

ASX Announcement

Race Oncology Announces Supply Agreement With Astex Pharmaceuticals for ASTX727 (Oral Decitabine and Cedazuridine) for Extramedullary AML & MDS Trial

- The agreement provides ASTX727 (oral decitabine and cedazuridine) for the RAC-006 clinical trial of Zantrene® for the treatment of patients with extramedullary AML and high risk MDS
- RAC-006 is the first clinical trial in the world to investigate the targeting of Fatso/Fat mass and obesity associated (FTO) protein as a potential cancer treatment.

30 March 2022 – Race Oncology Limited (“Race”) is pleased to announce that it has signed a clinical trial collaboration and supply agreement with Astex Pharmaceuticals, Inc (“Astex”), a subsidiary of Otsuka Pharmaceutical of Japan, to supply ASTX727 (oral decitabine and cedazuridine) for Race’s extramedullary acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS) study RAC-006.

Zantrene® (bisantrene dihydrochloride) 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 including AML. Race has generated pre-clinical data indicating that dosing Zantrene in combination with decitabine showed significantly greater cell killing across a genetically diverse panel of AML cell lines than either drug on its own (synergy).

ASTX727 is an orally administered, fixed-dose combination of the approved anti-cancer DNA hypomethylating agent, decitabine, together with cedazuridine, an inhibitor of cytidine deaminase (CDA). By inhibiting CDA in the gut and the liver, ASTX727 is designed to allow for oral delivery of decitabine and is given daily for five days in a 28-day cycle.

Under the terms of the agreement Astex Pharmaceuticals will provide ASTX727 free of charge to Race and include initial shipment of ASTX727 to nominated supply depots for use in Australia, Italy, Spain, Germany and the USA. Additional countries may be included, subject to agreement with Astex.

Race and Astex will also enter into a separate safety data exchange agreement (“SDEA”) to facilitate pharmacovigilance reporting requirements.

Race Chief Executive Officer, Mr Phillip Lynch said, “We are pleased to enter into this important collaboration with Astex and wish to thank them for their interest and support of this clinical trial targeting FTO using the novel combination of ASTX727 and low dose bisantrene in AML and high risk MDS patients unfit for high intensity chemotherapy.”

RAC-006 Clinical Trial Design

This open label Phase 2 trial will recruit up to 60 patients with ¹⁸F-FDG PET/CT imaging-identified extramedullary AML at 10 clinical sites using a two-stratum (arm) design. The first stratum will utilise Zantrene as a high dose, single agent, treatment over 7 days in patients with extramedullary AML who are able to tolerate high intensity chemotherapy, followed by one or more cycles of consolidation treatment of Zantrene in combination with Ara-C, a standard of care drug.

The second stratum will use Zantrene as a low dose FTO-targeted agent in combination with the oral hypomethylating agent ASTX727, for MDS/AML patients unwilling or unable to tolerate high intensity chemotherapy.

The primary endpoint will be complete response (CR) and complete response with incomplete haematological recovery (CRi) with an aim of bridging to an allogeneic hematopoietic stem cell transplant (Stratum 1), or safety and tolerability (Stratum 2). Key secondary endpoints include safety and tolerability of Zantrene in combination with Ara-C or ASTX727, overall and event-free survival, and FTO expression or other biomarkers with response to treatment.

-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.

In breakthrough preclinical research, Race has also discovered that Zantrene protects from anthracycline-induced heart damage, while in tandem acting with anthracyclines and proteasome inhibitors to improve their ability to target breast cancer. Race is evaluating this discovery.

The Company also has compelling clinical data for Zantrene as a chemotherapeutic agent and is in clinical trial in Acute Myeloid Leukaemia (AML).

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

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