

Aussie immuno-oncology firm Imugene bolsters pipeline with oncolytic virus acquisition

By Tamra Sami, Staff Writer

PERTH, Australia – Australian immuno-oncology company Imugene Ltd. signed a deal to in-license an oncolytic virus known as CF33 from the City of Hope Comprehensive Cancer Center in Los Angeles, in a move to bolster its pipeline and open up a new area of growth for the company, said CEO Leslie Chong.



Leslie Chong,
CEO, Imugene

Oncolytic viruses (OVs) are designed to selectively kill tumor cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival. The OV has potential applications across many cancers, including combination therapy with PD-1, PD-L1 and CTLA4 checkpoint inhibitors or with engineered immune cells.

OVs are attracting serious attention of big pharma companies such as Merck & Co. Inc., Boehringer Ingelheim GmbH

and Johnson & Johnson's Janssen unit, which have made three acquisitions in 2018 alone totaling more than \$1 billion, including Australian Viralytics Ltd., Chong said during a conference call Monday announcing the deal.

"CF33 comes with robust intellectual property and long patent life, compelling preclinical efficacy and safety, and is anticipated to enter a phase I clinical trial in early 2020," Chong said.

Under the licensing agreement, Imugene gains worldwide exclusive rights to develop and commercialize CF33, a chimeric poxvirus, for which it has agreed to pay City of Hope license fees comprising an up-front payment, annual maintenance fees that are creditable against future royalty payments, and performance-based development and commercial milestones, as well as sales-based royalty payments and sublicensing fees. Exact terms of the deal were not disclosed.

All up-front cash payments under the agreement will be funded through Imugene's existing cash reserves.

Deal includes Vaxinia acquisition

As part of the deal, Imugene will acquire 100% of the shares held in Vaxinia Inc. The shareholders of Vaxinia, which include

Imugene Chairman Paul Hopper, who is also former founder of Viralytics, along with 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.

The transaction includes an up-front cash payment of AU\$462,500 (US\$325,191) and the issue of ordinary fully paid Imugene shares valued at AU\$1.619 million.

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

The Vaxinia team are all ex-Viralytics team members. Merck acquired Viralytics for AU\$502 million (US\$394 million) in 2018. Viralytics developed Cavatak (CVA-21), an immunotherapy based on an OV coxsackievirus A21 formulation. (See *BioWorld*, Feb. 22, 2018.)

The opportunity to engage with members of the ex-Viralytics team through Vaxinia was also a big pull for Imugene, Chong said.

Analysts agreed. "This deal is of particular note given the Executive Chairman Paul Hopper was the Chairman of [Viralytics]. While we believe there to be significant upside potential from an investment in IMU, there remains significant risks," IIR said in a same-day research note.

CF33 is a chimeric poxvirus derived through recombination among multiple strains of vaccinia virus and other species of poxvirus. Vaccinia is a genetically stable double stranded DNA virus of the *Poxviridae* family. It has a track record of safe use as it was the active constituent of the vaccine that eradicated smallpox.

"CF33 is a virus that infects almost every cancer we've tested it against. It's a virus that kills cancers at much lower doses than anything that is currently in human testing. It allows us to insert genes that express proteins to make the cancer more immunogenic so the immune system can recognize it better," said Fong.

The virus efficiently shrank injected tumors and distant non-injected tumors in human triple-negative breast cancer, colon cancer, and ovarian cancer xenograft models in mice without adverse effects.

ISO a nimble biotech that knows OV's

During the Q&A segment, one investor asked how a small Aussie biotech could make such an acquisition when big pharma is actively pursuing these types of assets.



Yuman Fong, chair of surgery, City of Hope

Fong said he wasn't looking for a big pharma buyer because "big pharma has certain ways of moving things forward that are not always in the best interest of the field."

"I was looking for a smaller company that was more nimble about moving things forward, and a team that actually understands oncolytic viruses, because doing studies with oncolytic viruses is different than doing studies with drugs and small molecules and chemotherapies. You don't always have

to give the highest dose to have an effect; you don't have to track how much stays in the bloodstream in order to make it work because that's not where it does its job," he said.

CEO Chong said that the move diversifies the pipeline for shareholders and that Imugene has enough capital to get it through its clinical programs.

"Imugene has a platform in immuno-oncology, so now we have a plethora of items that will give us more shots on goal," she said.

The biotech is developing a pipeline of mimotope-based B-cell peptide vaccines against oncology targets that could replace or be used in combination with monoclonal

antibodies. The company hopes to be the first biotech out of the gate with its B-cell peptide vaccines in the immuno-oncology space.

Lead candidate B-cell peptide vaccine HER-Vaxx (IMU-131) was designed to treat tumors that overexpress HER2 such as gastric, breast, ovarian, lung and pancreatic cancers.

A phase Ib HER-Vaxx study in patients with HER2-positive metastatic gastric cancer completed enrollment in 2018 and met all its primary endpoints. The study is ongoing with patients continuing to receive HER-Vaxx every three months to maintain high levels of cancer-targeting antibodies.

A phase II study began in March 2019 dosing patients with HER2-positive metastatic gastric cancer at the highest phase Ib dose. Results from the phase II study are due to be complete in 2020.

Imugene plans to conduct combination studies in breast cancer with HER-Vaxx and Herceptin (trastuzumab, Roche Holding AG). Other indications could include bladder, ovarian and non-small-cell lung cancers. (See *BioWorld*, Jan. 22, 2018.)

"The CF33 acquisition strengthens Imugene's immuno-oncology pipeline, which is currently focused on B-cell vaccines. As the CF33 deal is a related party transaction and therefore contingent on shareholder approval, we maintain our published valuation of AU\$159 [million] or AU4.4 cents per share," Edison Research said in a same-day research note.

The company's market cap is roughly AU\$58 million. Imugene shares were trading on the Australian Securities Exchange (ASX:IMU) at AU1 cent on the news. ♦