Phase 1 data from a CD19-specific third generation CAR T cell study supports use of BioOra's automated manufacture for phase 2 trial

- Results from 25 patients with relapsed or refractory B-cell non-Hodgkin lymphomas on ENABLE phase 1 safety trial presented at ASH 2023.
- No severe (grade ≥ 3) cytokine release syndrome (CRS) and no immune effector cell-associated neurotoxicity syndrome (ICANS) of any grade.
- Three-month complete response rate of 52 percent.
- Three patients within a phase 1 expansion cohort received third generation CAR T cells using BioOra's automated manufacturing platform at the recommended phase 2 dose.
- BioOra's automated CAR T cell platform will be used in an upcoming Phase 2 efficacy trial.

WELLINGTON – 12 December 2023 – BioOra together with its founding partner, the Malaghan Institute of Medical Research, announced clinical results from the ENABLE phase 1 clinical trial at the 65th American Society of Hematology (ASH) Annual Meeting in San Diego.

Malaghan Institute's Clinical Director and Principal Investigator, Dr Rob Weinkove also presented on 11 December updated data from the phase 1 dose expansion cohort.

Twenty-five patients have received third generation CD19-specific CAR T cells (WZTL-002) as investigational treatment for relapsed or refractory B-cell non-Hodgkin lymphomas and reached the 3-month timepoint. No grade ≥ 3 CRS and no ICANS of any grade was seen, and a complete response rate of 52 percent was observed at three months. WZTL-002 is co-developed by the Malaghan Institute, Wellington Zhaotai Therapies Limited (WZTL), and BioOra.

Three of the 25 patients recruited within an ongoing phase 1 expansion cohort received CAR T cells produced using BioOra's automated technology. These three infusions were delivered in an outpatient setting at the recommended phase 2 dose (5×10^5 to 10^6 CAR T cells/kg), and were associated with no dose limiting toxicity, no grade ≥ 3 CRS, and no ICANS of any grade.

Professor Carl June, BioOra board member, and CAR T cell pioneer, says the results show this treatment appears safe and effective.

"ENABLE achieved anti-tumour effects on par with commercial CAR T cells. In addition, the trial's results show an improved safety profile with no patients experiencing severe CRS or neurotoxicity. I believe this opens the door to providing this therapy as outpatient treatment which means more patients in more geographies can receive these CAR T cells."

BioOra and the Malaghan Institute formed a partnership to co-develop and commercialise WZTL-002 based on BioOra's cost-competitive and automated manufacturing platform.

Data from the phase 1 and expansion cohort are informing design of a phase 2 study to be undertaken by the Malaghan Institute in partnership with BioOra. BioOra CEO, Andi Grant, says that BioOra is on track to commercialise WZTL-002.

"We congratulate the Malaghan Institute on the results of the ENABLE study."

BioOra is building upon this success by focusing on delivering CAR T for patients beginning in Australasia.

"By automating CAR T cell production, we can manufacture at speed, achieve efficiencies in production, and reduce costs. We anticipate bringing BioOra's knowledge and technology to future CAR T cell relationships in multiple geographies to improve access to CAR T cell therapies," says Grant.

About BioOra

Based in New Zealand, BioOra is a privately held biopharma joint venture between the Malaghan Institute of Medical Research and Bridgewest Ventures. It is commercialising CAR T cells by automating manufacture to introduce efficiency, scalability, and cost savings to facilitate access to these lifesaving treatments in New Zealand and beyond. As a follow on to the ENABLE trial, BioOra is partnering with the Malaghan Institute to further develop WZTL-002 for patients with lymphoma in Australasia.

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