

ASX Announcement

First Australian patient dosed in Phase 1b azer-cel clinical trial

- First Australian patient dosed at Royal Prince Alfred Hospital in Sydney for the Phase 1b trial of azer-cel (azercabtagene zapreleucel).
- Follows promising results from US cohorts, including multiple complete responses (CR) in patients who failed previous treatments.

SYDNEY, Australia, 3 January 2025: Imugene Limited (ASX:IMU), a clinical-stage immuno-oncology company, is pleased to announce that the first Australian patient has been dosed in the Phase 1b clinical trial of its allogeneic CAR T-cell therapy azer-cel (azercabtagene zapreleucel), at the Royal Prince Alfred Hospital (RPAH) in Sydney. The trial is focused on patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), one of the most challenging and aggressive forms of non-Hodgkin's lymphoma.

Azer-cel is one of the few allogeneic CAR T-cell therapies currently being evaluated in Australia. Azer-cel offers an off-the-shelf alternative to traditional autologous CAR T-cell therapies, which require lengthy manufacturing processes involving a patient's own cells. By utilising pre-manufactured donor T-cells, azer-cel has the potential to significantly shorten treatment timelines and expand accessibility for patients with limited options.

Imugene recently reported promising data from its US trial sites (see ASX announcement 2 September 2024), demonstrating the potential of azer-cel to deliver meaningful clinical outcomes. In the US cohorts, three patients achieved complete responses (CR) despite having relapsed following multiple prior treatments, including autologous CAR T therapies. Notably, patients treated in Cohort B – which includes lymphodepletion chemotherapy and interleukin-2 (IL-2) – have shown particularly robust and durable responses, with responses extending beyond 90 and 120 days.

Leslie Chong, Managing Director and CEO of Imugene, said: "Achieving first patient dosed for azer-cel in Australia represents a significant milestone for Imugene and for



Australian patients battling this devastating disease. The trial’s opening at RPAH in Sydney reflects our commitment to accelerating the development of innovative, off-the-shelf immunotherapies that have the potential to improve outcomes for patients with relapsed or refractory DLBCL. We are proud to bring this trial to Australia and look forward to expanding recruitment across multiple sites.”

About the azer-cel Phase 1b Trial

The azer-cel Phase 1b trial is an open-label, multi-centre study evaluating the safety, tolerability, and clinical activity of azer-cel in patients with relapsed or refractory DLBCL who have previously received autologous CAR T-cell therapies. The trial incorporates a novel combination of lymphodepletion chemotherapy and interleukin-2 (IL-2) to enhance the therapeutic activity of azer-cel.

About DLBCL

Diffuse large B-cell lymphoma (DLBCL) is the most common and aggressive subtype of non-Hodgkin’s lymphoma (NHL), accounting for over 80,500 cases globally each year. Despite advancements in therapy, a significant proportion of patients relapse or do not respond to existing treatments, highlighting a critical unmet need for new treatment options.

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About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies. Our pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers. Our pipeline also includes multiple immunotherapy B-cell vaccine candidates and an oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing novel cancer therapies that are currently marketed globally. Our vision is to help transform and improve the treatment of cancer and the lives of the millions of patients who need effective treatments. This vision is backed by a growing body of clinical evidence and peer-reviewed research. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Release authorised by the Managing Director and Chief Executive Officer Imugene Limited.