

## ASX Announcement

### First dose level cleared in IV combination arm of Phase 1 onCARlytics trial

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- The first dose level has been cleared in the intravenous (IV) combination arm of the OASIS trial, targeting adult patients with advanced or metastatic solid tumours
- This first in human study aims to make solid tumours express the validated CD19 target, rendering them vulnerable to be attacked by approved CD19 targeting therapies.
- Dose escalation to follow as the trial progresses toward full recruitment of 40-50 patients

**Sydney, Australia, 3 April 2025:** Imugene Limited (ASX: IMU), a clinical-stage immuno-oncology company, is pleased to announce it has received clearance from the Cohort Review Committee (CRC) to escalate the dose level in the intravenous (IV) combination arm of its Phase 1 onCARlytics trial.

With the successful completion of the safety observation period the IV combination arm will progress to a higher dose level.

Known as OASIS, the Phase 1 dose escalation onCARlytics clinical trial is targeting adult patients with advanced or metastatic solid tumours. The trial aims to evaluate the safety and efficacy of two routes of administration, intratumoural (IT) injection and intravenous (IV) infusion of either onCARlytics (a CD19-expressing oncolytic virus) alone, or in combination with CD19 targeting bispecific monoclonal antibody blinatumomab (Blinicyto®), which is a cancer immunotherapy.

OASIS is being conducted at seven sites in the U.S. including City of Hope, University of Cincinnati, MD Anderson Cancer Center, Emory, Roswell Park, University of Pittsburgh, Northwestern and University of Nebraska, with the potential to open a total of 10 sites to recruit approximately 40-50 patients with advanced solid cancers that have spread.

Imugene's Managing Director and Chief Executive Officer, Leslie Chong, said:



*“CD19 is a very significant target for blood cancers, but solid cancers like breast, lung or gastric do not have a common target on their cell surface, and therefore the aim with onCARlytics is to make available a target for CD19 therapies to treat these solid cancers. As the trial continues to progress and dose escalation is executed, we are eager to learn of the potential impact our treatment is having for patients in need.”*

The trial is titled: “A Phase I, Dose Escalation and Dose Expansion, Safety and Tolerability Study of onCARlytics (CF33-CD19), Administered Intravenously or Intratumorally in Combination with Blinatumomab in Adults with Advanced or Metastatic Solid Tumors.”

See <https://clinicaltrials.gov/study/NCT06063317>

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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.*