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Significant milestone reached in first NZ CAR T-cell trial as preparations made for larger phase 2 registration trial

The goal of CAR T-cell cancer therapy becoming a standard of care in New Zealand is another step closer with patient enrolment completed and a total of 30 patients treated within the Malaghan Institute's ENABLE phase 1 safety trial, says Malaghan Institute Clinical Director Dr Robert Weinkove.

Preliminary results of the first 21 patients treated in the trial's dose escalation cohort, presented at the American Society of Hematology meeting in December 2023, suggested the new third-generation CAR T-cell therapy, developed in collaboration with Wellington Zhaotai Therapies Limited, is safer than leading commercial CAR T-cell products, while remaining highly effective for B-cell non-Hodgkin lymphomas.

Since then, a further nine patients have been treated at the optimal dose as part of a dose expansion cohort, with outpatient management and automated CAR T-cell manufacturing by New Zealand company BioOra Limited. Enrolment and treatment is now complete. Trial participants remain under follow-up, with a primary analysis of all 30 patients treated expected in June 2024, followed by publication of the results.

Dr Weinkove says the dose expansion cohort has established manufacture and delivery of CAR T-cells using cutting-edge automation technology, and has laid the groundwork for a phase 2 registration trial later in 2024.

"The most remarkable finding in the ENABLE trial is the low rate of two common side effects of CAR T-cell therapies: neurotoxicity and cytokine release syndrome. This has allowed us to treat patients without planned hospital admission, saving healthcare dollars. We are preparing a larger phase 2 trial to confirm effectiveness and safety of our CAR T-cell therapy – and to use it earlier in lymphoma treatment."

The Malaghan Institute is preparing for a phase 2 trial that it hopes will support registration in New Zealand and Australia. The multi-site trial, ENABLE-2, will treat 60 patients over two years.

"We have aligned ENABLE-2 with health service priorities and with a view to regulatory approval. We are actively discussing what it would take to make this treatment – and others like it – available for those who need it here in New Zealand," says Dr Weinkove.

"The main barriers to CAR T-cell therapy globally are the burden of managing side effects and the cost of the CAR T-cells themselves. By combining an improved safety profile with cost-effective manufacturing, we aim to address both issues."

BioOra, incubated within the Malaghan Institute, was established with Bridgewest Ventures in 2021 to optimise and scale-up CAR T-cell manufacturing in New Zealand, with a view to regulatory approval and reimbursement for CAR T-cell therapy. If the phase 2 clinical trial leads to successful registration, the Malaghan–BioOra partnership provides a pathway for the therapy to reach New Zealand and Australian patients rapidly and equitably.

BioOra CEO Andi Grant says overseas commercial CAR T-cell therapies are very expensive due to labour and capital intensive clinical and manufacturing models.

"Here in New Zealand, BioOra has partnered with the Malaghan Institute to develop a unique automated process for this personalised therapy that will enable us to manufacture CAR T-cells more consistently at lower cost, and to treat more patients. We have combined this technology with expertise in the delivery and reimbursement of therapeutic products to ensure both this, and other CAR T-cell therapies, can reach New Zealand and Australian patients, and beyond."

BACKGROUND

The phase 1 ENABLE trial was funded by New Zealand's Ministry of Business, Innovation and Employment, the Thompson Family Foundation, and by private donors, with additional support from Leukaemia & Blood Cancer New Zealand and Life Blood. The Malaghan Institute's CAR T-cell research programme has been supported by Freemasons NZ, the Health Research Council and the Maurice Wilkins Centre.

About the Malaghan Institute of Medical Research

The Malaghan Institute is an independent biomedical research charity based in Wellington, New Zealand, with a focus on breakthrough discoveries in immunology and immunotherapy. Its key areas of research and discovery include cancer, infectious disease and allergic and inflammatory diseases. The Malaghan Institute is the sponsor of both the phase 1 safety trial and the phase 2 efficacy and registration trial for the WZTL-002 CAR T-cell product in New Zealand. www.malaghan.org.nz

About BioOra Limited

Based in New Zealand, BioOra is a biopharma joint venture between the Malaghan Institute and Bridgewest Ventures. It is automating CAR T-cell manufacture to introduce efficiency, scalability, and cost savings to facilitate access to these lifesaving treatments in New Zealand and beyond. BioOra and Malaghan have formed a co-development partnership to complete the studies of clinical safety and efficacy, and facilitate affordable access to CAR T-cell therapy in New Zealand and beyond www.bioora.com

About Wellington Zhaotai Therapies Limited

Wellington Zhaotai Therapies Limited is a New Zealand-registered joint venture between Hunan Zhaotai Medical Group (Changsha, China) and the Malaghan Institute (Wellington, New Zealand). Wellington Zhaotai Therapies provided an Australasian sublicense for its 1928T2z third-generation chimeric antigen receptor to the Malaghan Institute, which has been used to make the new CAR T-cell product. www.wellingtonzhaotai.com

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MEDIA ENQUIRIES

Gail Marshall | Head of Communications, Malaghan Institute of Medical Research
gmarshall@malaghan.org.nz | +64 21 360 432

Rachael Joel | for BioOra Limited
rachaelj@botica.co.nz | +64 21 403 504