14 May 2019

ASX Announcement

Bisantrene investigator-initiated AML trial to start in Israel

Highlights

- **Bisantrene to be used in AML patients for the first time in 25 years**
- **Trial led by high-profile international haematologist**
- **Recruitment and results expected over next 12 months**

14 May 2019: Race Oncology Limited ('Race') is pleased to announce that it has signed an agreement to conduct a trial of Race's cancer drug, Bisantrene, at the Sheba Medical Center in Israel.

The trial has been approved by the Israeli Ministry of Health and the hospital's Research Ethics Committee, so the expectation is that the trial can start immediately.

"This is a major development, as it's the first use of Bisantrene in patients since the drug disappeared more than 25 years ago," said Race Oncology CEO, Peter Molloy.

Bisantrene was lost after a series of mergers in the early 1990s, despite its potential as a treatment for AML. Race has rescued Bisantrene and is developing it for treating relapsed or refractory AML. Race has submitted an IND to conduct a US registration trial. Race is also pursuing investigator-initiated Phase II trials, such as this one at Sheba Medical Center.

The Sheba Medical Center trial, in 12 patients with relapsed/refractory AML, will be led by Professor Arnon Nagler as the principal investigator. Professor Nagler is a highly-regarded international leader in the leukaemia field (see 'About Professor Nagler').

"It's a testament to Bisantrene's contemporary potential in AML that an international leader of Professor Nagler's stature has decided to do this trial," said Mr Molloy.

"I am excited about the potential for Bisantrene in our leukaemic patients in whom the disease is unresponsive and have very few alternatives," said Professor Nagler. "A number of new targeted agents have become available, but these are only useful in the small percentage of patients who have specific, identifiable mutations," he added.

About the Trial

The trial 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.

About the Agreement

The trial agreement ("Agreement") is between Race Oncology Ltd ("Race"), The Sheba Fund for Health Services and Research ("Sheba"), and Professor Arnon Nagler ("Investigator"). The Agreement commenced on 14 May 2019 and continues until the trial is completed, which is expected to be no later than 1 December 2021. Under the agreement, Race is obliged to provide Bisantrene at no cost to Sheba and the Investigator, and to provide a grant to Sheba of €78,975 to support the trial. Race is also obliged to provide clinical trial insurance, which was arranged by Race prior to signing the agreement. All trial results will be jointly owned by Race and Sheba, and Race has the right to publish headline study results and to use the results in support of any regulatory submission for Bisantrene.

About Professor Nagler

Professor Arnon Nagler MD MSc is Professor of Medicine at The Tel Aviv University, Director of the Division of Hematology at Sheba Medical Center, and Director of the Bone Marrow transplantation and Cord Blood Bank at Sheba Medical Center. In addition, he is the chair of the ALWP (Acute Leukemia Working Party) of the EBMT (European Bone Marrow Transplantation society), co-chair of the Scientific Council of the EBMT and serves on the Editorial Board of several Journals. He is one of the pioneers of the non-myeloablative and reduced intensity/toxicity allogeneic transplantations for malignant and non-malignant disorders. His interests include haematopoietic stem cell transplantation, haematological malignancies, cord blood biology and transplantation and immunotherapy. Prof. Nagler has written numerous original articles, reviews and chapters for peer-review journals in leukaemia field and is the principal investigator for a multiple clinical studies including first-in-human trials for novel agents, like pidilizumab and BL8040 (CXCR4 antagonist). He has received several awards and has made numerous presentations at all international transplantation and haematology meetings, including ASH, ASBMT/CIBMTR, EBMT and EHA.

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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