IMUGENE
Developing Cancer Immunotherapies

ASX Announcement

Imugene opens first Australian site for azer-cel Phase 1b clinical trial

- The Royal Prince Alfred Hospital in Sydney is the first Australian site for the Phase 1b trial, with patient recruitment starting in November 2024
- The trial is Australia's only actively enrolling allogeneic CAR T-cell trial and is focused on relapsed or refractory diffuse large B-cell lymphoma (DLBCL)
- Imugene recently announced promising data from its US sites, with three complete responses including the first two treated in Cohort B (patients treated with azer-cel, lymphodepletion (chemotherapy)[1] and interleukin 2)

SYDNEY, Australia, 8 November 2024: Imugene Limited (ASX), a clinical-stage immuno-oncology company, is pleased to announce the opening of the first Australian site for its azer-cel (azercabtagene zapreleucel) Phase 1b clinical trial. The Royal Prince Alfred Hospital in Sydney will begin patient recruitment in November 2024, marking another significant milestone in the development of this promising off-the-shelf allogeneic CAR T-cell therapy.

This trial will be one of the only actively enrolling allogeneic CAR T-cell clinical trial in Australia, focusing on relapsed or refractory diffuse large B-cell lymphoma (DLBCL), a challenging form of non-Hodgkin's lymphoma. Azer-cel represents a promising therapeutic option for patients whose cancers have not responded to other treatments, including autologous CAR T-cell therapies.

Azer-cel is an allogeneic, off-the-shelf CAR T-cell therapy that targets CD19, a protein commonly found on the surface of B-cells, including cancerous cells in DLBCL. Unlike traditional autologous CAR T therapies, which require harvesting and engineering a patient's own T-cells, azer-cel uses donor T-cells, which are pre-manufactured and ready for use. This approach allows for quicker treatment and broader availability

compared to autologous therapies that have long production times and logistical challenges.

Data to date from the trial, which has been dosing patients at US centres, has demonstrated promising results with three patients achieving complete responses (CR) even after failing multiple previous treatments, including autologous CAR T (see ASX announcement 2 September 2024). In particular, patients in Cohort B of the trial, who received a combination of azer-cel, lymphodepletion (chemotherapy)[1], and interleukin-2 (IL-2), showed robust clinical activity. Two out of three of the evaluable patients in this cohort experienced complete responses, with the durability of these responses extending beyond 90 and 120 days. These early results suggest that azer-cel could offer a meaningful alternative for patients with limited treatment options.

"We're proud to be able to bring this trial to Imugene's home country and provide an opportunity for Australian patients to benefit from this unique technology," said Imugene's Managing Director and CEO Leslie Chong. " This is the first of up to five sites we plan to open in Australia, as we seek to speed up enrolment and deliver improved outcomes in this form of blood cancer."

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 patients with DLBCL, an aggressive type of non Hodgkin's lymphoma (NHL), who relapsed after prior treatment with autologous CAR T therapies. All patients treated with azer-cel and lymphodepletion (LD) demonstrated an acceptable safety profile. In addition, the current patients in Cohort B, treated with azer-cel, LD, and IL-2 are demonstrating clinically meaningful activity and durability.

About diffuse large B cell lymphoma (DLBCL)

DLBCL is an aggressive and fast-growing type of non-Hodgkin's lymphoma (NHL), a type of blood cancer. DLBCL is the most common type of NHL, with approximately 80,500 cases per year and approximately 30,000 new cases per year in the U.S.2

Relapsed/refractory DLBCL has a high unmet medical need; 60-65% of patients treated with treatments, including autologous CD19 CAR T, relapse.

References:

[1]Lymphodepletion (LD)/chemotherapy: Aug Cy: Flu 30mg/m2 x 3d, Cy 750mg/m2 x 3d2[1]NIH

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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 multiple immunotherapy B-cell vaccine candidates and an 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 new cancer therapies with many approved for sale and marketing for global markets.

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. Imugene is well funded and resourced, to deliver on its commercial and clinical milestones. Together with leading specialists and medical professionals, we believe Imugene's immuno-oncology therapies will 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.