

## ASX Announcement

### RC220 IND Approval Received from the Republic of Korea Ministry of Food and Drug Safety

- The Republic of Korea Ministry of Food and Drug Safety (MFDS) has approved the Investigational New Drug (IND) application for the Phase 1 clinical trial of RC220
- MFDS IND approval granted after an extensive review of the chemistry, manufacturing and controls, nonclinical and clinical data package for RC220
- IND approval enables patient recruitment at four sites in South Korea with local ethics approval received.

**24 September 2025** – Race Oncology Limited (“Race”) is pleased to announce the Republic of Korea (Korea) Ministry of Food and Drug Safety (MFDS) has approved the Investigational New Drug application to evaluate the safety, tolerability and pharmacokinetics of RC220 in combination with doxorubicin in solid tumour patients, subject to minor updates of the trial protocol.

MFDS IND approval follows a detailed review of the comprehensive RC220 data package that includes dossier modules covering nonclinical pharmacology and toxicology, chemistry, manufacturing and controls (CMC) for the active pharmaceutical ingredient (API) drug substance (RCDS1/(E,E)-bisantrene) and the RC220 drug product, specifications and analytical methods, together with the clinical trial protocol.<sup>1</sup> The requirements for MFDS IND approval are similar in rigour to the regulatory frameworks of the United States Food & Drug Administration (FDA) for IND applications, and the European Medicines Agency (EMA) for the Investigational Medicinal Product Dossier (IMPD).

IND approval enables activation of the three pre-selected clinical trial sites in Korea; Samsung Medical Center, Asan Medical Center, and Ewha Woman’s University Medical Center. These sites received local Institutional Review Board (IRB) ethics approvals in July and August and can now be activated to begin patient enrolment. The fourth Korean site, Severance Hospital, is expected to be activated following IRB approval, anticipated in the next month.

The Korean regulatory approval follows regulatory clearance in Australia (ASX Announcement: 14 March 2025 & 31 March 2025) and Hong Kong (ASX Announcement: 2 September 2025).

**Race Oncology CEO and Managing Director, Dr Daniel Tillett commented,** *“IND approval from the Korean MFDS is the result of focused effort from the Race team, working closely with the Korean regulators to achieve this important milestone. This approval allows patient enrolment in Korea and confirms the strength of the RC220 data package. We look forward to collaborating with our clinical partners in Korea to evaluate the potential of RC220 in combination with doxorubicin as a treatment option for adult patients with solid tumours.*

*The Korean healthcare and regulatory systems are internationally recognised for their high standards. Patient recruitment into oncology trials in Korea has historically been robust. We are excited to commence patient enrolment in Korea and further progress our global development strategy for RC220.”*

-ENDS-

## Q&A

How similar is the Korean MFDS IND approval process to that used by the US FDA and EU EMA?

All three regulatory bodies adhere to equivalent international standards and guidelines established by the International Conference of Harmonisation (ICH) and are members of ICH.<sup>2</sup> While the dossier package structure and format vary between regulators, the level and detail of content required are very similar. For example, all three regulators require nonclinical GLP-compliant safety pharmacology and toxicology studies, GMP-compliant CMC for the drug substance and drug product, along with a detailed clinical study summary. The Korean MFDS IND application requires additional data, such as full validation of the CMC package even for early phase trials, while the FDA may allow flexibility in CMC requirements for Phase 1 trials if patient safety isn't compromised. Put simply, the data package rigour required to obtain Korean MFDS IND approval is equal to that required by either the FDA or EMA.

Does Korean MFDS IND approval mean US FDA IND approval is guaranteed for RC220?

While the approval process is very similar between the different regulators, approval by one does not automatically guarantee approval by another regulator. Different regulators can have slightly different data requirements that may require dossier modifications before approval. On a positive note, any modifications required are normally minor and do not compromise ultimate approval.

## References

1. [https://www.mfds.go.kr/eng/wpge/m\\_17/denofile.do](https://www.mfds.go.kr/eng/wpge/m_17/denofile.do)
2. <https://www.ich.org/page/members-observers>



## About Race Oncology (ASX: RAC)

Race Oncology (ASX: RAC) is an ASX-listed clinical stage biopharmaceutical company with a dedicated mission to be at the heart of cancer care.

Race's lead asset, RCDS1 (E,E-bisantrene), is a small molecule anticancer agent. RCDS1 has demonstrated therapeutic activity in cancer patients with a well characterised safety profile.

Race is advancing a proprietary formulation of RCDS1 (RC220) to address the high unmet needs of patients across multiple oncology indications, with a clinical focus on combinations with an anthracycline (doxorubicin), where we aim to deliver both cardioprotection and enhanced anticancer activity in solid tumour indications. Race is also exploring the use of RC220 as a low intensity treatment for acute myeloid leukaemia and other cancers.

Race Oncology has collaborated with Astex, MD Anderson, Sheba City of Health, UNC School of Medicine, University of Wollongong and University of Newcastle, and is actively exploring partnerships, licence agreements or a commercial merger and acquisition to accelerate access to RC220 for patients with cancer across the world.

Learn more at [www.raceoncology.com](http://www.raceoncology.com).

If you have any questions on this announcement or any past Race Oncology announcements, please go to the Interactive Announcements page in our Investor Hub [announcements.raceoncology.com](http://announcements.raceoncology.com)

*Race encourages all investors to go paperless by registering their details with the Company's share registry, Automic Registry Services, at [www.automicgroup.com.au](http://www.automicgroup.com.au).*

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