

ASX Announcement

## Imugene Enhances Portfolio with Compelling Oncolytic Virus from City of Hope, a Cancer Centre in Los Angeles, California

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- FDA Investigational New Drug (IND) package
- Worldwide, exclusive licence with long patent life
- Phase 1 clinical trial anticipated to commence in 2020
- Ex-Viralytics members part of project team for development of the oncolytic virus

**Sydney, 15 July 2019:** Australian immuno-oncology company Imugene Ltd (ASX:IMU), today announced that it would acquire Vaxinia Pty Ltd and separately acquire a worldwide exclusive license to a promising oncolytic virus technology, known as CF33, developed at City of Hope, a world-renowned independent research and treatment centre for cancer, diabetes and other life-threatening diseases based in Los Angeles, California.

CF33 is a chimeric vaccinia poxvirus from the lab of Professor Yuman Fong, Chair of Surgery at City of Hope, and a noted expert in the oncolytic virus field.

Oncolytic viruses (OVs) are designed to both selectively kill tumour cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

OVs have the potential to transform oncology by directly causing tumour cell death, and also by delivering a potent payload in a targeted fashion that activates the immune system.

Imugene's CEO, Ms Leslie Chong said " we are delighted to be able to licence such a promising next generation oncolytic virus in a competitive market place where big pharma companies are actively seeking OV technologies. CF33 comes with robust intellectual property and long patent life, compelling pre-clinical efficacy and safety, and is anticipated to enter a Phase 1 clinical trial in 2020."

OVs are attracting the serious attention of big pharma companies such as Merck, Boehringer Ingelheim and Janssen which have made three acquisitions in 2018 alone totalling over \$1.0 billion, including former ASX-listed company Viralytics.

"Further, the opportunity to separately engage with members of the ex-Viralytics team through Vaxinia was cogent for Imugene, and brings to Imugene senior executives with direct involvement in two of the

largest OV transactions in biotech history being Amgen's acquisition of Biovex for USD\$950 million and Merck's acquisition of Viralytics for A\$502 million." Ms Chong added.

A Phase 1 clinical trial in 30 patients with advanced solid tumors is expected to commence in 2020 across a number of US cancer centres.

### **Licence agreement**

Under the terms of the licence agreement, Imugene acquires the exclusive world-wide rights to develop and commercialize the CF33 OV, for which it has agreed to pay City of Hope license fees comprising an upfront, annual maintenance fees which are creditable against future royalty payments, performance based consideration linked to the achievement of certain value-inflection development milestones and commercial outcomes, as well as net sales based royalty payments, and sublicensing fees.

All upfront cash payments under the Licence Agreement will be funded through Imugene's existing cash reserves.

### **Vaxinia Pty Ltd**

As part of the overall transaction, Imugene has entered into a binding agreement to acquire 100% of the shares held in Vaxinia, whose major shareholder is Paul Hopper, Imugene's Executive Chairman.

Completion of the acquisition is subject to a number of customary conditions precedent, and shareholder approval at a general meeting to be convened shortly.

The transaction, includes an up-front cash payment of \$462,500 and the issue of ordinary fully paid Imugene shares valued at \$1.619 million based on the seven day VWAP prior to this announcement.

The shareholders of Vaxinia, which include inter alia, Imugene's Chairman Paul Hopper, City of Hope's Chair of Surgery and Professor Yuman Fong, the CF33 inventor, and an ex-Viralytics executive, will be eligible for further payments in equity on the achievement of performance -related milestones (unless an earlier change of control event for Imugene occurs, at which time the outstanding shares payable under the remaining milestones will vest). These milestones include granting of the Investigational New Drug (IND) by the FDA, dosing the first patient in a Phase 1 clinical trial, and the Phase 1 clinical trial demonstrating safety, and will be further detailed in the Notice of Meeting to be mailed to shareholders shortly.

All shares issued as consideration to the Vaxinia shareholders will rank equally with existing Imugene shares and will be subject to voluntary escrow for a period of six months from the date of issue.

The decision to acquire Vaxinia was made by the independent directors of Imugene, with Paul Hopper recused from the process given he is a beneficiary of the transaction via his shareholding in Vaxinia.

All upfront cash payments under the share sale agreement will be funded through Imugene's existing cash reserves.

Completion under the licence agreement and share sale agreement are conditional upon each other. The completion date for the transaction is expected to be in early September 2019.

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### **About the CF33 Oncolytic Chimeric Poxvirus**

Oncolytic virotherapy (OV) utilizes naturally occurring or genetically modified viruses to infect, replicate in, and kill cancer cells, while sparing healthy cells. The first OV for human therapy was recently approved by the US Food and Drug Administration (FDA): T-VEC (talimogene laherparepvec, Amgen), for the treatment of metastatic melanoma. Intriguingly, many cancer cell characteristics that lead to chemo- and radiation-resistance enhance the success of oncolytic virotherapy

CF33 is a chimeric poxvirus derived through recombination among multiple strains of vaccinia virus and other species of poxvirus, thus it is better than a virus based on a single strain. One hundred chimeric orthopoxviruses and 100 chimeric parapoxviruses were generated.

Preclinical data has demonstrated that CF33 is more efficacious than all parental viruses and some viruses in clinical trials.

CF33 efficiently shrank injected tumours and distant non-injected tumours in human triple negative breast cancer, colon cancer, ovarian cancer xenograft models in mice without adverse effects at a dose that is 2-5 orders of magnitude lower than doses used for oncolytic viruses under clinical testing.

Especially impressive is that CF33 can shrink multiple types of cancer at an extremely low dose (1000 PFU). Importantly, CF33 shrinks not only injected tumours, but also non-injected distant tumours (abscopal effect).

CF33 showed superior replication and cancer cell killing in NCI-60 cell lines and is more potent than all the parental and competitor viruses in most of the NCI-60 cell lines except for a few cell lines in which none of the viruses showed any effect at the low MOI (0.01).

## 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 tumors. 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 product pipeline 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. 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.