

ASX Announcement

Imugene Phase 1 onCARlytics trial doses first patient in Intravenous (IV) combination arm

- Dosed the first patient with cholangiocarcinoma, or bile tract cancer, in the intravenous (IV) infusion combination arm of the trial 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 40-45 patients with advanced solid cancers that have spread
- Subject to the rate of patient enrolment, preliminary early combination data are expected in the fourth quarter of 2024
- World-first onCARlytics trial designed to convert hard-to-treat “targetless” tumors to CD19-expressing solid tumors that can be targeted

Sydney, Australia, 24 June 2024: Imugene Limited (ASX: IMU), a clinical stage immuno-oncology company, announced that its CD19 oncolytic virotherapy drug candidate onCARlytics (CF33-CD19), has dosed the first patient in the intravenous (IV) infusion combination arm of the Phase 1 clinical trial.

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.

Imugene Managing Director & CEO Leslie Chong said: “We are pleased to enroll the first IV combination patient and further advance our OASIS trial, which combines our CD19 oncolytic virus with the already approved and marketed CD19 bispecific in patients with advanced solid cancers. While CD19 has been a powerful target for blood cancers, no



such targets currently exist for solid cancers. We aspire to change that with onCARlytics, which causes cancers to display CD19 on their cell surface so that an approved CD19 therapeutics can target and kill the cancer. If successful, onCARlytics could open up 90 percent of the market as CD19 products are only approved in blood cancer and provide a new treatment option for patients with solid tumors.”

OASIS is currently being conducted at three sites in the U.S. (City of Hope, University of Cincinnati, and MD Anderson Cancer Center), with the potential to open a total of 10 sites to recruit approximately 40-45 patients with advanced solid cancers that have spread. The primary objective of the trial is to evaluate the safety and efficacy of onCARlytics, either by IT injection or IV infusion, either alone, or in combination with blinatumomab. In February, the first patient with bile tract cancer was dosed in the IV monotherapy arm of the trial at City of Hope in California. Subject to the rate of patient enrolment, preliminary early combination data are expected in the fourth quarter of 2024.

CD19 has been a powerful target for blood cancers, which make up around 10% of all cancers. Solid cancers like breast, lung, gastric, and colon, etc. do not have a common target on their cell surface and so the goal of onCARlytics is to present a target for CD19 therapies. onCARlytics is a CD19 oncolytic virus that enters solid tumor cells and causes them to display a marker or protein on the surface of the cancer cell called CD19, thus making the cancer cell a target for already approved CD19-targeting drugs, such as blinatumomab, that kill blood cancers with CD19 targets on their cells. If successful, onCARlytics could open up 90% of the cancer market and allow CD19 therapies to become an option to treat patients with solid tumors (valued at ~USD\$532B by 2032¹).

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>

1. <https://www.precedenceresearch.com/solid-tumor-cancer-treatment-market>



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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.