
PsiVac and Lonza Enter a Strategic Agreement for the Process Development and cGMP Manufacturing of Ixovex-1

- The strategic agreement covers process development and cGMP manufacturing of Ixovex-1, a unique patented oncolytic virus designed to address key limitations of first- and second-generation oncolytic viruses and to provide personalized therapy for cancer patients
- PsiVac grants Lonza the exclusive right to cGMP manufacture Ixovex-1
- Process development activities started at Lonza's Houston facility, and a phase 1 clinical trial is planned for Q2 2022

Imad Mardini, Chief Operating Officer, PsiVac:

"We are delighted to collaborate with Lonza recognizing their team of experts who will lead the process development and GMP manufacture of Ixovex-1, a highly potent next-generation, tumor-selective oncolytic virus that can be used in a wide variety of solid tumors".

Ghassan Alusi, Founder and Chairman, PsiVac:

"This marks another key milestone in the development of Ixovex-1 and brings greater hope to patients through the life-saving potential of this unique oncolytic virus."

Alberto Santagostino, SVP, Head of Cell & Gene Technologies, Lonza:

"PsiVac's radical new approach to introducing a critical single base pair mutation to create viruses, rather than engineer the viral genome, holds the promise to deliver a step-change in efficacy and enhanced safety for patients. Our process development expertise and manufacturing capabilities will support PsiVac to scale and produce Ixovex-1 to demonstrate this science through a clinical trial."

London, UK and Basel, Switzerland, 8 February 2021 – PsiVac, a subsidiary of Ixogen; a UK biotechnology research and development company focused on the development of new therapeutic cancer treatments for solid tumors, and Lonza, a world leader in contract manufacturing, today announced their agreement for the process development and cGMP manufacturing of Ixovex-1.

Under the terms of the parties' strategic agreement, PsiVac will grant Lonza the exclusive right to cGMP manufacture the Ixovex-1 product.

Ixovex-1 is the first patented adenovirus with a single base pair mutation, enabling the creation of highly selective viruses that replicate rapidly. To gain patent protection, other oncolytic viruses have been engineered to add or delete part of the viral genome to achieve selectivity for tumor cells, which has been found to weaken replication efficiency. Ixovex-1 has no insertion or deletion, making this therapy a unique and highly effective oncolytic virus.

In preclinical trials, PsiVac demonstrated that the replication of Ixovex-1 was significantly attenuated in healthy cells, suggesting this virus will be safer than more traditional oncolytic viruses. PsiVac has also generated compelling efficacy data in killing a broad range of tumor cells, including head and neck, bladder, liver, pancreatic and ovarian, suggesting that it could have potential utility in a wide range of solid tumor indications.

Having shown that Ixovex-1 is safe, powerful, and replication efficient, PsiVac is now ready to move to human clinical trials. Lonza has carried out successful small-scale feasibility production studies, paving the way for upscaling and GMP production.

The process development activities were initiated at Lonza's Houston (USA) facility. A phase 1 clinical trial for Ixovex-1 is planned for Q2 2022.

About Lonza

Lonza is the preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to prevent illness and enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. These enable our customers to commercialize their discoveries and innovations in the healthcare sector.

Founded in 1897 in the Swiss Alps, today Lonza operates across three continents. With approximately 14,000 full-time employees, we are built from high-performing teams and of individual talent who make a meaningful difference to our own business, as well as to the communities in which we operate. The company generated sales of CHF 4.5 billion in 2020 with a CORE EBITDA of CHF 1.4 billion. Find out more at www.lonza.com.

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About PsiVac

PsiVac is a UK based Research & Development Biotechnology Company founded in 2019 by Professor Ghassan Alusi who recognized the need for dramatically more effective therapies to treat patients that suffered from Head and Neck Cancers and other solid tumours generally.

Today PsiVac is a preclinical stage company pioneering the next generation of oncolytic virus therapy to improve the treatment of patients with cancer with exclusive rights to a patented modified adenovirus derived from the common cold virus. In preclinical studies, Ixovex-1 has demonstrated high efficacy and an impressive safety and tolerability profile. The PsiVac team is supported by a preeminent Scientific Advisory Board and are excited to commence their Phase I studies. Find out more at www.psivac.com.

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