IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Encouraging early efficacy in CAR T naïve lymphomas in azer-cel Phase 1b trial

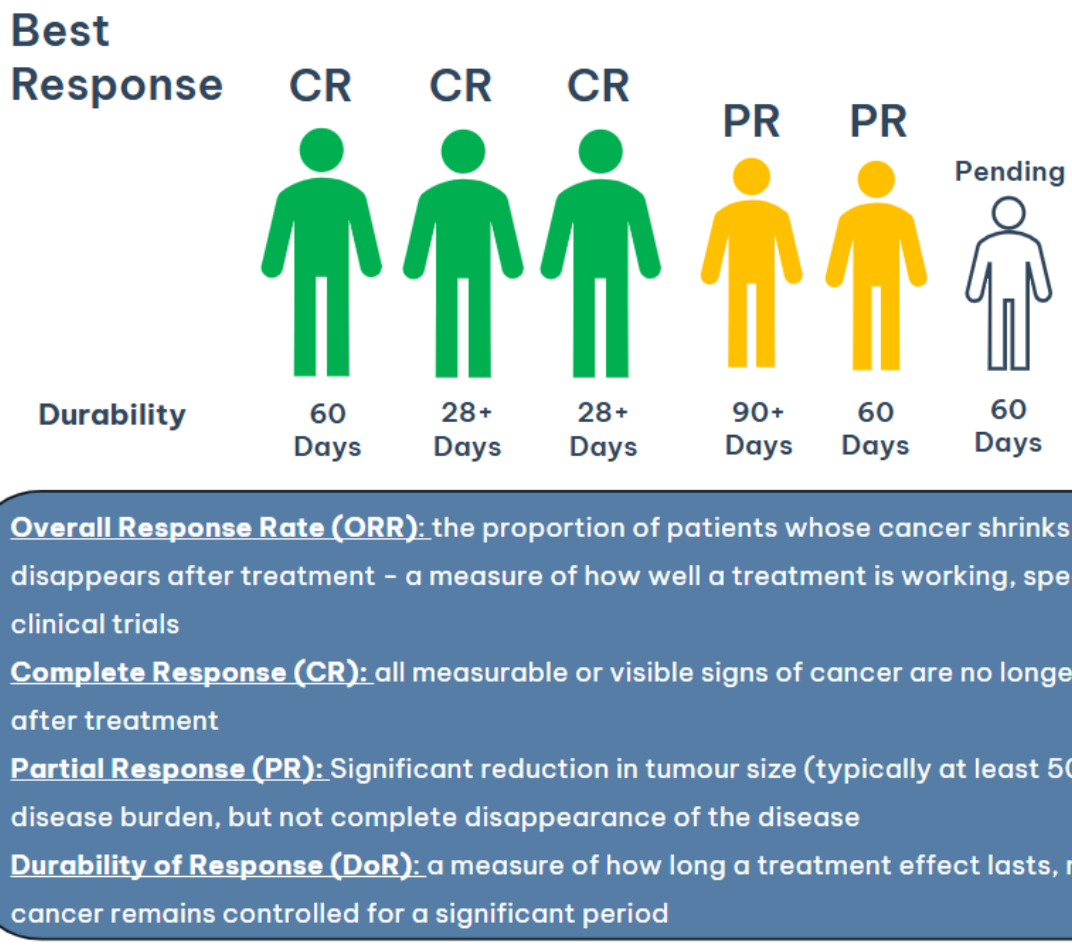
- 83% Overall Response Rate (ORR) in six evaluable heavily pretreated CAR T-naïve patients, no prior CAR T treatment (5/6 responders, with results from the sixth patient pending)
- 50% Complete Response (CR) rate (3/6 patients)
- 10 patients treated to date across multiple CD19+ B-cell malignancies, including Diffuse Large B-cell Lymphoma (DLBCL), Follicular Lymphoma (FL), Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL), Marginal Zone Lymphoma (MZL), Waldenström macroglobulinemia (WM) and Primary CNS lymphoma (PCNSL), with follow-up scans pending for four additional patients in CAR T naïve cohort
- Enrolment progressing significantly faster than the CAR T-relapsed DLBCL cohort, supporting a potential expedited clinical path

Sydney, Australia, 29 October 2025: Imugene Limited (ASX: IMU), a clinical-stage immuno-oncology company, is pleased to announce the first efficacy results from the CAR T-naïve niche indication portion of its ongoing Phase 1b trial of azer-cel (azercabtagene zapreleucel) — an off-the-shelf, allogeneic CD19 CAR T therapy being evaluated across a spectrum of B-cell lymphomas.

Of six evaluable CAR T-naïve patients (patients with no previous CAR T treatment), five (83%) achieved an overall response including three (50%) complete responses. The result of the sixth patient's follow-up scan is pending.

A total of ten patients have been treated in this cohort thus far, with further results to come upon patient follow-up. These initial results encompass several rare lymphoma subtypes, notably WM, MZL and PCNSL — areas of significant unmet clinical need where no CAR T products are currently approved.

Azer-cel continues to demonstrate a manageable safety profile consistent with previously reported results in relapsed diffuse large B-cell lymphoma (DLBCL). Importantly, enrolment into the CAR T-naïve expansion is proceeding significantly faster than the earlier CAR T-relapsed DLBCL cohort, reflecting the substantial clinical demand and investigator enthusiasm for an allogeneic approach.



For approved, autologous CD19 CART products, the average time to best response is 2-3 months with some patients taking up to 6 months to achieve their best response.

Imugene has an FDA Type C meeting in November to discuss pivotal study design options for azer-cel in CAR T-relapsed DLBCL, while also advancing the CAR T-naïve program to generate a broader evidence base across additional indications, including rare lymphomas to expand registrational options. Chief Executive Officer Leslie Chong said "We are encouraged by these early signals of efficacy in the CAR T-naïve population, with at least five of the first six evaluable patients responding to treatment. As best responses can be seen up to 90 days or more after treatment, we look forward to further data on the

depth and durability of these outcomes. Enrolment in this portion of the trial is proceeding at a remarkable pace, positioning us to explore an expedited development pathway for azer-cel."

In the CAR T relapsed DLBCL portion of the same Phase 1b study, azer-cel has achieved an 81% overall response rate to date, including multiple complete and partial responses, with several patients remaining in durable remission beyond a year. Patients in this cohort had typically failed an average of three prior lines of therapy, including autologous CAR T. These findings reinforce azer-cel's potential as an allogeneic alternative for patients who relapse following existing CAR T treatments and complement the strong early data now emerging in the CAR T-naïve setting.

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 with DLBCL. The study has recently expanded to include and treat CAR T naïve patients diagnosed with a broad range of Non-Hodgkins lymphomas including primary central nervous system lymphoma (PCNSL), chronic lymphocytic leukemia (CLL)/ small lymphocytic lymphoma (SLL), marginal zone lymphoma (MZL), Waldenstrom macroglobulinemia (WM) and follicular lymphoma (FL). 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.

About primary central nervous system lymphoma (PCNSL)

PCNSL is a rare and aggressive form of non-Hodgkin lymphoma (NHL), a type of blood cancer that originates in the brain, spinal cord, leptomeninges, or eyes, usually without evidence of systemic disease. In the U.S., there are approximately 1,500 to 1,800 new cases per year with limited approved treatment options and is a high unmet need. Currently, there are no CAR T-cell products approved for the treatment of PCNSL providing a unique opportunity for azer-cel to treat CART naïve patients.

About other types of B Cell Lymphoma

Other subtypes of non-Hodgkin lymphoma (NHL) include chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), the most common slow growing leukemia that can become resistant to therapy; marginal zone lymphoma (MZL), a slow-growing B-cell lymphoma that arises in lymphoid tissues associated with mucosal sites like the stomach and lung; Waldenström macroglobulinemia (WM), a rare slow-growing lymphoma characterized by excess IgM production, which can cause multiple complications ; and follicular lymphoma (FL), a common slow-growing NHL that can become more aggressive. While several targeted therapies and monoclonal antibodies are available for these types of B Cell Lymphoma, relapsed or refractory disease remains an ongoing challenge, highlighting the ongoing need for continued innovation and new and better treatments.

About Interleukin 2 (IL-2)

IL-2 is a cytokine (a protein that affects what happens between cells in the immune system) that helps T-cells (which are part of the immune system that help fight cancer) grow and survive. IL-2 has been shown to help T cells live longer and to enhance the cancer killing functions of CAR T cells, making them more effective at targeting and killing cancer cells.

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About Imugene (ASX:IMU)

Imugene is a clinical stage immuno-oncology company developing a range of new and novel immunotherapies that seek to activate the immune system of cancer patients to treat and eradicate tumours. Our unique platform technologies seek to harness the body's immune system against tumours, potentially achieving a similar or greater effect than synthetically manufactured monoclonal antibody and other immunotherapies.
Our pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to treat blood cancers. Our pipeline also includes oncolytic virotherapy (CF33) aimed at treating a variety of cancers in combination with standard of care drugs and emerging immunotherapies such as CAR T's for solid tumours. We are supported by a leading team of international cancer experts with extensive experience in developing novel cancer therapies that are currently marketed globally.
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 peer-reviewed research. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies may become foundation treatments for cancer. Our goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market.

Release authorised by the Managing Director and Chief Executive Officer Imugene Limited.