IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Imugene's Azer-cel Granted FDA Fast Track Designation for CLL/SLL and MZL

- Fast Track Designation granted for azer-cel in two blood cancer indications: relapsed or refractory Chronic Lymphocytic Leukaemia / Small Lymphocytic Lymphoma (CLL/SLL) and relapsed or refractory Marginal Zone Lymphoma (MZL)
- The designation facilitates expedited development and review for therapies addressing serious conditions with unmet medical need
- Phase 1b data demonstrates 100% ORR in the CAR T-naive CLL/SLL cohort and 83% ORR in MZL including four complete responses
- Fast Track Designation supports more frequent FDA engagement; potential eligibility for Accelerated Approval and Priority Review

SYDNEY, Australia, 9 JUNE, 2026: Imugene Limited (ASX:IMU), a clinical-stage immuno-oncology company, is pleased to announce that the US Food and Drug Administration (FDA) has granted Fast Track Designation to azer-cel (azercabtagene zapreleucel) for two indications: relapsed or refractory Chronic Lymphocytic Leukaemia / Small Lymphocytic Lymphoma (CLL/SLL) and relapsed or refractory Marginal Zone Lymphoma (MZL).

The FDA's Fast Track Designation is designed to facilitate the development and expedite the review of drugs that treat serious or life-threatening conditions and meet an unmet medical need. Benefits include more frequent meetings with the FDA to discuss development plans, the option for rolling review of regulatory submissions, and potential eligibility for Accelerated Approval and Priority Review upon meeting the relevant criteria.

Azer-cel is an off-the-shelf, CD19-directed CAR T-cell therapy engineered to overcome the logistical constraints of autologous CAR T therapies, which typically require three to six weeks to manufacture from a patient's own cells. By using pre-manufactured donor

T-cells, azer-cel can be ready to administer within days. For patients with relapsed or refractory disease who have exhausted standard treatment options, that speed is clinically significant.

Chronic Lymphocytic Leukaemia / Small Lymphocytic Lymphoma (CLL/SLL)

CLL/SLL is one of the most common blood cancers in adults. Many patients experience disease progression despite multiple prior treatments. Clinical data from the Phase 1b basket study demonstrates a 100% ORR in the CAR T-naive CLL/SLL cohort, in patients who had received a median of three or more prior lines of therapy. Azer-cel's activity in CAR T-naive patients is significant in demonstrating the potential of an off-the-shelf allogeneic approach to deliver responses in patients who have not previously received cellular therapy.

Marginal Zone Lymphoma (MZL)

MZL is an indolent but incurable B-cell lymphoma. Patients who relapse following standard therapies including anti-CD20 chemoimmunotherapy have limited remaining options. Updated clinical data from the Phase 1b basket study, which post-dates the ASCO data cut, shows an 83% ORR in MZL, based on five of six evaluable patients responding, including four complete responses, in patients who had received a median of two or more prior lines of therapy.

Leslie Chong, Managing Director and CEO of Imugene, commented: "FDA Fast Track Designation for both CLL/SLL and MZL reflects the meaningful clinical activity we are seeing with azer-cel across multiple B-cell malignancies. For patients who have exhausted standard treatment options in these indications, we believe azer-cel represents a genuinely promising approach, and this designation will support closer engagement with the FDA as we advance the program."

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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.