

ASX Announcement

Azer-cel FDA IND Transferred to Imugene

Sydney, Australia, 28 September 2023: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce the US Food and Drug Administration (FDA) has transferred the Investigational New Drug (IND) Application for its allogeneic CD19 CAR T azer-cel from Precision Biosciences Inc. (NASDAQ GS: DTIL) to Imugene, following the exclusive worldwide license acquired in August.

Imugene MD & CEO, Ms Leslie Chong said, “We are actively progressing the ongoing multi-centre Phase 1b ([ClinicalTrials.gov ID NCT03666000](https://clinicaltrials.gov/ct2/show/study/NCT03666000)) study using the recommended Phase 2 regimen of azer-cel as we prepare for the start of a potential Phase 2 registrational study at the earliest opportunity, and we expect the Clinicaltrials.gov ID will be updated to reflect Imugene being the sponsor imminently.”

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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