

## ASX Announcement

### **Azer-cel demonstrates two additional Complete Responses in CD19 CAR-T Phase 1b Trial with 57% Complete Response Rate**

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#### **Key Highlights:**

- Two additional Complete Responses (CRs) have been observed in Imugene's Phase 1b trial of azer-cel, an allogeneic off-the-shelf CD19 CAR T therapy in relapsed/refractory diffuse large B-cell lymphoma (DLBCL), a type of blood cancer
- Four out of seven patients (Cohort B, see ASX announcement 2 September 2024) have now achieved a complete response following treatment with azer-cel, lymphodepletion (chemotherapy), and low-dose interleukin 2 (IL-2)
- These patients had previously failed 4-5 lines of therapy, including autologous CAR-T, reinforcing the potential of azer-cel in this high-unmet-need population
- 13 US sites and up to 5 sites in Australia will actively enrol into the trial
- Ongoing durability (length of time without disease) update to follow as the data matures – longest durability ongoing at 10 months
- Poster presentation featured at the 2025 ASTCT Tandem Meetings

**SYDNEY, Australia, 14 February 2025** – Imugene Limited (ASX: IMU), a clinical-stage immuno-oncology company, is pleased to announce more positive results from its Phase 1b clinical trial evaluating azer-cel (azercabtagene zapreleucel) in patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL).

Following the previously reported results on 2 September 2024, two additional patients in the previously reported Cohort B – treatment with azer-cel, lymphodepletion (chemotherapy), and interleukin 2 (IL-2) – have now achieved a Complete Response (CR, being the disappearance of all signs of cancer in response to the treatment), bringing the total to four out of seven evaluable patients in this cohort.

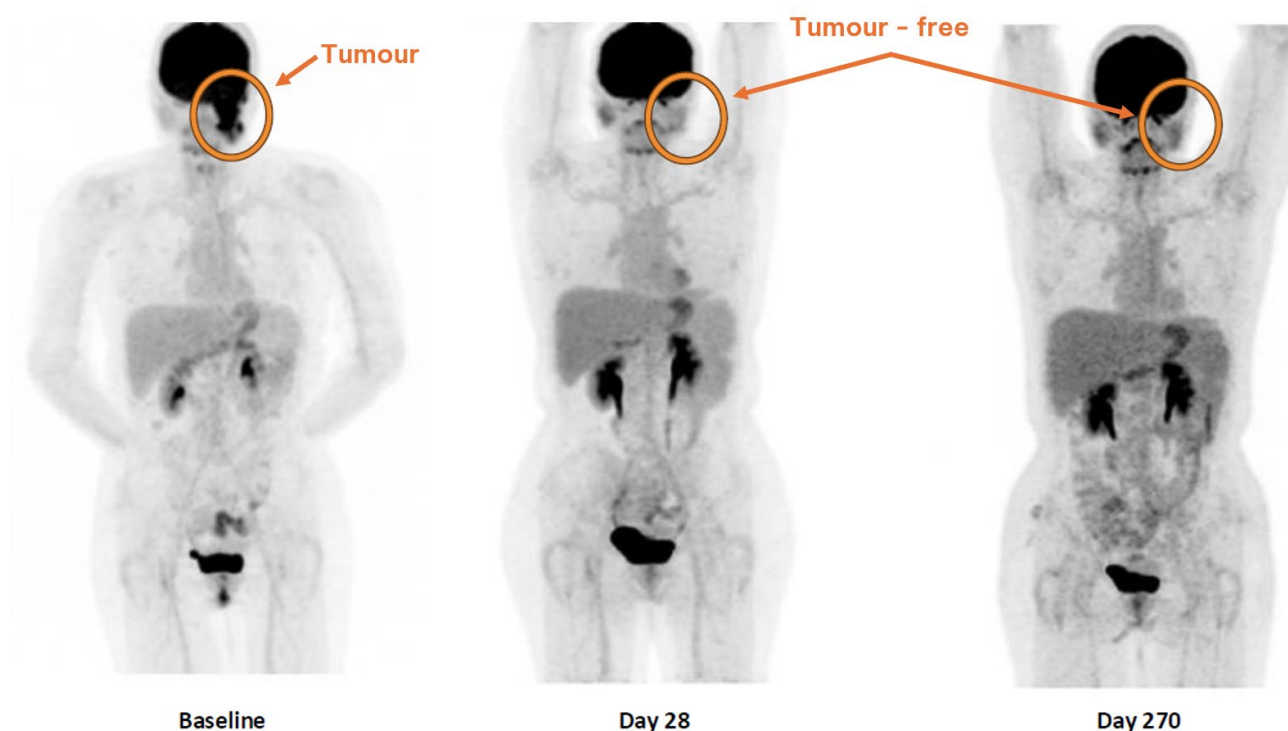


**Best Overall Response**  
**Azer-cel, lymphodepletion (chemotherapy) with IL-2**  
**N=7 Evaluable Patients**

Complete Response (CR)	4
Stable Disease (SD)	2
Progressive Disease (PD)	1
Complete Response Rate	57%

Evaluable: patients who qualify for at least their first 28-day scan

“All four Complete Responses in Cohort B were achieved in patients who had failed at least 4 lines of therapy in this hard-to-treat population, including autologous CAR T therapy,” said Dr Paul Woodard, Chief Medical Officer of Imugene. “This suggests that azer-cel, in combination with IL-2, may offer a meaningful therapeutic option where other treatments have not succeeded. We are continuing to monitor these patients for persistence of response, with the longest durability ongoing at 10 months. We look forward to providing further updates as data matures.”



*Image 1: Complete metabolic response sustained for >10 months ongoing*



The company remains focused on continuing enrolment in Cohort B and evaluating the long-term durability of responses. Azer-cel is being developed as a potential off-the-shelf CAR T-cell therapy, addressing key limitations of autologous CAR T approaches, including treatment accessibility and manufacturing constraints.

The 2025 Tandem Meetings event for the Transplantation & Cellular Therapy Meetings of ASTCT (American Society for Transplantation and Cellular Therapy) and CIBMTR (Center for International Blood and Marrow Transplant Research) highlights the latest research breakthroughs in hematopoietic cell transplantation (HCT), cellular therapy and gene therapy. Imugene poster presentation at this event takes place at 6:45pm Hawaii Standard Time on 13 February (3:45pm AEDT 14 February) can be viewed at the same time on Imugene's website at <https://imugene.com/investors/conference-presentations/>

The poster presentation is titled: Administration of Low-Dose, Subcutaneous (SC) Interleukin-2 (IL-2) Markedly Enhances the Pharmacokinetic (PK) Profile of Azercabtagene Zapreleucel (azer-cel), an Allogeneic Anti-CD19 Chimeric Antigen Receptor (CAR) T-Cell Therapy, without Compromising Safety and Early Evidence of Clinical Activity in Patients with Diffuse Large B-Cell Lymphoma (DLBCL) Who Have Relapsed after Prior CD19-Directed CAR T-Cell Products.

### **About the Phase 1b azer-cel trial**

The azer-cel allogeneic CAR T trial is an ongoing, open-label, multi-centre Phase 1b clinical trial in the U.S. and Australia, for patients with DLBCL, an aggressive type of non-Hodgkin's lymphoma blood cancer (NHL), who relapsed after prior treatment with autologous CAR T therapies. Treatment with azer-cel, lymphodepletion (LD) and IL-2 in Cohort B is showing promising results with evidence of meaningful clinical activity, and durability of response. Additionally, the safety profile is manageable and generally well tolerated.



### **About diffuse large B cell lymphoma (DLBCL)**

DLBCL is an aggressive and fast-growing type of non-Hodgkin's lymphoma (NHL), a type of blood cancer. DLBCL is the most common type of NHL, with approximately 80,500 cases per year and approximately 30,000 new cases per year in the U.S.

Relapsed/refractory DLBCL has a high unmet medical need; 60-65% of patients treated with approved therapies, including autologous CD19 CAR T, relapse.

### **About Interleukin 2 (IL-2)**

IL-2 is a cytokine (a protein that affects what happens between cells in the immune system) that helps T-cells (which are part of the immune system that help fight cancer) grow and survive. IL-2 has been shown to help T cells live longer and to enhance the cancer killing functions of CAR T cells, making them more effective at targeting and killing cancer cells.

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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.*