

ASX Announcement

Azer-cel granted FDA Fast Track Designation in blood cancer DLBCL

- **Fast Track Designation granted for Imugene's allogeneic CAR T-cell therapy azer-cel for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL)**
- **The designation facilitates expedited development and review for therapies addressing serious conditions**
- **Supports Imugene's efforts to accelerate timelines for patients with high unmet need**

SYDNEY, Australia, 19 March 2025: Imugene Limited (ASX:IMU), a clinical-stage immuno-oncology company, is pleased to announce that the US Food and Drug Administration (FDA) has granted Fast Track Designation to its allogeneic CAR T-cell therapy, azer-cel (azercabtagene zapreleucel), for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

The FDA's Fast Track Designation is designed to facilitate the development and expedite the review of drugs that address serious or life-threatening conditions and meet an unmet medical need. Benefits of this designation include more frequent meetings with the FDA to discuss development plans, the option for rolling review of regulatory submissions, and potential eligibility for Accelerated Approval and Priority Review upon meeting relevant criteria.

Azer-cel is an off-the-shelf, CD19-directed CAR T-cell therapy engineered to overcome the logistical challenges of autologous CAR T therapies, such as prolonged manufacturing times and limited patient access. By leveraging pre-manufactured donor T-cells, azer-cel allows for rapid treatment delivery. Clinical data from the ongoing Phase 1b trial has demonstrated significant promise to date, particularly in patients who failed multiple prior therapies including autologous CAR T.



The therapy incorporates a novel combination of lymphodepletion chemotherapy and interleukin-2 (IL-2) to enhance CAR T persistence and efficacy. Azer-cel has shown a manageable safety profile, with no instances of immune effector cell-associated neurotoxicity syndrome (ICANS) observed in key patient cohorts.

Leslie Chong, Managing Director and CEO of Imugene, commented: “Receiving FDA Fast Track Designation is a testament to the transformative potential of azer-cel for patients battling relapsed or refractory DLBCL. We are committed to working closely with the FDA to bring this important therapy to patients as efficiently as possible.”

DLBCL is the most common and aggressive form of non-Hodgkin’s lymphoma, with a significant portion of patients experiencing relapse or resistance to standard treatments.

Azer-cel addresses this critical unmet need by offering a novel therapeutic approach for this challenging blood cancer.

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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 novel cancer therapies that are currently marketed globally.

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.