17 September 2018

ASX Announcement

Race signs agreement with NSF Health Sciences to file IND

17 September 2018: Race Oncology Limited ('RAC') is pleased to announce it has executed an agreement with Washington D.C.-based advisory firm, NSF Health Sciences, to facilitate its IND[1] filing in the US for leukaemia drug Bisantrene.

Under the agreement, NSF Health Sciences ("NSF") will prepare, review, and submit Race Oncology's IND in support of Bisantrene's further clinical development.

This will involve incorporating pre-IND and Type C meeting comments from the FDA, assembling the non-clinical and clinical modules for the IND from previous clinical studies and published literature, in addition to incorporating the proposed clinical trial protocol and investigator's brochure. The contracted cost of the NSF program to file the IND is USD69,900.

NSF also will act as the US Agent for Race Oncology with the FDA, serving as Race's interface with the FDA regarding agency correspondence, IND amendments, protocol amendments, pharmacovigilance and other reporting.

Assuming the IND is accepted by the FDA, it will allow Race to conduct its pivotal trial, which is a key step towards US marketing approval of Bisantrene for the treatment of relapsed/refractory Acute Myeloid Leukaemia (AML).

"The IND will be an important milestone for Race," said Race CEO, Peter Molloy. "NSF will help us successfully navigate the process and prepare Race to start the adult registration trial in the second half of 2019."

To achieve this, allowing time for FDA discussion on the protocol, the IND would need be filed by the end of Q1 2019.

Once the IND is accepted by the FDA, Race can also submit a clinical trial protocol to conduct a rare childhood AML study under its recently-announced 'Rare Paediatric Disease' designation. If successful, this could lead to a valuable and saleable Priority Review Voucher (PRV).

[1] Investigational New Drug application with FDA

"Race has three important and largely independent value domains: FDA approval for adult AML, a potential PRV after a smaller paediatric study, and revenues from Named Patient Programs outside the US," said Mr Molloy. "NSF will help us add value on two of these important fronts."

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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.

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