



5 June 2018

ASX Announcement / Media Release

## Race cancer drug success in AML reported by French doctors

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### HIGHLIGHTS

- Case report: two girls with relapsed AML successfully treated with Bisantrene.
- Bisantrene described as “a novel chemotherapy lost to development, with potential benefits over classical anthracyclines.”
- “These findings support renewed investigation of Bisantrene in AML.”
- Bisantrene is “therapeutically active, with a unique safety profile that is particularly appropriate for the treatment of paediatric AML.”

**Tuesday 5 June 2018: Race Oncology Limited (“RAC”)** is pleased to announce a case report describing the successful use of Bisantrene to treat childhood relapsed/refractory AML (Acute Myeloid Leukaemia). The report will be published at a forthcoming oncology conference in France.

The case report describes two girls in France who were successfully treated with Bisantrene in 1984 and 1991. Both remain alive today.

“One of the girls was seven years old when diagnosed with AML in 1984,” said Race CEO, Peter Molloy. “She had relapsed after multiple lines of standard chemotherapy and was treated with one 7-day course of Bisantrene, followed by other chemotherapy.”

“She had a complete response to the treatment, which allowed her to receive a bone marrow transplant. As a result, she’s alive today and the mother of three children,” said Mr Molloy.

The other girl was 13 years old when diagnosed in 1990 and also had relapsed after multiple lines of standard chemotherapy. In 1991, she received Bisantrene treatment in combination with two standard chemotherapy agents.

“She also had a complete response, which allowed her to receive a bone marrow graft,” said Mr Molloy. “Thankfully, she is still alive today and has a three-year old child.”

The authors of the case study report are Prof. Guy Leverger, a leading French haematology-oncologist from the Armand Trousseau children’s hospital in Paris, and Prof. Yves Bertrand, also a leading haematology-oncologist, from the Institute of Paediatric Hemato-Oncology in Lyon.



Both doctors were involved in the original Bisantrene studies in France, which were published in the 1980s and 1990s and which contributed to the French marketing approval for Bisantrene.

Prof. Leverger said the findings support renewed investigation of Bisantrene in AML:

“The long-term follow-up with these two salvage paediatric patients I treated decades ago provides interesting insight into a novel chemotherapy lost to development, and with potential benefits over classical anthracyclines,” said Prof. Leverger.

Bisantrene was the subject of more than 40 Phase II clinical studies and showed much promise in AML. However, it was lost in a series of Big Pharma mergers during the 1990s. Race is actively executing a plan to revive Bisantrene and get it approved for sale by the FDA for treatment of AML, including undertaking a pivotal clinical trial.

The case report by the French doctors will be presented as a poster at the International Conference on Leukaemia and Hematologic Oncology in Paris on 21 June 2018.

The poster is titled: “Long-term Survival Case Reports of Two Paediatric Relapsed or Refractory Acute Myeloid Leukaemia Patients Treated with Bisantrene Combination Therapy.”

The report concludes: “Published efficacy results from prior salvage studies of bisantrene in adult and paediatric AML and the long-term case reports presented here, support a renewed interest in its clinical development. Bisantrene is therapeutically active, with a unique safety profile that is particularly appropriate for the treatment of paediatric AML.”

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### **About Bisantrene**

Bisantrene is a small-molecule chemotherapy drug related to the anthracyclines, the most frequently prescribed cancer drugs and first line of treatment for many cancers, but has been shown to have greatly reduced cardiac toxicity. Bisantrene was tested in more than 40 clinical studies before it was lost in a series of pharmaceutical mergers in the 1990s. The initial clinical opportunity for Bisantrene is for relapsed/refractory AML patients. Race owns two patents on the drug, both of which have received notice of allowance in the US, and has been granted an Orphan Drug Designation in the US for AML, which confers seven years of market exclusivity in US from date of FDA approval.

### **About Race Oncology (RAC.ASX)**

Race Oncology is a specialty pharmaceutical company that listed on the Australian Securities Exchange (ASX) in July 2016. Race’s 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 that was the subject of more than 40 phase II clinical studies during the 1980s and 1990s, then lost in a series of big pharma mergers.

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