

ASX Announcement

Race Initiates FTO Biomarker Research Collaboration with Chaim Sheba Israel

- Patients from the Phase 1b/2 relapsed/refractory (R/R) Acute Myeloid Leukemia (AML) Zantrene® trial at the Chaim Sheba Medical Center, Israel will be screened for FTO overexpression and related biomarkers
- Research will yield the first human FTO biomarker data from patients treated with Zantrene
- FTO analysis to be supervised by the world-recognised RNA biomarker expert Dr Dan Dominissini.

27 October 2021 – Race Oncology Limited (“Race”) is pleased to announce it has entered into a research collaboration with Dr Dan Dominissini of the Chaim Sheba Medical Center, Israel to analyse clinical patient samples from the ongoing Zantrene® Phase 1b/2 trial in relapsed/refractory Acute Myeloid Leukaemia (R/R AML) for FTO and FTO-related biomarkers (ASX Announcement: 9 August 2021).

The biomarker testing will include FTO gene sequencing, FTO protein levels (intracellular staining and flow cytometry), FTO mRNA levels, and analysis of the m⁶A/A ratio in mRNA from patient tumour samples before, during and after treatment with Zantrene.

Dr Dominissini is a world-renowned expert in RNA methylation and m⁶A RNA methylation and has authored more than 32 publications in high impact peer-reviewed journals including *Nature*, *Science* and *Cell*.

This research collaboration has strategic importance for Race as the data will advance Race’s ‘Three Pillar’ strategy announced at the 2020 AGM (ASX Announcement: 30 November 2020).

Race CSO Dr Daniel Tillett said *“We are delighted to be extending our successful collaboration with the team at Chaim Sheba to generate important data on the effects of Zantrene on FTO and related molecules. These data will give us the first insights into the effect of Zantrene in patients on FTO and m⁶A RNA methylation and continues to advance our Three Pillar Strategy.”*

Dr Dominissini from Chaim Sheba said *“Conceptual and technological breakthroughs since 2011, by our group and others, have introduced the novel notion that internal chemical modifications of mRNA and long non-coding RNA are abundant, dynamic and sometimes reversible events, which constitute essential regulatory elements in RNA metabolism. Dedicated cellular machineries that install (‘writers’), remove (‘erasers’) and recognize (‘readers’) the various RNA modifications have been discovered, revealing essential roles for mRNA and lncRNA modification in various cellular, developmental and disease processes, and providing*

avenues for therapeutic intervention. N6-methyladenosine (m6A) is the most prevalent internal mRNA modification, removed by the enzyme FTO, with established key roles in carcinogenesis. We are excited to see these basic discoveries translated into the clinic by the Zantrene study of Race Oncology for relapsed or refractory AML. We hope that our scientific collaboration will advance the understanding of the correlation between FTO and m6A status in AML and response to treatment."

Relapsed or Refractory Acute Myeloid Leukemia

Primary refractory or relapsed acute myeloid leukemia is associated with poor prognosis and remains a major therapeutic challenge. Primary refractory AML is defined by the absence of complete remission (CR), manifested by blast count of $\geq 5\%$ 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 patient's relapse. In both clinical situations, refractory and/or relapsed AML, active disease remains a major therapeutic challenge despite recent advances.

Study Design

Samples will be taken from patients participating in the existing study, "An open-label, Phase 1b/2 study of intravenous FluCloZan (fludarabine, clofarabine, Zantrene (bisantrene dihydrochloride))" 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 FluCloZan and a Phase 2 expansion stage to determine efficacy and confirm safety of the FluCloXan regimen at the RP2D in up to 17 subjects.

-ENDS-

About Race Oncology (ASX: RAC)

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

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 of Zantrene.

Learn more at www.raceoncology.com.

Release authorised by:

Phil Lynch, CEO/MD on behalf
of the Race Board of Directors
phillip.lynch@raceoncology.com

Media contact:

Jane Lowe
+61 411 117 774
jane.lowe@irdepartment.com.au