

ASX Announcement

Azer-cel hits major milestone with first patient dosed in Phase 1b Allogeneic CAR T Clinical Trial

- **First patient in Phase 1b follows successful Phase 1 trial in 84 patients at leading US Centres**
- **Azer-cel is currently being studied in an ongoing multi-centre Phase 1b CAR T clinical trial in patients with blood cancer called non-Hodgkin's lymphoma (NHL)**
- **The Phase 1b trial is a precursor to a Phase 2 registrational (subject to FDA agreement) in 2024**
- **Strong safety and efficacy signals to date from 84 Phase 1 patients dosed with azer-cel**
- **Azer-cel clinical drug supplied from Imugene's state-of-the-art manufacturing facility in North Carolina**

SYDNEY, Australia, 10 November 2023: Imugene Limited (ASX:IMU), a clinical stage immuno-oncology company, is pleased to announce dosing of the first patient in a Phase 1b clinical trial using azer-cel (allogeneic off-the-shelf CD19 CAR T, a type of cell therapy), manufactured and supplied from Imugene's state-of-the-art facility in North Carolina.

Following completion of the Phase 1b study there is potential to start a registrational study in 2024 and become the first approved allogeneic CAR T cell therapy for cancer.

The patient who was dosed at Banner Health (Phoenix Arizona) suffers from a difficult to treat sub-set of NHL called Diffuse-Large B-cell lymphoma (DLBCL). Dr Paul Woodard, Imugene's Chief Medical Officer said, "Patients with DLBCL who have relapsed after autologous CART therapy have limited therapeutic options and are an unmet medical need. New and effective therapies are needed for these patients."



As announced in September 2023, Imugene received positive feedback from the FDA on the azer-cel manufacturing process to be used in the registrational (to-market) clinical trial, and potentially for manufacturing of the commercial drug product. Imugene's manufacturing facility is a state-of-the-art GMP (Good Manufacturing Process) site where the proprietary next generation azer-cel process has evolved into a potential first-in-class cell therapy drug.

Imugene MD & CEO, Ms Leslie Chong said, "It is a great credit to our team that the Phase 1b study has been initiated and the first patient dosed, in under three months since acquiring the technology."

The Phase 1b allogeneic (allo) CAR T study is an ongoing multi-centre Phase 1b clinical trial in patients with non-Hodgkin's lymphoma (NHL) and B-cell acute lymphocytic leukemia (ALL). Azer-cel has demonstrated clinically meaningful activity with an acceptable safety profile, including promising results in DLBCL patients who relapsed following CAR T.

Beyond using azer-cel in blood cancers, in the future it will also be combined with Imugene's own onCARlytics for treatment of patients with solid tumours, opening a potentially large market for azer-cel in the 90% of oncology not beyond blood cancers.

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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.