



ASX AND MEDIA RELEASE

Race Oncology responds to frequently asked questions from shareholders

20 July 2016, Perth, Australia: Race Oncology Limited (ASX: RAC) today released a documents titled: *'Frequently Asked Questions about Race Oncology'* to clarify the Company's plans and prospects for shareholders. The information will also be available on the Company's website.

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About Race Oncology

Race Oncology is a specialty pharmaceutical company, whose business model is to pursue later stage assets, principally in the cancer field. The Company's first important asset is a chemotherapy drug, called Bisantrone, which was the subject of more than 40 phase II clinical studies during the 1980s and 1990s. Race Oncology owns recent patent filings on Bisantrone and has secured Orphan Drug Designation in the US. The Company's goal is to complete final development of Bisantrone and bring this valuable cancer drug to market.

Frequently Asked Questions about Race Oncology

Q. Is Race Oncology a 'biotech' company?

No. Race Oncology can best be described a 'specialty pharmaceutical company' that seeks late stage drug assets that have been overlooked or shelved by large pharmaceutical companies, but which can be revitalised and brought to market quickly to generate revenues. Bisantrene is Race Oncology's first drug asset and the Company will consider expanding its portfolio in the future.

In contrast, drug development biotech companies are generally focused on early stage drug development programs that require substantial investments over many years and carry high risk. The time to market and risk/cost profile for Race Oncology is significantly different to such companies.

Q. How was Bisantrene 'lost'?

Bisantrene was developed in the 1980s, showed great promise in Acute Myeloid Leukaemia (AML) in 5 phase 2 studies, was approved in France for AML in 1990, and then disappeared after a series of big pharma mergers. Perhaps it was simply lost in the merger processes or perhaps it was shelved after one or more mergers because AML was considered such a small market that it would never generate blockbuster sales. Whatever the case, the Company believes that the opportunity for Bisantrene in AML is as attractive today as it was when the drug disappeared.

Q. Bisantrene is an old drug; why pursue it now, when so many new cancer drugs are coming through?

None of the new drugs seem to be the answer for AML. At the recent ASCO (American Society for Clinical Oncology) conference in Chicago (3-7 June 2016), leading oncologists in the AML field reported that the new immunotherapy and other targeted drugs have made no real headway with AML, partly because of the genetic and molecular heterogeneity of the disease, which makes AML a 'moving target'. As a result, the treatment of AML has not changed in 30 years and AML remains essentially incurable once the standard of care (SOC) fails. The SOC for AML involves chemotherapy for 7 days (a combination of cytarabine and daunorubicin); in certain cases and where a suitable donor exists, this may be followed by bone marrow transplant. In many cases, patients respond to the SOC, but then relapse, after which they have few, if any, treatment options. Bisantrene becomes an option in those cases, because of its lack of cross-resistance with other chemotherapy drugs and proven efficacy in AML.

Q. If it's so good, why won't it become first line therapy for AML?

To date, Bisantrene has not been tested as a first-line therapy for AML, only relapsed/refractory (r/r) AML. Further, the SOC is so well established that Bisantrene is unlikely to be adopted as a first line treatment for AML in the near term. In the meantime, however, there is a clear opportunity for Bisantrene in r/r AML.

Q. How much was invested in Bisantrene before the drug was lost or shelved?

There are more than 40 published phase 2 studies on Bisantrene, covering more than 2,000 patients, to assess its efficacy and safety in a range of cancers, including AML. Based on a recent estimate of the per-patient cost for oncology clinical studies at US\$60,000¹ it is likely that if those studies were conducted today, the cost would exceed \$100million. By obtaining new patents on Bisantrene and FDA Orphan Drug Designation, Race Oncology has become the beneficiary of the historical R&D investment in Bisantrene.

Q. How secure is the Bisantrene IP?

The two Bisantrene international patent applications are owned by Race Oncology following their legal transfer from Update Pharma Inc., the US company that filed them. In addition, Race Oncology has inherited the FDA Orphan Drug Designation on Bisantrene, which confers 7 years of in-market exclusivity on Bisantrene in AML, once it is registered in the US. During the current year, the Company intends to apply for Orphan Drug Designation in Europe as well, which would provide 10 years of in-market exclusivity across Europe.

Q. What are Race Oncology's near-term goals?

The Company's overall development goal in the next year is to file an IND (Investigational New Drug application) with the FDA, and gain the FDA's assent to complete the development of Bisantrene under 505(b)(2). This means that the FDA would allow Race Oncology to use and apply all the available historical clinical and other data on Bisantrene and thereby not have to repeat those studies. This would allow Race Oncology to essentially pick up Bisantrene where Lederle left off, and move forward with final clinical development towards FDA approval.

In parallel and regardless, the Company is preparing to launch Bisantrene in up to four European countries during 2017/18, under a Named Patient Program (NPP). The Company is currently in discussions with several European NPP partners that specialise in facilitating and operating NPP sales programs in those European markets where it is legal to sell orphan drugs that are not yet approved elsewhere in the world – these include France, Italy, Finland and Turkey.

Q. Does Race Oncology have enough cash to achieve its immediate goals?

The Company has enough funds to cover its budgeted expenses for up to 18 months.

¹ "Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies" (2013). Report by Battelle Technology Partnership Practice for PhRMA.