24 April 2019

ASX Announcement

Bisantrene IND Update

24 April 2019: Race Oncology Limited ('Race') advised today that its IND (Investigational New Drug application) for the Bisantrene Phase 2/3 clinical trial is now on a clinical hold with the FDA, pending resolution of outstanding FDA questions.

This means the trial cannot start until outstanding FDA questions are resolved.

"As we have previously stated, the trial cannot start until we have funding from a licensing partner, so the clinical hold has no immediate impact on timing of the trial," said Race CEO, Peter Molloy. "In the meantime, the feedback from the FDA has been very helpful in understanding what is needed to prepare the trial for execution, when we are ready to do so."

Questions and feedback from the FDA covered a range of topics, including safety, pharmacology, manufacturing and the trial protocol.

"We were able to answer many of the FDA's questions during the IND review period," said Mr Molloy. "We now have time to attend to the outstanding questions."

As announced on 25 March 2019, because of the size and scope of the IND dossier for Bisantrene, the Company expected the discussions with the FDA to extend beyond the normal 30-day review period for an IND.

"The questions from the FDA are normal and to be expected in an IND like this," said Professor Borje Andersson, Race's scientific advisor. "One important area for discussion with the FDA is the clinical protocol design and we look forward to working with the FDA to ensure the trial design is optimal for registration of Bisantrene."

"The existing clinical data on Bisantrene are very strong and demonstrate not only efficacy but also unparalleled cardiac safety," added Prof. Andersson. "This is a drug that has a clear role in AML and I sincerely hope we will see it available for use in treating this disease, in both adults and children."

About Professor Borje Andersson

Borje S. Andersson is Professor, Department of Stem Cell Transplantation in the Division of Cancer Medicine at University of Texas MD Anderson Cancer Center in Houston, Texas and Director of the Department's program for Molecular Pharmacology and Translational Drug Development. He is also Adjunct Professor, University of Houston College of Pharmacy in Houston. He received his medical degree from Karolinska Institute Faculty of Medicine and is board-certified in medical oncology, internal medicine and haematology. He has been an active researcher in the leukaemia field and his recent research has focused on the development of less toxic and more efficacious pre-transplant conditioning therapies, and improving the understanding of leukaemic cell resistance to bifunctional DNA-alkylating agents.

About Race Oncology (RAC.ASX)

Race Oncology is a specialty pharmaceutical company whose business model is to pursue later-stage drug assets in the cancer field that have been overlooked by big pharma. The company's first asset is Bisantrene, a chemotherapy drug, which was the subject of more than 40 clinical studies during the 1980s and 1990s before the drug was abandoned after a series of pharmaceutical mergers. Race is seeking to gain US FDA approval for Bisantrene for AML under the accelerated 505(b)(2) regulatory pathway.

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