ASX Announcement

Race Receives Positive Guidance on Zantrene via Pre-IND Meeting with US FDA

- **Race Oncology has received positive feedback and guidance from the US FDA regarding Zantrene and its clinical plans**
- **FDA has indicated the clinical hold issues raised with Race's previous IND submitted in 2019 have been satisfactorily addressed**
- **FDA guidance provides a viable path for the clinical advancement of Zantrene in the US.**

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23 November 2022 – Race Oncology Limited ("Race") is pleased to announce that it has received confidential and constructive guidance by way of a pre-Investigational New Drug (pre-IND) meeting with the US Food and Drug Administration (FDA) for Zantrene (bisantrene dihydrochloride). Race submitted a pre-IND meeting package to the FDA in September 2022, which included a summary of the preclinical and clinical data for Zantrene, an overview of the proposed clinical development plan, and specific questions on the requirements to open an Investigational New Drug (IND) application.

Opening an IND is a requirement before undertaking clinical trials in the United States and is a key step in the process of obtaining a New Drug Application (NDA) and marketing approval for a new drug. In written correspondence, the FDA provided insightful and helpful feedback on the proposed clinical development plan for Zantrene and acknowledged that Acute Myeloid Leukemia (AML) continues to have significant unmet clinical needs which require new treatment solutions.

Importantly, the FDA agreed that Race had adequately addressed outstanding clinical hold issues from an earlier IND application submitted in 2019 (ASX announcement: 25 April 2019). Under current US regulations, if the FDA does not place a clinical hold within 30 days of an IND submission the trial can proceed.

The FDA also confirmed that the FDA505(b)(2) application pathway is a possible regulatory pathway for Zantrene, whereby some of the data from studies completed on Zantrene in the public domain can contribute to the full regulatory package required for a New Drug Application (NDA). The FDA provided guidance on the data requirements for opening an IND for Zantrene, including helpful counsel related to the AML patient populations that should be studied.

While Race has no current plans to undertake any clinical trials in the US, receiving timely guidance from the FDA provides valuable commercial optionality as Race's clinical activities and partnership discussions continue to advance.

Race Oncology Chief Scientific Officer, Dr Daniel Tillett said: *"The clear guidance the FDA has provided Race on the regulatory requirements needed to undertake future clinical trials of Zantrene in the US is highly encouraging. While we are not planning on running clinical trials in the US in the short to medium term, having the option to run US trials, when appropriate, is extremely valuable."*

Race Oncology Chief Executive Officer, Phil Lynch said: *"As Race becomes increasingly clinical in its operations, FDA guidance is invaluable to ensuring our readiness, and to having the necessary optionality, when we seek to pursue our USA based clinical plans."*

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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®.

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 cancer.

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.

Learn more at www.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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