

ASX Announcement

Imugene Doses First Patient in BTK Inhibitor Combination Cohort of azer-cel Phase 1b Study

- First patient dosed in Bruton Tyrosine Kinase inhibitor (BTKi) combination cohort of azer-cel Phase 1b study at the prestigious Baylor University located in Waco, Texas
- Patient with Mantle Cell Lymphoma (MCL); failed prior BTKi therapy
- The combination of azer-cel with a BTKi explores whether concurrent treatment may improve the activity of azer-cel, an “off the shelf” CAR T cell therapy and BTKi
- The global BTKi market reached approximately US\$12.0 billion in 2025

Sydney, Australia, 28 May 2026: Imugene Limited (ASX: IMU) a clinical-stage immuno-oncology company, today announces the enrolment of first patient into the BTK inhibitor combination cohort of its ongoing Phase 1b basket study of azer-cel. **Azer-cel** is an off-the-shelf, allogeneic CAR T cell therapy being evaluated across multiple advanced blood cancers with significant unmet medical need.

Patients in this third cohort will be treated with azer-cel in combination with a BTKi with the objective of evaluating safety and preliminary efficacy. These patients have previously failed BTKi therapy, an established standard of care therapy across multiple B-cell malignancies. including follicular lymphoma (FL), chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL). Enrolment is ongoing across ten US and five Australian sites

Despite their efficacy as front-line and subsequent treatments, many patients ultimately develop resistance or intolerance to BTKi therapy, representing a significant area of unmet medical need. The combination of azer-cel with a BTKi aims to explore whether concurrent dosing may enhance the activity of azer-cel and BTKi in this setting.



The addition of the BTKi combination cohort expands the clinical scope of the azer-cel program and may support further partnering and collaboration opportunities. By broadening the range of eligible B-cell malignancies in the Phase 1b study, the Company is better positioned to prioritise indications where azer-cel demonstrates the strongest clinical potential, supporting a disciplined and capital-efficient development strategy. The global BTKi market was valued at approximately US\$12.0 billion in 2025.

Chief Executive Officer Leslie Chong said “The enrolment of first patients into the BTKi combination cohort is a meaningful step in expanding the clinical scope of the azer-cel program. BTKi-relapsed patients represent a significant population with limited options, and we believe the concurrent combination approach has the potential to address this unmet need.

We look forward to reporting safety and preliminary efficacy data as patients become evaluable, and to continuing to build the evidence base for azer-cel across B-cell malignancies.”

Further updates will be provided as 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 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 recently expanded into a BTKi combination cohort, for patients with a range of B-cell malignancies who have previously failed BTKi therapy. 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.

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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.

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