

ASX Announcement

Phase 1 clinical trial opens with onCARlytics CD19 virus technology

- **First patient dosed in Phase 1 trial**
- **Therapy seeks to turn and render solid cancers visible & vulnerable, to attack from approved CD19 drugs such as Amgen’s Blincyto[®], Gilead’s Yescarta[®] and in the future, Imugene’s azer-cel**
- **World-first for clinical trial initiation of a CD19 oncolytic virus combination with a CD19 drug**
- **Clinical trial being conducted at City of Hope in California and multiple sites across the U.S.**

Sydney, Australia, 26 October 2023: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, is pleased to announce that its CD19 oncolytic virotherapy drug candidate onCARlytics, has commenced a Phase 1 clinical trial, with the first patient now dosed.

The first-in-class Phase 1 clinical trial of onCARlytics (on-CAR-19, CF33-CD19 HOV4), known as OASIS, is being conducted in patients with solid tumours and 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>

When combined with the CD19 targeting bispecific monoclonal antibody blinatumomab (Blincyto[®] Amgen), onCARlytics has the potential to target and eradicate solid tumours that otherwise cannot be treated with Blincyto[®] therapy alone.

The clinical trial, for adult patients with advanced or metastatic solid tumours, aims to evaluate the safety and efficacy of two routes of administration, intratumoral (IT) injection and intravenous (IV) infusion, either alone, or in combination with blinatumomab.



The study is a dose escalation trial and is being conducted in the United States.

The first patient with ovarian cancer has been dosed at City of Hope's NCI-Designated Comprehensive Cancer Center in Duarte, California, USA.

Imugene Managing Director and CEO Leslie Chong said: "This is a milestone we've been eagerly anticipating, given the encouraging signs we have seen from the pre-clinical work performed to date. We believe onCARlytics may provide a new solution for clinicians treating solid tumours that have previously been untreatable using CD19-targeting biological drugs, and we hope our technology can bring much needed relief to patients in want of new treatments."

I am particularly pleased with the speed at which our team drove the pre-clinical data from a novel therapy, into a Phase 1 trial in a little over two years, and reflects the enthusiasm for this promising therapy, from all involved."

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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.