



ASX AND MEDIA RELEASE

Race signs agreement with Camargo Pharmaceutical

26 July 2016, Perth, Australia: Race Oncology Limited (ASX: RAC) today announced that it had signed an agreement with Camargo Pharmaceutical Services, Inc., a leader in 505(b)(2) drug development in the US.

Under the services agreement, Camargo will assemble a technical dossier on Bisantrone, prepare and submit a pre-IND meeting request with the FDA, complete and submit a pre-IND package to the FDA, and attend the meeting with the FDA, in conjunction with Race Oncology. The purpose of the pre-IND meeting is to gain FDA concurrence on the use of the 505(b)(2) pathway for Bisantrone, guidance on the proposed clinical trial to be conducted under the IND, and guidance on the ongoing development process for Bisantrone. The project is expected to take approximately six months. Once the pre-IND meeting is successfully concluded, the final IND can be completed and submitted.

The 505(b)(2) new drug application (NDA) is one of FDA drug approval pathways. 505(b)(1) is the standard application process for new drugs, which have not previously been tested in humans. The 505(b)(2) pathway allows sponsors (Race Oncology, in this case) to use historical published technical and clinical data as part of its application and thereby avoid unnecessary duplication of studies already performed. There are 8 published Phase 1 studies and more than 44 published phase 2 studies on Bisantrone that could be brought to bear in the application.

“Camargo are experts in 505(b)(2) applications,” said Managing Director, Peter Molloy. “Having them on board to manage this process is very valuable to Race.”

Camargo CEO, Ken Phelps, said: “All of us on the Camargo team look forward to working with Race Oncology and their products, getting them to market in the least amount of time and with lowest possible cost, and positioning them to take advantage of the 505(b)(2) regulatory pathway, all to benefit and improve patients’ lives.”

About Camargo

Camargo Pharmaceutical Services, LLC is the most experienced global strategist providing comprehensive drug development services specialized for the 505(b)(2) approval pathway and global equivalent processes. By assessing the scientific, medical, regulatory and commercial viability of product development opportunities, Camargo systematically builds and executes robust development plans that align with business strategies and ensure FDA buy-in every step of the way. Routinely holding three to six pre-IND meetings a month, Camargo works with product developers across more than 25 countries. Visit camargopharma.com for more information.

About Race Oncology

Race Oncology Limited is a specialty pharmaceutical company, whose business model is to pursue later stage assets, principally in the cancer field. The Company's first important asset is a chemotherapy drug, called Bisantrene, which was the subject of more than 40 phase II clinical studies during the 1980s and 1990s. Race Oncology owns recent patent filings on Bisantrene and has secured Orphan Drug Designation in the US. The Company's goal is to complete final development of Bisantrene and bring this valuable cancer drug to market. Visit raceoncology.com for more information.

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