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ASX Announcement / Media Release

Race Oncology produces first batch of Bisantrene

HIGHLIGHTS

- **Cancer drug Bisantrene comes off the production line in United States**
- **Race Oncology delivers on key milestone: Completion of formulation development and first GMP production**
- **Projected Bisantrene stock enough to treat several hundred patients**

12 September, 2017: Race Oncology Limited ("RAC") is pleased to announce it has produced its first commercial batch of Bisantrene on schedule.

"Race Oncology has achieved one of the most important milestones in the path to commercialisation of a new drug, with the production of its first GMP batch of Bisantrene, on schedule," said Race CEO Peter Molloy.

Once released for sale, the product will be available for supply to hospitals in various countries under a Named Patient Program (NPP) for treatment of Acute Myeloid Leukaemia (AML).

RAC has previously stated that its first NPP market is France, followed by Italy, Turkey and South Korea.

The first production batch is expected to provide enough Bisantrene stock to treat up to sixty patients under the NPP. A further four production batches are scheduled for completion during September – in total, enough to treat several hundred patients.

The drug is being produced under GMP (Good Manufacturing Practice) by RAC's contract manufacturer, IRISYS LLC in San Diego California. IRISYS also successfully completed the formulation and process development that was needed prior to GMP production.

Mr Molloy was in San Diego to witness the finished product coming off the production line and stated: "Our manufacturing partner, IRISYS, has done an outstanding job in delivering this outcome and doing so on schedule."

The first batch of Bisantrene is scheduled to undergo quality control checks over the next 3-4 weeks before being released, after which it would be available for sale by RAC under the NPP.

Bisantrene is manufactured in 10mL vials that contain 250mg of the drug as a lyophilised powder. The powder is reconstituted as a solution and injected into an intravenous bag for administration to a cancer patient.

Based on the recommended dosage over seven days of treatment, a typical adult patient with Acute Myeloid Leukaemia (AML) may require 14 vials for a single course of treatment.

“This series of production runs will produce enough Bisantrene stock for several hundred courses of treatment. We are planning additional production next year as needed to meet demand,” said Mr Molloy.

“RAC continues to deliver on its stated timetable towards making Bisantrene available to patients through the NPP,” said Mr Molloy. “NPP sales allow us to generate cash flow to support our longer-term goal of FDA approval.”

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. In five published studies, Bisantrene produced an average clinical response rate of 48% in heavily pre-treated and/or refractory AML patients. Race has filed two patents on the drug and has been granted an Orphan Drug Designation in the USA for AML – conferring 7 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 a chemotherapy drug, Bisantrene, which was the subject of more than 40 phase II clinical studies during the 1980s and 1990s, then lost in a series of pharma mergers.

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Bisantrene manufacturing conducted at IRISYS facility in San Diego, California. After completion of all current production batches, Race will have enough vials of Bisantrene to treat several hundred patients

Bisantrene 250mg in vials

Bisantrene Lyophilized powder and reconstituted solution for administration

Race CEO Peter Molloy holds one of the first vials of Bisantrene to come off the production line in San Diego