

ASX Announcement

Imugene Reports one Complete Response and one Partial Response in BTKi Combination Cohort of azer-cel Phase 1b Trial

- Two further responses achieved at Day 28: one Complete Response (CR) in Mantle Cell Lymphoma (MCL) and one Partial Response (PR) in Chronic Lymphocytic Leukemia (CLL)
- Two additional evaluable patients, one with Richter's Transformation (DLBCL/RT) had Stable Disease (SD), and one patient with MCL had Progressive Disease (PD)
- These four additional patients evaluated in Cohort 3 of the azer-cel Phase 1b trial, which combines azer-cel with a Bruton Tyrosine Kinase inhibitor (BTKi) in patients whose disease has progressed on a BTKi therapy, bringing the total in this cohort to seven evaluable patients
- All patients enrolled had previously received and progressed on BTKi therapy, representing a heavily pre-treated population with high unmet medical need and fewer remaining treatment options
- Patient enrolment remains ongoing across ten US and five Australian sites

BTKI COMBINATION COHORT: N=7

71% Overall Response Rate on early numbers

BEST
RESPONSE



Overall Response Rate (ORR): the proportion of patients whose cancer shrinks or disappears after treatment (CR+PR)

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



SYDNEY, Australia, 5 October 2026: Imugene Limited (ASX: IMU), a clinical-stage cellular therapy company, today reports updated patient data from the BTK inhibitor (BTKi) combination cohort of its ongoing Phase 1b basket study of azer-cel (azercabtagene zapreleucel).

Four further patients in Cohort 3 reached their Day 28 assessment. Two of the four responded: one Complete Response (CR) in a patient with Mantle Cell Lymphoma (MCL) and one Partial Response (PR) in a patient with Chronic Lymphocytic Leukemia (CLL). Of the other two patients, one with Richter's Transformation (Diffuse Large B-Cell Lymphoma / Richter's Transformation, DLBCL/RT) had Stable Disease (SD), and one with Mantle Cell Lymphoma (MCL) had Progressive Disease (PD).

CLL and MCL are high-risk B-cell malignancies where progression on standard BTKi therapies poses a critical clinical challenge. Patients who relapse on or become refractory to BTKi regimens face limited subsequent treatment options and poor overall survival outcomes.

All patients enrolled in this combination cohort have relapsed on or are refractory to prior BTKi therapy. The trial is evaluating whether concurrent administration of azer-cel with a BTKi can enhance antitumor activity in B-cell malignancies. The global BTKi market reached over US\$12.0 billion in 2025.

Executive Chairman, Paul Hopper, said: "Observing additional responses in our BTKi combination cohort provides compelling further validation of this strategy. The key here is that we are treating patients who have all progressed on BTK inhibitors and who have high unmet need hematologic cancer with few therapeutic options. With the combination of azer-cel and continuation of the BTK inhibitor, we are seeing a high response rate including in challenging tumor types like MCL and CLL."

Cohort 3 adds to the azer-cel Phase 1b study data. Across the Phase 1b study, azer-cel has now demonstrated a 75% Overall Response Rate (ORR) across a total evaluated population of 55 patients. This includes a 68% ORR in CAR T-relapsed/refractory DLBCL (Cohort 1, n=22), a 81% ORR in CAR T-naïve patients (Cohort 2, n=26), and a 71% ORR in the BTKi combination cohort (Cohort 3, n=7). These pooled results reinforce the



consistent therapeutic potential of azer-cel across diverse, difficult-to-treat patient populations.

RESPONSE ACROSS THREE COHORTS

N=55



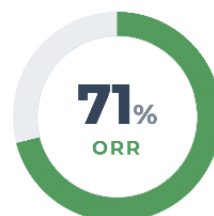
Cohort 1

CAR-T Relapsed/Refractory
DLBCL · n=22



Cohort 2

CAR-T naïve · n=26



Cohort 3

BTKi Combination · n=7

75%

**COMBINED ORR
COHORT 1, 2 & 3**

41 of 55 patients responded

Further clinical updates will be reported as patient enrolment continues and data matures.

Azer-cel is an off-the-shelf, allogeneic CAR T cell therapy targeting CD19 for the treatment of blood cancers. Derived from healthy donor T cells, azer-cel is available for administration within days, bypassing the three-to-six-week manufacturing delay characteristic of autologous CAR T products.

About the Phase 1b azer-cel trial

The ongoing, open-label Phase 1b trial of azer-cel in the U.S. and Australia evaluates three main patient populations: CAR T-relapsed patients, CAR T-naïve patients, and BTKi combination cohort of patients with B-cell malignancies who previously progressed on BTKi therapy. Across a broad range of non-Hodgkin lymphomas (including FL, CLL/SLL, MZL, WM, and MCL), treatment with azer-cel, lymphodepletion, and IL-2 has yielded meaningful clinical activity including multiple complete responses in the BTKi cohort, with a manageable safety and tolerability profile.

For more information please contact:

General Investor Enquiries

shareholderenquiries@imugene.com

Connect with us on LinkedIn @Imugene Limited

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About Imugene (ASX:IMU)

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. We are supported by a leading team of international cancer experts with extensive experience in developing novel cancer therapies.

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 together with leading specialists and medical professionals, we believe Imugene's cellular therapy may become foundation treatments for cancer. Our goal is to ensure that Imugene is at the forefront of this rapidly growing global market.

Release authorised by the Executive Chairman, Imugene Limited.