

## First Patient Dosed in KOALA CAR-T Trial for Multiple Myeloma

**Melbourne, Australia, 26<sup>th</sup> August 2026** – Cell Therapies Pty Ltd today announced the successful manufacture and release of the first clinical dose for the KOALA trial, a first-in-human study evaluating a novel CAR T-cell therapy for patients with relapsed or refractory multiple myeloma.

The first patient has now been dosed with **PMCC-COE-KMA**, an investigational CAR T-cell therapy being developed by Peter MacCallum Cancer Centre's Centre of Excellence in Cellular Immunotherapy (CoE) and licensed by Australian biotechnology company HaemaLogiX Ltd.

The KOALA trial will evaluate the safety and efficacy of PMCC-COE-KMA in patients with multiple myeloma whose disease is no longer responding to standard therapies and who are not currently eligible for other CAR T-cell treatments.

PMCC-COE-KMA is designed to target **Kappa Myeloma Antigen (KMA)**, a receptor found on multiple myeloma cells and absent from healthy immune cells. Researchers hope this differentiated approach may enable a more targeted anti-myeloma effect while reducing treatment-related toxicities.

As the manufacturing partner for the trial, Cell Therapies is responsible for producing clinical doses of PMCC-COE-KMA at its GMP-licensed cell therapy manufacturing facility in Melbourne. The company's specialised manufacturing facility is co-located with Peter Mac, providing a streamlined pathway from research and development through to clinical delivery.

**Cell Therapies CEO Dr Bev Menner** said the first patient dosing represents an important milestone for Australian-developed cell therapies.

"The successful treatment of the first patient in the KOALA trial is a significant achievement for everyone involved and demonstrates the power of bringing together world-class research, clinical expertise and advanced manufacturing capabilities."

"Cell Therapies is proud to manufacture the clinical product for this pioneering study and to support the translation of innovative Australian science into potential new treatment options for patients with multiple myeloma."

"This milestone highlights the value of Australia's cell therapy ecosystem and showcases how partnerships between researchers, biotechnology companies and specialised manufacturers can accelerate the development of next-generation therapies."

**Commented [BM1]:** Is there a better word that 'specialised' that we can use here?

The Centre of Excellence in Cellular Immunotherapy and HaemaLogiX collaborated to advance PMCC-COE-KMA from early-stage development through to approval by the Therapeutic Goods Administration (TGA) to proceed into clinical testing.

**Professor Simon Harrison**, Director of Peter Mac's Centre of Excellence in Cellular Immunotherapy, welcomed the milestone.

"This investigational therapy aims to deliver a more targeted anti-myeloma effect while sparing the patient's immune system, potentially reducing side effects that often require careful management."

"The dosing of the first patient is an important step in evaluating this novel approach, and we look forward to continuing patient enrolment and assessing its potential benefit for people living with multiple myeloma."

**Dr Rosanne Dunn**, Chief Scientific Officer at HaemaLogiX, said: "We are delighted with the encouraging results from the first safely treated patient, and very pleased to be moving forward to dosing the second patient at a higher dose of KMCAR™ T-cell therapy. Multiple myeloma is the world's second-most common blood cancer, and there is a significant need for therapies that do not cause immunodeficiency which may result in life threatening infections."

"Seeing this work translate from the laboratory into human trials with positive safety data is a very important step forward for our immunotherapy programs. Our thanks to the first patient for joining the study and to our colleagues at Peter MacCallum Centre of Excellence for Cellular Immunotherapy for their commitment to progressing this important study."

CAR T-cell therapy involves collecting a patient's T-cells, genetically modifying them in a specialised manufacturing facility, and reinfusing the engineered cells to recognise and attack cancer. While several CAR T-cell therapies are approved for certain blood cancers, PMCC-COE-KMA is the first investigational therapy specifically designed to target KMA in multiple myeloma.

The KOALA trial is being led by Principal Investigator **Dr Mark Dowling**, with further patient enrolment ongoing.

#### **About Cell Therapies**

Cell Therapies is Australia's largest GMP-licensed manufacturer dedicated exclusively to cell and gene therapies. The company develops and manufactures cellular therapy products for clinical trials and commercial applications, supporting patients across Australia and the Asia-Pacific region. Through its specialised facilities and expertise, Cell Therapies enables the translation of innovative research into life-changing therapies.