



ABL and Imugene partner to advance oncolytic virus candidate towards later phase clinical trials

- Process optimization and manufacturing collaboration will advance development of candidates based on Imugene's chimeric pox vaccinia platform CF33 up to later phase clinical trials
- Partnership further confirms ABL's expertise in handling GMP vaccinia-based oncolytic viruses

Rockville, Maryland, US, and Sydney, Australia, October 18, 2022 – ABL, a pure play Contract Development and Manufacturing Organization (CDMO) with specialized expertise in the development and manufacturing of solutions for biopharma including viruses for gene therapies, oncolytic viruses and vaccine candidates, and Imugene (ASX: IMU), a clinical stage immuno-oncology company developing a range of new treatments that seek to activate the immune system of cancer patients to identify and eradicate tumors, today announce their partnership. ABL will manufacture Imugene's oncolytic virus for its MAST (Metastatic Advanced Solid Tumors) clinical studies evaluating the safety and efficacy of the novel cancer-killing virus CF33-hNIS (VAXINIA).

ABL has a strong background in handling a broad range of viruses, such as vaccinia, which require work under BSL-2 environments and aseptic conditions. Through this collaboration, Imugene will gain access to ABL's top-of-the-line CDMO services, providing a true end-to-end solution with comprehensive analytical support, GMP manufacturing of vaccinia viruses and fill-finish of the drug product, with customizable and flexible development and manufacturing solutions.

Imugene has started the clinical development of its oncolytic virus candidates VAXINIA and CHECKVacc (CF33-hNIS-antiPDL1). These are based on the chimeric pox vaccinia platform CF33, invented by Professor Yuman Fong, chairman of Sangiacomo Family Chair in Surgical Oncology at the City of Hope Cancer Center in California (US). The City of Hope has shown that the oncolytic virus it developed can shrink colon.lung.breast, ovarian and pancreatic cancer tumors in preclinical laboratory and animal models.

"Reliability of drug supply is a major hurdle for the clinical development of many modern biological oncology drug candidates. De-risking this critical component of clinical development by working with ABL is a significant milestone for Imugene," said Leslie Chong, managing director and CEO of Imugene.

"ABL is honored to have Imugene's trust and to enter into a long-term partnership for the development and manufacturing of CF33, a new generation of oncolytic virus, for its later phase clinical trial plans," said Thierry Van Nieuwenhove, CEO of ABL.

"We look forward to working with Imugene in this collaborative partnership based on openness and transparency. This deal strengthens ABL's reputation as a leading service provider of GMP vaccinia-based oncolytic viruses," said Karim Pirani, strategic business development at ABL.

Access to clinical drug product supplies which match and pair the clinical trial development plans with the regulatory requirements of phase II/III and registrational trials is a critical component of drug development. Imugene first used the City of Hope's Center for Biomedicine and Genetics (CBG) for its phase I trial. However, to support its future drug product supply needs, that require an ample drug supply for extended later phase clinical trials, it selected ABL, a CDMO that can provide added expertise and scale.





Imugene plans to work with ABL as a partner of choice over the long-term, remaining active throughout the entirety of the CF33 platform's life cycle. Imugene is currently transferring to ABL its technology for the manufacturing and analytical processes. ABL will then deliver the first phase of the project with a cGMP batch of VAXINIA targeted to be manufactured and released in 2023.

Oncolytic viruses are designed to selectively kill tumor cells, while activating the immune system against cancer cells, with the potential to improve clinical response and survival. The rise in cancer around the globe and increased investment in R&D for effective therapies are driving the expansion of the oncolytic virus therapy market.

Effective immediately, under the terms of the agreement the collaboration is funded from existing budgets and resources. The agreement is for a five-year term, noting that the delivery of the first clinical batch of VAXINIA is anticipated within 12 months. It includes customary termination and intellectual property provisions for a contract manufacturing agreement.

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 tumors, 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, such as CAR-T for solid tumors. Imugene is supported by a leading team of international cancer experts with extensive experience in developing new cancer therapies, with many approved for sale and marketing in global markets.

The company's 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, Imugene believes that its immuno-oncology therapies will become foundation treatments for cancer. Its goal is to ensure that Imugene and its shareholders are at the forefront of this rapidly growing global market. www.imugene.com

About ABL, an Institut Mérieux company

ABL is a pure play Contract Development and Manufacturing Organization (CDMO) specialized in the development and manufacturing of gene therapies, oncolytic viruses and vaccine candidates. ABL's mission is to provide GMP viral vectors from early-stage to market, contributing to the success of its clients' immunotherapy and gene therapy innovations. ABL's CDMO services include manufacturing of bulk drug substance, fill-finish of drug products, process and assay development, bioanalytical testing and regulatory support.

ABL is a subsidiary of the Institut Mérieux. It operates from various locations in Europe and the US.

www.abl-biomanufacturing.com





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