



21 June 2018

ASX Announcement / Media Release

Bisantrene approval in UK for supply as an unlicensed medicine

21 June 2018: Race Oncology Limited ("RAC") is pleased to announce that approval has been received from the MHRA* for importation and distribution of Bisantrene as an unlicensed medicine in the UK. The letter from the MHRA was received by Race's distribution partner, Durbin PLC, on 20 June 2018.

Under MHRA regulations, the supply of unlicensed medicines in the UK is allowed subject to MHRA approval and in response to unsolicited requests from doctors for treating patients with unmet medical needs.

The current approval allows Durbin to import and supply Bisantrene to UK-based doctors and hospitals in response to such requests.

The initial approval is for 75 courses of treatment (14 vials per course), but Durbin can apply for additional approvals as needed.

No further approval is needed to commence supply of Bisantrene in response to physician requests or to invoice hospitals that receive the drug. In the UK, the use of unlicensed medicines is typically funded by the hospital that administers the drug.

The MHRA approval also allows Durbin to supply Bisantrene outside the UK to all 28 other countries in the EEA (European Economic Area), subject to local approval and importation rules in each country. For example, in France, an ATU is required in order to import and supply an unlicensed medicine.

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. Race owns two patents on the drug, both of which have received notice of allowance in the US, and has 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.

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, a chemotherapy drug that was the subject of more than 40 phase II clinical studies during the 1980s and 1990s, then lost in a series of big pharma mergers.

* Medicines and Healthcare products Regulatory Agency

Media contact:

Heidi Cuthbert

0411 272 366

E: heidi.cuthbert@multiplier.com.au