

ASX Announcement

Imugene Reports First Complete Response in Concurrent BTKi Cohort of azer-cel Phase 1b Trial

- First patient in the concurrent Bruton Tyrosine Kinase inhibitor (BTKi) cohort of the azer-cel Phase 1b study has achieved a complete response (CR)
- This Follicular Lymphoma (FL) patient had previously received and failed BTKi therapy, representing a population with limited remaining treatment options
- BTKi therapy addresses a US\$12.0 billion global market; with a proportion of patients developing resistance with their disease progressing over time
- Patient enrolment is ongoing across ten US and five Australian sites

SYDNEY, Australia, 30 June 2026: Imugene Limited (ASX: IMU), a clinical-stage immuno-oncology company, today reports the first patient data from the concurrent BTK inhibitor (BTKi) cohort of its ongoing Phase 1b basket study of azer-cel (azercabtagene zapreleucel).

This **Follicular Lymphoma (FL) patient**, who had previously failed BTKi therapy, achieved a **complete response** at the Day 28 assessment.

FL is the most common indolent B-cell lymphoma and, while many patients respond to initial treatment, it remains a high unmet need with standard therapies and most patients will relapse over time.

All patients enrolled in the concurrent BTKi cohort have relapsed on or are refractory to BTKi therapy, a standard treatment across multiple B-cell malignancies. Despite the established efficacy of BTK inhibitors, a significant proportion of patients develop resistance over time and are left with limited remaining options. This cohort evaluates whether concurrent dosing of azer-cel with a BTKi may restore or enhance therapeutic activity in this setting. The global BTKi market reached approximately US\$12.0 billion in 2025.



Leslie Chong, Managing Director and CEO of Imugene, said, "This initial data provides further confidence in the potential of azer-cel in patients who have exhausted standard treatment options, including BTK inhibitors. Given how widely BTKi therapies are used, we believe this combination approach could represent a meaningful development pathway for azer-cel."

To date, four patients have been dosed in the concurrent BTKi combination cohort, including the first patient with mantle cell lymphoma. Further updates will be provided as additional data becomes available, and the dataset matures.

Azer-cel is an off-the-shelf, allogeneic CAR T cell therapy which targets CD19 to treat blood cancers. Azer-cel is derived from healthy donor T cells and ready for administration within days, without the three-to-six-week manufacturing lead time required for autologous CAR T 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 CAR T relapsed patients and CAR T naïve patients diagnosed with a broad range of Non-Hodgkins lymphomas including follicular lymphoma (FL), chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL), Waldenstrom macroglobulinemia (WM), and mantle cell lymphoma (MCL). The trial has most recently expanded into a concurrent BTKi cohort, for patients with a range of B-cell malignancies who have previously failed BTKi therapy. Treatment with azer-cel, lymphodepletion and IL-2 has produced meaningful clinical responses across multiple indications, including a complete response in the first evaluable patient from the BTKi combination cohort. Additionally, the safety profile is manageable and generally well tolerated.

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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 Managing Director and Chief Executive Officer Imugene Limited.