25 March 2019

ASX Announcement

Race files Bisantrene IND with FDA

25 March 2019: Race Oncology Limited ('RAC') announced today that it had filed its IND (Investigational New Drug application) for Bisantrene and received receipt from the FDA confirming qualification of the file for submission. Race had previously advised the market of a target filing date of 31 March 2019.

"This is a major milestone in the approval pathway for Bisantrene," said Race CEO, Peter Molloy.

The IND is the core regulatory document that will allow Race to undertake a registration clinical trial of Bisantrene in the treatment of adult AML (Acute Myeloid Leukaemia). Once successfully completed, that trial could allow Bisantrene to be approved in the US.

"The filing of the IND definitively brands Bisantrene as a Phase III asset," said Mr Molloy.

A standard IND is subject to a 30-day review period by the FDA, after which the proposed trial can proceed, if the FDA has no questions. Because of the large size and scope of the Bisantrene dossier, Race believes that FDA will have a number of questions and that the Q&A process will likely push the start of the trial into the second half of 2019.

"This is in line with our timetable for the adult AML trial, which in any case, is subject to our securing funding for the trial, potentially from a licensing partner," said Mr Molloy.

One reason for more extensive discussions with the FDA in this case, is the size of the IND. Most INDs are filed prior to commencement of human trials and tend to be relatively small dossiers that are supplemented progressively as new data emerges.

Because Bisantrene is entering the clinical and regulatory process at Phase III, the IND comprises the entire history of Bisantrene's preclinical and clinical development, along with Phase III quality manufacturing and other data.

As a result, the IND is around 2,000 pages long, including references and attachments. It also includes hundreds of pages presenting the pre-clinical data on Bisantrene and its extensive clinical history, with 1,800 treated patients.

"Compiling this IND has been a massive undertaking over more than six months, involving all Race personnel and NSF Health Sciences, our US regulatory consultants," said Mr Molloy.

The IND dossier also includes approximately around 200 pages of new chemistry, manufacturing and quality control (CMC) data, which has all been generated by Race over the last three years.

"Overall, this was the most complex and detailed IND I have ever been a part of," said Dr Daniel Levy, Race's CMC consultant on the project. "We had to create from scratch an entire CMC package to Phase III standards."

In addition to underpinning the adult AML approval of Bisantrene, the IND will be the core regulatory document and springboard for Race's planned trial in paediatric AML. Race has received a Rare Paediatric Disease designation for Bisantrene from the FDA, and upon a successful paediatric trial, could receive a valuable and saleable 'Priority Review Voucher' (PRV). The Company is now in advanced discussions around the funding and conduct of the paediatric trial.

"Apart from supporting the adult and paediatric registration programs, the IND is the ultimate technical dossier for use in licensing discussions," added Mr Molloy. The Company announced in November 2018 that it had appointed Biosynergy Partners LLC to pursue licensing deals for Bisantrene.

"This IND is the culmination of nearly three years of work and manufacturing and regulatory investment at Race, and now, it provides the launching pad for all our value creating programs," said Mr Molloy.

"I regard this IND as our most important achievement to date," added Mr Molloy.

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.

Media contact:

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