18 July 2018

ASX Announcement

Bisantrene receives 'Rare Paediatric Disease' designation from FDA

HIGHLIGHTS

- FDA grants Rare Paediatric Disease designation for Bisantrene in childhood AML
- Qualifies Bisantrene for potential award of Priority Review Voucher

Wednesday 18 July, 2018: Race Oncology Limited ('RAC') is pleased to announce that it has received a letter from the FDA advising that Bisantrene has been granted Rare Paediatric Disease (RPD) designation for treatment of childhood Acute Myeloid Leukaemia (AML).

The RPD designation means Bisantrene has the opportunity to be awarded a *Priority Review Voucher* (PRV) from the FDA at the time of marketing approval for the designated indication. A PRV grants the holder an accelerated 6-month review of a drug application by the FDA.

To be awarded the PRV, Race will need to conduct a clinical trial in the designated indication (childhood leukaemia) under a US IND (Investigational New Drug) application. The protocol, including the type and number of subjects, endpoint(s) and other parameters, will need to be agreed with the FDA, and the trial results will need to meet the agreed endpoint(s). The commencement date, duration, size and cost of the trial will not be precisely known until the Company has further discussions with the FDA. Upon approval of Bisantrene for the designated indication, the PRV may be awarded by the FDA, but there is no guarantee of the award.

Once awarded, a PRV can be sold to another pharmaceutical company for use with another drug and indication. The accelerated review conferred by the PRV can have very substantial value to some companies and accordingly there is an active secondary market for PRVs. Since 2016, PRVs have been selling in the range of US$110-130 million each (approx. A$150-175 million). More information on the PRV system including secondary market sale prices is available at: http://priorityreviewvoucher.org/

"This is a game-changing outcome for Race that adds substantial value to the Company," said Race CEO, Peter Molloy.

"We already have clear evidence of efficacy in paediatric AML," said Mr Molloy, referring to the case reports of two French girls who were successfully treated with Bisantrene during the 1980s and 1990s (see ASX releases of 4 June and 26 June 2018).

"To date, we have focused our clinical development plan on adult AML, which is the largest population of AML patients," said Race CEO, Peter Molloy. "Now, in parallel to the adult program, we plan to expedite a paediatric program directed towards securing the PRV."

The value of the PRV is entirely independent and in addition to the value for Bisantrene as a treatment for AML. Race indicated that its current intention is to sell the PRV if awarded.

"Selling the PRV does not affect the overall value of Bisantrene," said Mr Molloy. "Bisantrene could still be launched, licensed or sold as a treatment for adult and paediatric AML, without any significant diminution of its value as a result of the PRV transaction."

The RPD designation was granted in response to a submission from Race, which argued that childhood AML can be considered a substantively different disease to adult AML based on genetic markers disproportionately found in childhood AML and therefore that it constituted a "rare paediatric disease".

The FDA agreed, stating that based on the Company's submission, Bisantrene meets the requirements for a treatment that indication. Race's submission included historical clinical efficacy and safety data on Bisantrene in childhood AML.

"Apart from the potential value of the PRV, the FDA designation is important affirmation of the potential clinical value of Bisantrene," said Mr Molloy.

About Bisantrene

Bisantrene is a chemotherapy drug that was tested in more than 40 clinical studies before it was lost in a series of pharmaceutical mergers in the 1990s. Race is rediscovering and rescuing Bisantrene and the initial clinical opportunity is for treatment of relapsed/refractory AML. Race owns two recent patents on the drug, both of which have been granted in the US. Bisantrene has also 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; and Rare Paediatric Disease designation in the US, which could lead to a valuable Priority Review Voucher.

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. Race has successfully manufactured Bisantrene and is seeking to complete the development necessary to gain FDA approval, while also making the drug available as an unlicensed medication under named patient programs outside the US.

Media contact:

Heidi Cuthbert
+61 411 272 366
E: heidi.cuthbert@multiplier.com.au