

## ASX Announcement

### Phase 1 onCARlytics solid tumour trial advances to combination arm treatment

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- The OASIS trial is a first-in-class clinical trial combining a CD19-expressing oncolytic virus, which flags solid tumours for attack by CD19-targeting therapeutics such as Amgen's Blincyto®, Gilead's Yescarta® and Imugene's own allogeneic CAR T, azer-cel
- OASIS potentially represents a paradigm shift in solid tumour treatment
- Cohort Review Committee (CRC) observed no safety issues in the onCARlytics monotherapy lead-in study and recommended opening of the combination arm of the study
- Ovarian, breast and melanoma patients treated to date in the monotherapy arm

**Sydney, Australia, 11 March 2024:** Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that its Phase 1 clinical trial of CD19 oncolytic virotherapy drug candidate onCARlytics (on-CAR-19, CF33-CD19 HOV4) has cleared its first cohort within the intratumoural monotherapy arm of the study and is therefore ready to commence combination dosing solid tumour patients with CD19 targeting drug blinatumomab (Blincyto® marketed by Amgen).

Known as OASIS, the first-in-class clinical trial is targeting adult patients with advanced or metastatic solid tumours, and aims to evaluate the safety and efficacy of two routes of administration, intratumoural (IT) injection and intravenous (IV) infusion, either alone, or in combination with blinatumomab.

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>.



The combination arm of the study will see onCARlytics combined with CD19 targeting bispecific monoclonal antibody blinatumomab (marketed as Blincyto® by Amgen which currently is specifically approved only for liquid blood cancers). OnCARlytics has the potential to target and eradicate solid tumours that otherwise cannot be treated with Blincyto® therapy alone and will represent a paradigm shift in solid tumour treatment.

OASIS is a dose escalation trial that will be conducted across multiple sites across the United States, with 52 patients proposed to take part in the trial.

Imugene Managing Director and CEO Leslie Chong said:

“It’s once again a credit to our team and collaborators to see yet another study progressing positively and on schedule. Completion of this first monotherapy intratumoural cohort where ovarian, breast and melanoma patients were dosed paves the way for us to move into an important combination dosing with Blincyto®, where we’ll be eager to see the greater potential of onCARlytics in targeting and eradicating solid tumours.”

OnCARlytics is a CD19-expressing oncolytic virus that enters tumour cells and forces them to express the CD19 protein on the cell surface, presenting a target for CD19 targeting therapies.

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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 Imugene Limited.*