & MD Phillip Lynch said: *"This study led by Professor Nagler who has good experience with Zantrene®, supports the building of additional data in AML in line with our Three pillar strategy plan. We hope to see improved patient outcomes in what has been historically a difficult to treat disease. We plan on using our trademarked name, Zantrene®, in referring to bisantrene dihydrochloride. It's one of our registered trademarks and its protection is enhanced by its ongoing and appropriate use."*

Clinical Trial Summary

Study Title	An Open-label, Phase Ib/II, Two-stage, Study of Zantrene® (Bisantrene) in combination with Fludarabine and Clofarabine as Salvage Therapy for Adult Patients with Relapsed or Refractory Acute Myeloid Leukaemia (AML)
Registration	NCT04989335
Phase of Development	Phase 1b/2
Active Ingredient	Bisantrene dihydrochloride, Fludarabine, Clofarabine (FluCloZan)
Study Description	Phase 1b/2 study of FluCloZan, IV, in cohorts of adult patients with R/R AML using a 2-stage design: a Phase 1b lead-in dose escalation stage to establish the MTD or RP2D of FluCloZan and a Phase 2 expansion stage to determine efficacy and confirm safety of the FluCloZan regimen at the RP2D.
Principal Investigator	Professor Arnon Nagler
Sponsor	Race Oncology
Indication/population	Adult men and women 18 to 65 years of age with relapsed and/ or refractory Acute Myeloid Leukemia (R/R AML) presenting with non-CNS extramedullary disease.
Number of Subjects	Phase 1b: up to 12 patients Phase 2: up to 17 patients in the expansion phase
Study Period	36 – 40 months
Study Design	A two-cohort dose escalation schema using a standard 3 + 3 design will be employed followed by an expansion phase at the RP2D. As the patient population is considered relapsed and/or refractory to existing treatments, a comparator arm will not be used.
Statistical methods	Simon 2 stage design
End Points	Primary Phase 1b Dose Escalation: number of subjects experiencing a DLT in each cohort Phase 2 Expansion: Overall Response Rate (ORR) defined as the proportion of subjects with CR and CRi between Day 30 to Day 42 Secondary: Transplant/allo-HSCT rates (for transplant/allo-HSCT-eligible subjects); Combined CR and CRi and PR response rate; Morphologic leukemia-free state (MLFS); Partial remission (PR); Stable disease (SD); Progressive disease (PD); Relapse; Disease free survival (DFS); Overall survival (OS); Time to next treatment (for transplant/allo-HSCT-ineligible subjects)
Participating Centres	1 Chaim Sheba Medical Center, Tel Hashomer, Israel
Dates	First patient August 6, 2021; Last patient (anticipated): Q3 CY2023

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About Race Oncology (ASX: RAC)

Race Oncology is an ASX listed precision oncology company with a Phase 2/3 cancer drug called Zantrene® (bisantrene dihydrochloride).

Zantrene® is a potent inhibitor of the Fatso/Fat mass and obesity associated (FTO) protein. Overexpression of FTO has been shown to be the genetic driver of a diverse range of cancers. Race is exploring the use of Zantrene® 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 Zantrene® 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 and regulatory approval of Zantrene®.

See more at www.raceoncology.com.

About Professor Nagler

Professor Arnon Nagler MD MSc is Professor of Medicine at The Tel Aviv University, Director of the Division of Hematology at Sheba Medical Center, and Director of the Bone Marrow transplantation and Cord Blood Bank at Sheba Medical Center. In addition, he is the chair of the ALWP (Acute Leukemia Working Party) of the EBMT (European Bone Marrow Transplantation society), co-chair of the Scientific Council of the EBMT and serves on the Editorial Board of several Journals. He is one of the pioneers of the non-myeloablative and reduced intensity/toxicity allogeneic transplantations for malignant and non-malignant disorders. His interests include haematopoietic stem cell transplantation, haematological malignancies, cord blood biology and transplantation and immunotherapy. Prof. Nagler has written numerous original articles, reviews and chapters for peer-review journals in leukaemia field and is the principal investigator for multiple clinical studies including first in-human trials for novel agents, like pidilizumab and BL8040 (CXCR4 antagonist). He has received several awards and has made numerous presentations at all international transplantation and haematology meetings, including ASH, ASBMT/CIBMTR, EBMT and EHA.

Release authorised by:

Phil Lynch, CEO/MD on behalf

of the Race Board of Directors

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