

ASX Announcement

Phase 1 onCARlytics trial doses first patient in intravenous monotherapy arm

- The first patient with bile tract cancer in the intravenous monotherapy arm of the trial has been dosed at City of Hope in California
- The OASIS trial is a world-first in combining a CD19-expressing oncolytic virus with a CD19 targeting drug
- The trial is expected to recruit 52 patients with advanced or metastatic solid tumours
- Expansion planned to multiple sites across the US

Sydney, Australia, 15 February 2024: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that its CD19 oncolytic virotherapy drug candidate onCARlytics (on-CAR-19, CF33-CD19 HOV4), has dosed the first patient in the intravenous monotherapy arm of the Phase 1 clinical trial.

Known as OASIS, the first-in-class 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, 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 include onCARlytics combined with CD19 targeting bispecific monoclonal antibody blinatumomab (marketed as Blincyto® by Amgen).



onCARlytics has the potential to target and eradicate solid tumours that otherwise cannot be treated with Blincyto® therapy alone.

OASIS is a dose escalation trial being conducted in the United States, with the first IV patient dosed at City of Hope in California. Additional sites are expected to open for recruitment across the US with 52 patients proposed to take part in the trial.

Imugene Managing Director and CEO Leslie Chong said: “We’re pleased to see onCARlytics continue to advance in the clinic after the first patient on the trial was dosed in late October, and this move into intravenous administration marks another milestone in our mission to bring innovative cancer treatments to patients in need. With the combination arm of the study still to come, we eagerly await the chance to see more on the potential onCARlytics holds.”

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.