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25 July 2019

ASX Announcement

First patient treated in Bisantrene trial in Israel

25 July 2019: Race Oncology Limited ('Race') announced that the first patient has been treated with Race's cancer drug, Bisantrene, in the trial at the Sheba Medical Center in Israel ("Sheba").

The trial agreement with Sheba was announced by Race on 14 May 2019. Today, Race was advised by Sheba that the first relapsed/refractory AML patient had been recruited into the trial and completed their seven-day course of treatment with Bisantrene, without any major complications.

"This is a major milestone for Race, because it's the first treatment with Bisantrene since the drug disappeared more than 25 years ago," said Race Oncology CEO, Peter Molloy.

"We sincerely hope that the treatment will assist this patient and those that follow in this important clinical trial," said Race's Chief Medical Officer, Dr Samar Al-Behaisi. "I am excited that Bisantrene is finding real clinical use again after such a long dormancy."

The trial protocol calls for the recruitment of up to 12 patients with relapsed/refractory AML over 12 months. Under the terms of the Israel Ministry of Health's approval for the trial and the agreement between Race and Sheba, there are limitations on reporting of trial results while the trial is in progress. Race indicated that it will advise the market of trial outcomes as these are provided by Sheba and agreed for release.

About the Trial

The trial, led by Professor Arnon Nagler, is titled "Bisantrene for relapsed/refractory acute myelogenous leukemia (AML)". The primary objective of the Phase II trial will be to generate clinical remissions (CR) in patients with AML, who are resistant to other therapy (refractory), have relapsed after previous therapy, or cannot receive further anthracycline treatment. The trial is expected to recruit 12 adult subjects over 12 months and report CR and a range of secondary endpoints, including leukaemia free survival (LFS) and overall survival (OS). All patients are expected to receive Bisantrene 250mg/m^2/day for 7 days, in conjunction with conventional supportive care. In the event of a CR, patients will receive a 3-day consolidation course of Bisantrene also at 250mg/m^2/day.

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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. Bisantrene has compelling Phase II data in acute myeloid leukaemia (AML) and Race is seeking to gain US FDA approval for Bisantrene for AML under the accelerated 505(b)(2) regulatory pathway. Bisantrene is the subject of two recently granted US patents and has been awarded US Orphan Drug designation and a Rare Paediatric Disease designation.

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