



**IMUGENE**

Developing Cancer  
Immunotherapies

ASX:IMU

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# Azer-cel Gains Momentum Following ASCO and FDA Recognition

June 2026

# CEO UPDATE

**Leslie Chong**  
Imugene CEO & Managing Director



**Since our last update, azer-cel has continued to build momentum. The results from the CAR T-naive cohort across CLL/SLL and MZL are encouraging, and the new BTKi combination cohort adds meaningful breadth to what is already a compelling therapeutic candidate.**

This month, the FDA granted Fast Track Designation to azer-cel for two indications: CLL/SLL and MZL. This is a recognition of the data we have been accumulating and enables a closer, more structured dialogue with the FDA as the program advances.

In May, updated azer-cel data was presented at the American Society of Clinical Oncology Annual Meeting in Chicago, selected for oral presentation from more than 8,500 abstracts.

The updated data presented showed the MZL response rate has improved to 83%, including four complete responses with CLL at 100% response rate. ASCO selection is a meaningful signal from the global oncology community and it was inspiring to witness such an engaged audience.

Imugene recently amended the Phase 1b protocol to evaluate azer-cel in combination with a BTK inhibitor, enrolling patients who have previously failed BTKi therapy. On May 28, the first patient in this new cohort received a dose of azer-cel. By treating them concurrently with azer-cel and a BTKi, we are testing whether we can extend the window of response. It is a significant population with limited options, and it positions azer-cel within a global BTKi market worth US\$12 billion.

Our clinical progress and vision continue to gain external validation, highlighted by recent media coverage of the azer-cel program. A patient story that aired recently on WIN News served as a powerful reminder of the real-world impact behind our science. I encourage you to check out the replay available on our YouTube channel.

It is the shared dedication of our team, our clinicians, and our shareholders that allows us to deliver these life-changing advancements.

Thank you for your continued belief in our mission and your ongoing support.



## AZER-CEL TRIAL GIVING PATIENTS MORE TIME AT HOME

Victoria's first azer-cel patient recently shared their story with WIN News, highlighting the potential impact of off-the-shelf cell therapies for Australians living outside major cities.

For many regional patients, access to advanced cancer treatment can mean lengthy travel, extended stays away from home and significant disruption to family life. These challenges are particularly acute when treatment options are limited and time is critical.

Unlike conventional CAR T therapies, which are manufactured individually from a patient's own cells and can take several weeks to produce, azer-cel is pre-engineered from healthy donor cells and available when needed. For patients facing aggressive disease, reducing the time between treatment decision and treatment delivery may be particularly important.

The potential benefits extend beyond speed. If approved, off-the-shelf therapies such as azer-cel could help broaden access to advanced cell therapies by supporting treatment at a wider range of centres, reducing some of the geographic barriers faced by regional Australians.

The patient, who lives in rural Victoria, had spent years battling chronic lymphocytic leukaemia and had exhausted many available treatment options. Encouraged by their family to keep fighting, they enrolled in the azer-cel clinical trial and received treatment in October 2024.

Their story offers a powerful reminder that innovation is not only about advancing science. It is also about improving access, reducing treatment burden, and helping patients spend more time where they want to be: at home with their families and communities.



[Watch the story in full](#)

# CLINICAL UPDATE



Leslie Chong, Imugene CEO & MD at the ASCO 2026 Exhibit Hall

## FDA FAST TRACK: TWO NEW DESIGNATIONS FOR AZER-CEL

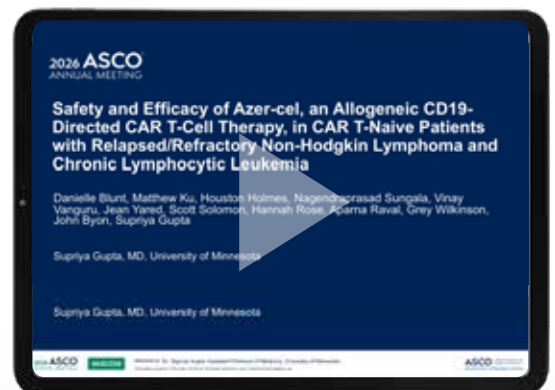
The US Food and Drug Administration has granted Fast Track Designation to azer-cel for two blood cancer indications: relapsed or refractory chronic lymphocytic leukaemia / small lymphocytic lymphoma (CLL/SLL) and relapsed or refractory marginal zone lymphoma (MZL).

Fast Track Designation is awarded to therapies that address serious conditions with unmet medical need. In practical terms, it means more frequent engagement with the FDA, the option to submit sections of a regulatory application on a rolling basis rather than all at once, and potential eligibility for Accelerated Approval and Priority Review.

The designations are supported by Phase 1b trial data showing a 100% overall response rate in the CAR T-naive CLL/SLL cohort with one patient at 6 months turned from a partial response to a complete response and an 83% overall response rate in MZL, including four complete responses.



The Fast Track process



Read the full ASCO presentation here



Imugene Oral Presentation at ASCO 2026

## AZER-CEL DATA PRESENTED AT ASCO

On 29 May 2026, Imugene presented azer-cel data at the American Society of Clinical Oncology Annual Meeting in Chicago, the world's largest oncology conference, attended by more than 40,000 clinicians, researchers, and investors. This year more than 8,500 abstracts were submitted. Azer-cel was selected for a rapid oral presentation.

For an Australian clinical-stage company to reach this stage at ASCO is rare. It reflects the quality of the data, the rigour of the program, and the work of every investigator, patient, and team member involved.

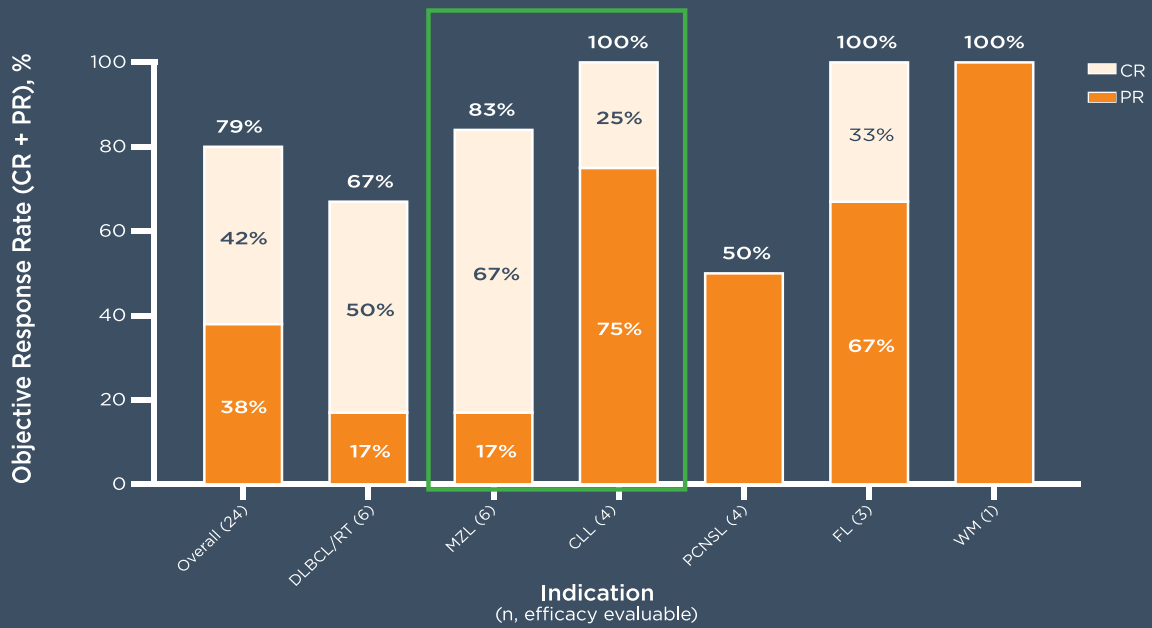
Dr Supriya Gupta of the University of Minnesota presented the data at the Rapid Oral Abstract Session on lymphoma and chronic lymphocytic leukemia. The abstract (Abstract #7012) was published at [asco.org/abstracts](https://asco.org/abstracts) on 22 May 2026.



Leslie Chong, Imugene CEO & Managing Director at the Entrance to ASCO, 2026



Leslie Chong and Professor Joy Ho, Head of Haematology and Director of Research at Royal Prince Alfred Hospital at ASCO 2026.



## RESULTS & KEY TAKEAWAYS

### 2026 American Society of Clinical Oncology (ASCO) oral presentation

- Enrolling across multiple CD19+ B-cell malignancies including DLBCL, FL, CLL/SLL, MZL, WM and PCNSL
- 24 Evaluable heavily pretreated CAR-T naïve patients

### Responses observed across all indications including;

- 100% Overall Response Rate (ORR) in multiple indications including CLL/SLL, FL and WM
  - 83% ORR in MZL with 5/6 responders achieving a Complete Response (CR) or Partial Response (PR)
- 
- Fast Track Designation for CLL and MZL received in June, 2026
  - No approved CAR-T therapies in several of these indications
  - Clear opportunity to expand into high-value niche populations

#### Acronym Key

**DLBCL:** Diffuse Large B-Cell Lymphoma

**MZL:** Marginal Zone Lymphoma

**CLL:** Chronic Lymphocytic Leukemia

**PCNSL:** Primary Central Nervous System Lymphoma

**FL:** Follicular Lymphoma

**WM:** Waldenström Macroglobulinemia



# FIRST PATIENT DOSED IN BRUTON TYROSINE KINASE INHIBITOR (BTKI) COMBINATION COHORT

Imugene recently amended the Phase 1b protocol to evaluate azer-cel in concurrent combination in patients who have previously failed a BTKi therapy. The first patient in this cohort has recently been dosed at the prestigious Baylor University located in Texas.

## What is a BTK inhibitor?

BTK inhibitors replaced chemotherapy as the standard of care for several blood cancers over the past decade. A significant proportion of patients eventually develop resistance; their cancer returns, and options become extremely limited.

## Why azer-cel?

Azer-cel is an off-the-shelf CAR T therapy that can be ready within days, not the four to six weeks required to manufacture a personalised CAR T product. For patients whose cancer has progressed through a BTKi, that speed is clinically significant.

## The market

BTK inhibitors generated more than US\$9 billion in combined revenue in 2024 across the top three drugs alone. The global market was valued at US\$12.0 billion in 2025 and is forecast to reach US\$21-23 billion by the early 2030s.

- **Jaypirca (pirtobrutinib)** - Eli Lilly; US\$506 million in 2025; First and only non-covalent (reversible) BTKi approved by the U.S. FDA for adult patients with relapsed or refractory CLL/SLL who have been previously treated with a covalent BTKi
- **Imbruvica (ibrutinib)** - AbbVie / Johnson & Johnson; US\$3.3 billion in 2024
- **Calquence (acalabrutinib)** - AstraZeneca; US\$3.1 billion in 2024
- **Brukinsa (zanubrutinib)** - BeiGene/BeONE; US\$2.6 billion in 2024; fastest growing, up 105%, approved in 70+ markets.

Azer-cel does not compete with these drugs at the front line. It targets the patients who come after them, those for whom BTKi therapy has already failed and who currently have limited or no further treatment options left.

Baylor University Medical Centre in Texas





## Remuneration update

Following the remuneration strike at the November 2025 AGM, the Remuneration Committee has taken several steps. There will be no salary increases for the Chair or CEO. The Board and CEO will forego 50% of their long-term equity incentive entitlements. The Chair and CEO have reinvested up to 50% of their 2025 bonuses in on-market share purchases. A comprehensive review of remuneration policies will be completed ahead of the 2026 AGM.

## LOOKING AHEAD

### Anticipated 2026/2027 Milestones

- > R&D Tax Incentive Refund expected in coming months
- > Regular and ongoing Phase 1b data on CAR-T naïve lymphoma patients and BTKi and azer-cel combination
- > Initiation of manufacturing, supply and operational activity for registration/pivotal study
- > FDA re-engagement
- > On-going Strategic Business and Development Activities
- > Potential Conference Presentations: e.g. EHA, ASH



# FROM THE CHAIR



Dear Fellow Shareholders,

**It has been an encouraging first half of 2026 for Imugene, with the azer-cel program continuing to build solid clinical and regulatory foundations.**

Watching azer-cel presented on the main stage at ASCO in Chicago was a proud moment for everyone connected to this company, and a tangible sign that Australian clinical-stage science can compete at the highest level. The FDA’s Fast Track Designations for CLL/SLL and MZL, and the opening of the BTKi combination arm, mean the program is now broader in scope, better supported by regulators, and targeting a larger patient population than before.

On governance, the actions taken by the Remuneration Committee following last year’s AGM reflect a genuine commitment to shareholder alignment, and we look forward to presenting our updated remuneration framework at the 2026 AGM.

We are aware that the current market valuation does not reflect the strength of the science and the regulatory progress the team has delivered. Small-cap biotech is in a difficult market right now, and we do not take lightly, the patience shareholders have shown. The Board’s focus is on continuing to build the evidence base that we believe will, in time, be recognised.

Warm regards,

**Paul Hopper**  
Executive Chairman

## About

Imugene is a clinical stage cell therapy company developing an Allogeneic CAR T for blood cancers. Our lead asset is an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers.

## Contact

[info@imugene.com](mailto:info@imugene.com)

[imugene.com](http://imugene.com)

## Financial Snapshot as at 1 June 2026

ASX code	IMU
Market cap	\$46m
Performa Cash balance	\$5.963m (as at 31 March 2026)
Additional \$9.62m received from capital raise on 29 April 2026	
Industry	Biotechnology

**Note:** All figures are in Australian dollars. Market capitalisation calculations based on ordinary shares (415.8) only and excludes the dilutive impact of options, performance rights and warrants outstanding.