IMUGENE
Developing Cancer Immunotherapies

## ASX Announcement

# Imugene Licenses Allogeneic CD19 CAR T with Potential to Commence Registrational Study in 2024

- License to first in class allogeneic (off the shelf) CD19 CAR T cell therapy, azercabtagene zarpreleucel (azer-cel), for autologous (auto) CAR T relapsed patients with blood cancers
- Potential to start a registrational study in 2024 and become the first approved allogeneic (allo) CAR T cell therapy for cancer
- One of the most extensive data packages for an allo CAR T product with over 84 patients treated with safety, compelling efficacy, and durability
- Azer-cel is designed to address high and growing unmet need in the post auto CAR T setting of Diffuse Large B Cell Lymphoma (DLBCL), earlier lines of therapy and other blood cancer indications
- Azer-cel is highly complementary to Imugene's onCARlytics platform
- Exclusive License includes 3 additional encouraging target assets

**Sydney, Australia, 16 August 2023:** Imugene Limited (ASX:IMU or the Company) today announced that it has entered into an agreement with Precision Biosciences, Inc. (NASDAQ GS: DTIL) of North Carolina, USA, to acquire a worldwide exclusive license to Precision's azer-cel allogeneic CD19 CAR T cell therapy program.

Imugene MD & CEO, Ms Leslie Chong said, "Azer-cel has one of the most extensive clinical data sets for a CD19 directed allogeneic cell therapy, a fast-to-market development strategy and a potential registration-enabling clinical trial in 2024 for patients with 3$^{rd}$ and 4$^{th}$ line DLBCL. We plan to complete the ongoing multi-centre Phase 1b (ClinicalTrials.gov ID NCT03666000) study using the recommended Phase 2 regimen as we prepare for the start of a potential registrational study at the earliest opportunity. We are very excited as azer-cel has the potential to be the first approved allo CAR T."

Ms Chong said, “By adding azer-cel to the Imugene pipeline, our onCARlytics program will form the foundation of a novel and broadened approach to cell therapy. CD19 is a well validated clinical target in blood cancers. OnCARlytics can enhance the expression of CD19 on solid tumours. Azer-cel is a supercharged allogeneic T cell designed to identify and kill malignant cells expressing CD19. We are thrilled about the potential benefit for patients from the combination of these two technologies.”

In the ongoing multi-centre Phase 1b clinical trial that includes 84 patients with non-Hodgkin’s lymphoma (NHL) and acute lymphocytic leukemia (ALL), azer-cel demonstrated clinically meaningful activity with an acceptable safety profile. Notably, the azer-cel data were especially strong in patients with DLBCL who had relapsed following auto CAR T therapy. Azer-cel achieved 83% Overall Response Rate (ORR), 61% Complete Response (CR) Rate with 55% durable response greater than or equal to six months in this difficult to treat auto CAR T relapse setting (n=18). It is estimated that 60-70% of patients treated with an approved auto CD19 CAR T cell therapy such as Kymriah®, Yescarta® or Breyanzi® will unfortunately have cancer progression or recurrence.

In the broader group of patients with relapsed/refractory NHL, irrespective of prior treatment with auto CAR T cell therapy, azer-cel showed encouraging response rates and an acceptable safety profile with a 58% ORR and 41% CR rate across all doses and lymphodepletion (chemotherapy) regimens.

Additionally, no Grade 3 or greater cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), infection or graft versus host disease was observed in the most recent cohort with the appropriate lymphodepletion treatment.

Azer-cel continues to demonstrate promising results in DLBCL patients who relapsed following CAR T, and high overall response rates with molecular remissions in this patient setting are encouraging. Based on this dataset, azer-cel has the potential to improve outcomes in this large and growing population with high unmet need.

A positive meeting was held with the FDA in June 2023 to seek guidance for entering a Phase 2 registration study. Further, chemistry, manufacturing, and controls (CMC) discussions have gone well with the FDA and the intended commercial azer-cel product will be tested in the clinic and will be utilized in the potential registrational clinical trial.

Under the terms of the licence agreement, Imugene acquires the exclusive world-wide rights to develop and commercialize the azer-cel technology in oncology for which it has agreed to pay Precision Biosciences:

- US$8 million cash and US$13 million deferred consideration on closing. The deferred consideration has a term of 12 months and may be converted into shares and/or redeemed for cash at the election of Imugene.
- US$8 million on satisfactory completion of the Phase 1b clinical trial shortly to commence. Imugene may elect to pay by the issue of Imugene shares.
- Up to US$198 million performance-based payments over the development life of azer-cel linked to the achievement of certain value-inflection development milestones, including approval in multiple indications and sales in US and EU
- Industry standard royalties on net sales.

Imugene will also acquire the lease to a state-of-the art 32,800 sq feet GMP manufacturing facility in North Carolina, drug material for completion of a Phase 1b clinical trial and a highly experienced cell therapy and manufacturing team of approximately 50 personnel.

All cash payments to initiate the licence agreement will be funded through Imugene's existing cash reserves with the option to make some payments in Imugene equity, should Imugene elect to do so. Imugene will pay an introduction fee of US$3 million to Chimeric Therapeutics Limited in connection with the transaction.

Ms. Chong continued, “We are confident in our understanding of product composition, dosing, activity, and safety. Based on recent discussions with the FDA, we believe there is rationale to advance azer-cel into a potential registrational study for patients already treated with auto CAR T as early as 2024. This accelerated development timeline would position azer-cel to be the first FDA-approved allogeneic CAR T therapy for blood cancers.”

Precision CEO Mr Michael Amoroso said, “We are delighted to form this partnership with Imugene to develop the exciting azer-cel technology. Our mutual commercial and scientific interests are closely aligned particularly through the formation of a Joint Steering Committee, through which Precision will allow Imugene to avail itself of our deep expertise in manufacturing and cell therapy. The opportunity for Imugene to combine its OnCARlytics technology with azer-cel opens a new frontier for Imugene and shows great promise. We look forward to following Imugene’s progress with great interest”.

*This release has been authorised by the Directors of Imugene Limited.*

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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 product pipeline includes an off-the-shelf (allogeneic) cell therapy CAR T drug azer-cel (azercabtagene zapreleucel) which targets CD19 to attack blood cancer, 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.