ASX Announcement

CF33 Oncolytic Virus Clinical Trial Program Update

SYDNEY Australia 21 October 2019: Imugene Limited (ASX: IMU) is pleased to provide an update on the preliminary clinical development plan (CDP) for the proposed exclusive license of the patents covering the CF33 oncolytic virus technology, which is subject to shareholders' approval at an Extraordinary Meeting of Shareholders to be held on 18th November 2019.

The CF33 oncolytic virus (OV) was developed in the lab of Professor Yuman Fong, an internationally recognised surgeon and scientist at City of Hope, a world-renowned independent research and treatment centre for cancer, diabetes and other life-threatening diseases based in California.

CF33 has been developed in two different constructs: one version of the OV is "armed" with an immune checkpoint inhibitor inserted in the virus, which is known as CheckVacc; and the other an unarmed construct, known as Vaxinia.

It is planned by Imugene that two separate Phase 1 clinical trials will be conducted in 2020 to test a CheckVacc construct and a Vaxinia construct of the OV.

1. CheckVacc

Pre-clinical studies conducted at City of Hope by Professor Fong have shown encouraging results in triple negative breast cancer (TNBC) when CF33 is combined with an immune checkpoint inhibitor (ICI), specifically a PD-L1 inhibitor to yield CheckVacc. TNBC is an aggressive subtype of breast cancer affecting 20% of breast cancer patients with poor prognosis upon diagnosis of metastases, largely due to lack of effective targeted therapy.

Immune check point inhibitors have shown efficacy in TNBC's. In March 2019 the FDA approved Genentech's, member of the Roche group, PD-L1 ICI Atezolumumab (Tecentriq) for TNBC. Immune checkpoint blockade has shown great promise as novel class of drugs to treat certain types of advanced cancers in the last 5 years. Yet only a limited percentage of cancer patients achieve objective clinical responses through ICI treatments, leaving significant room for improvement partly due to complicated regulatory circuits of immune functions in cancer. Professor Fong's preclinical studies have shown that CF33/ICI combinatorial therapy may be applicable to a much wider population of cancer patients [1].

The Phase 1 trial commencing in 2020 will be an open-label, dose-escalating, non-randomized, single-center phase 1 study of CheckVacc administered intratumorally in patients with metastatic TNBC with injectable metastatic lesions. The purpose of the study will be to evaluate the safety and initial evidence of efficacy of the CF33-antiPDL1 combination oncolytic virus against TNBC.

2. Vaxinia

The impressive activity of the CF33 oncolytic virus Vaxinia has been demonstrated in multiple solid tumour types in validated invivo models of pancreatic [2], colorectal [3], lung [4], TNBC [5] and colon [6] cancers. Importantly, Vaxinia outperforms the industry leading OV's from Amgen and Genelux. Vaxinia is more potent than its competitors and a strong advantage is the level of dosing required, at least in preclinical animal models, is much lower.

The Phase 1 MAST (Mixed Advanced Solid Tumors) trial commencing in 2020 will be an FDA IND Imugene sponsored open-label, dose-escalating, non-randomized, multi-center (including Australian hospitals) phase 1 study of Vaxinia administered intratumorally or intravenously in patients with solid tumors (lung, TNBC, melanoma, bladder, GI) The purpose of the study will be to evaluate the safety and initial evidence of efficacy of the CF33 Vaxinia oncolytic virus against solid tumors.

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Appendix

Professor Fong and his world-class researchers at City of Hope have published widely in the past 18 months on their invention of the CF33 family of oncolytic viruses. All references cited below are from peer-reviewed, high-impact medical journals.

References

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3. O'Leary MP, Warner SG, Kim SI, Chaurasiya S, Lu J, Choi AH, Park AK, Woo Y, Fong Y, Chen NG. **A Novel Oncolytic Chimeric Orthopoxvirus Encoding Luciferase Enables Real-Time View of Colorectal Cancer Cell Infection**. Mol Ther Oncolytics. 2018, 22;9:13-21
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5. Choi AH, O'Leary MP, Lu J, Kim SI, Fong Y, Chen NG. **Endogenous Akt Activity Promotes Virus Entry and Predicts Efficacy of Novel Chimeric Orthopoxvirus in Triple-Negative Breast Cancer**. Mol Ther Oncolytics. 2018, 5;9:22-29.
6. Warner SG, Kim SI, Chaurasiya S, O'Leary MP, Lu J, Sivanandam V, Woo Y, Chen NG, Fong Y. **A Novel Chimeric Poxvirus Encoding hNIS Is Tumor-Tropic, Imageable, and Synergistic with Radioiodine to Sustain Colon Cancer Regression**. Mol Ther Oncolytics. 2019, 11;13:82-92.

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 a proposed exclusive license of an oncolytic virotherapy (CF33) subject to shareholders approval at the EGM scheduled for 18 Nov, 2019, 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.