

ASX Announcement

Imugene Reports 100% & 80% Overall Response Rate in Subset Indications in azer-cel Phase 1b study

- **100% Overall Response Rate (ORR)** in Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL/SLL)
- **80% ORR** in Marginal Zone Lymphoma (MZL)
- Enrolment in the CAR T-naïve cohort progressing faster than in the earlier CAR T-relapsed DLBCL cohort, reflecting strong clinical interest

Sydney, Australia, 10 March 2026: Imugene Limited (ASX: IMU) a clinical-stage immuno-oncology company, today provides an update on the **CAR T-naïve cohort of its ongoing Phase 1b basket study of azer-cel**, an off-the-shelf, allogeneic CAR T cell therapy being evaluated across multiple advanced B-cell malignancies with significant unmet medical need.

In encouraging early signals, a **100% Overall Response Rate (ORR)** was observed in Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL/SLL) (4/4 Partial Responses, PR) in patients who had received a median of ≥ 3 prior lines of therapy. In CLL/SLL, complete responses are rare and partial responses have been sufficient to support regulatory approvals.

An **80% ORR** was observed in Marginal Zone Lymphoma (MZL) (3/5 Complete Responses, CR; 1/5 PR) in patients who had received a median of ≥ 2 prior lines of therapy.

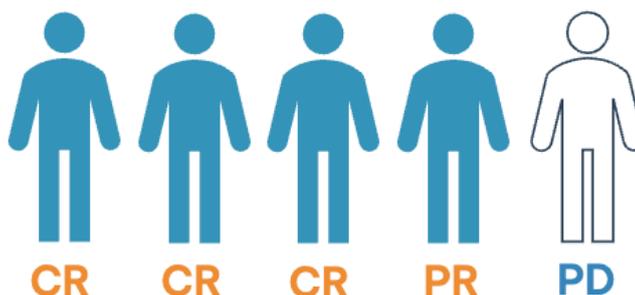
CLL Best Response
100% ORR



In CLL/SLL, CRs are uncommon and ORR (including PRs) has supported regulatory approvals (U.S. FDA guidance).



**MZL Best
Response
80% ORR**



Overall Response Rate (ORR): the proportion of patients whose cancer shrinks or disappears after treatment - a measure of how well a treatment is working, specifically in clinical trials

Complete Response (CR): all measurable or visible signs of cancer are no longer detectable after treatment

Partial Response (PR): Significant reduction in tumour size (typically at least 50%) or disease burden, but not complete disappearance of the disease

Progressive Disease (PD): cancer has grown or spread, despite treatment

The azer-cel Phase 1b CAR T-naïve cohort is structured as a multi-indication basket trial, which expands the potential registrational pathway and allows the Company to prioritise the indications where azer-cel is demonstrating the most promising activity, thereby potentially supporting a fast-to-market strategy with capital-efficient development.

The basket study currently includes **Primary Central Nervous System Lymphoma (PCNSL)** (≥ 1 prior line of therapy containing high-dose methotrexate), **Diffuse Large B-Cell Lymphoma (DLBCL)** (≥ 1 prior line of therapy including anti-CD20 and anthracycline), and **Waldenström's Macroglobulinemia (WM)** (≥ 2 prior lines of therapy including anti-CD20 chemoimmunotherapy).

As part of a focused strategy, the Company is also evaluating:

- **Chronic Lymphocytic Leukemia / Small Lymphocytic Lymphoma (CLL/SLL)** (prior BTKi and BCL2i or prior BTKi with high-risk features)
- **Marginal Zone Lymphoma (MZL)** (≥ 2 prior lines of therapy including anti-CD20 chemoimmunotherapy).



Clinical data across these indications continues to mature, and the Company intends to prioritise those indications demonstrating the strongest clinical activity, while certain other indications may not be pursued further.

Enrolment in the CAR T-naïve expansion cohort is progressing faster than in the earlier CAR T-relapsed DLBCL cohort, reflecting strong clinical demand and investigator support for an allogeneic approach. Durability of response, depth of response and safety continue to mature, and patient enrolment is ongoing.

Bruton Tyrosine Kinase inhibitor (BTKi) Combination Protocol Amendment

BTKis are approved drugs used to treat B-cell cancers, primarily CLL.

BTKis have largely replaced traditional chemotherapy as the standard first-line treatment for CLL.

The global market for BTK inhibitors (BTKis) has become a massive sector in oncology, with annual sales reaching approximately **\$12.1 billion** in 2025, shared between J&J/Abbvie, BeOne, Astra Zeneca & Eli Lilly

The Company has amended the Phase 1b protocol to evaluate azer-cel in combination with a BTKi and to include patients with mantle cell lymphoma (MCL). The combination arm will enrol patients who have previously failed BTK inhibitor therapy to evaluate safety and preliminary efficacy, including response rates, in the relevant patient populations.

Chief Executive Officer Leslie Chong said “We are encouraged to see activity emerging across multiple lymphoma subtypes within the CAR T-naïve cohort, which highlights the potential breadth of azer-cel in areas of significant unmet medical need.

The addition of the BTK inhibitor combination arm represents a meaningful opportunity to expand the clinical scope of the program, particularly for advanced patients who have failed prior BTK inhibitor therapy. We believe this strategy may further strengthen the positioning of azer-cel while aiming to improve outcomes for patients with limited treatment options”



Imugene is actively enrolling patients to the Phase 1b azer-cel trial at ten sites in the US and five sites in Australia. Further updates will be provided as additional patients become evaluable and data matures.

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 CAR T relapsed patients with DLBCL. The study has recently expanded to include and treat CAR T naïve patients diagnosed with a broad range of Non-Hodgkins lymphomas including chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL), Waldenstrom macroglobulinemia (WM), mantle cell lymphoma (MCL) and follicular lymphoma (FL). Treatment with azer-cel, lymphodepletion (LD) and IL-2 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 160,000¹ global 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% of patients treated with approved autologous CD19 CAR T relapse.

¹Science Direct Volume 60, Issue 5, November 2023

About other types of B Cell Lymphoma

Other subtypes of non-Hodgkin lymphoma (NHL) include chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), the most common slow growing leukemia that can become resistant to therapy; relapsed/refractory mantle cel lymphoma (MCL), marginal zone lymphoma (MZL), a slow-growing B-cell lymphoma that arises in lymphoid tissues associated with mucosal sites like the stomach and lung; Waldenström macroglobulinemia (WM), a rare slow-growing lymphoma characterized by excess IgM production, which can cause multiple complications ; and follicular lymphoma (FL), a



common slow-growing NHL that can become more aggressive. While several targeted therapies and monoclonal antibodies are available for these types of B Cell Lymphoma, relapsed or refractory disease remains an ongoing challenge

For more information please contact:

Leslie Chong
Managing Director and Chief Executive Officer
info@imugene.com

General Investor Enquiries
shareholderenquiries@imugene.com

Media Enquiries
communications@imugene.com

Connect with us on LinkedIn @Imugene Limited
Follow us on Twitter @TeamImugene
Watch us on YouTube @ImugeneLimited

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 oncolytic virotherapy (onCARlytics) 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. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies may 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.

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