

## ASX Announcement

### Imugene receives positive feedback from FDA on an improved manufacturing process for azer-cel

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- FDA gives positive feedback on an improved manufacturing process for azercabtagene zapreleucel (azer-cel), an allogeneic (off the shelf) CD19 CAR T cell therapy, for autologous (auto) CAR T relapsed patients with blood cancers
- Improved manufacturing process allows for increased robustness, consistency, and scalability
- Potential to start a pivotal study in 2024 and become the first approved allogeneic CAR T cell therapy for cancer
- Azer-cel is highly complementary to Imugene's onCARlytics platform

**Sydney, Australia, 11 September 2023:** Imugene Limited (ASX:IMU or the Company) today announced that it has received positive feedback from the FDA on the azer-cel (allogeneic CD19 CAR T) manufacturing process to be used in the pivotal clinical trial and potentially for manufacturing of the commercial product.

Imugene MD & CEO, Ms Leslie Chong said, "Azer-cel has the potential to be the first CD19 directed allogeneic cell therapy and having the FDA support on the manufacturing process that can be used for the pivotal trial is an extremely important milestone for Imugene as it improves the overall robustness and scalability of the product."

Azer-cel is currently being studied in an ongoing multi-centre Phase 1b clinical trial in patients with non-Hodgkin's lymphoma (NHL) and 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.



With the positive feedback from the FDA on the manufacturing process, the intended commercial azer-cel product will be tested in the clinic and will be utilized in the potential pivotal clinical trial. Imugene is manufacturing azer-cel at our state-of-the-art, 32,800 sq feet GMP manufacturing facility in North Carolina.

Beyond using azer-cel in blood cancers, it will also be combined with onCARlytics for treatment of patients with solid tumours.

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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.

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