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New Kit Predicts Retroviral Particle Clearance in Biopharmaceutical Manufacturing

SOUTHPORT, N.C., Nov. 07, 2022 (GLOBE NEWSWIRE) -- [Cygnus Technologies](#), part of Maravai LifeSciences (Maravai) (NASDAQ: MRVI), the leading assay and services provider for the detection and characterization of process-related impurities in biopharmaceuticals, announced today the launch of the MockV® RVLP Kit. This kit enables bioprocess scientists to quantify the removal of Retrovirus-Like Particles (RVLPs) produced endogenously by Chinese Hamster Ovary (CHO) cell lines during biopharmaceutical manufacturing. The kit includes a highly purified and concentrated stock solution of RVLPs along with the necessary reagents for accurate and reliable RVLP quantification.

Viral contamination is an inherent risk during the manufacture of biopharmaceutical products such as antibodies, gene therapies, vaccines, and plasma derivatives. Whether introduced initially from raw materials or later through specific manufacturing operations, unmitigated viral contamination has led to serious health implications and plant shutdowns. Global regulatory agencies require sponsoring companies to validate the viral clearance efficacy of their purification process steps prior to clinical trials or regulatory approval.

Cygnus's MockV® technology addresses the barriers imposed by live viral clearance studies through the novel and patent-protected use of viral surrogates, or "Mock Viral Particles (MVPs)". MVPs are engineered to mimic the physical and chemical characteristics of viruses but are themselves non-infectious. They can therefore be handled safely and easily to predict the outcomes of CRO-led spiking studies early in process development. In this way, Cygnus's MockV® technology can play an important role in helping biopharmaceutical companies develop manufacturing processes that effectively remove viral contamination, leading to the production of safe biotherapeutics.

Cygnus's MockV® RVLP Kit is the second product line in the MockV® portfolio and the first introduced since the acquisition of MockV Solutions by Maravai in 2020. The stock solution of RVLP provided by this kit contains an actual non-infectious retrovirus-like contaminant generated during CHO production. In the early 1990s, global regulatory agencies such as the FDA realized the prevalence of this particle and became concerned about the retroviral safety of CHO-derived biopharmaceuticals. Since then, the biopharmaceutical industry has relied on CROs to propagate Xenotropic Murine Leukemia Virus (XMuLV) as a model retrovirus to demonstrate effective clearance. With the availability of the MockV® RVLP Kit, biopharmaceutical companies can now independently assess the removal of the original retroviral particle of regulatory concern, derived directly from CHO cells.

Christine Dolan, Cygnus Technologies Chief Operating Officer, commented, "We are

tremendously excited to launch this highly anticipated viral clearance kit within our MockV® product line. This launch is the culmination of significant innovation and thoughtful application by the product line inventor, David Cetlin and his team.” Cetlin added, “The RVLP Kit addresses an unmet need for the industry to perform these studies in their own lab and on their timeline. Our vision is that the data our customers will generate through the use of this kit will influence their process development and optimization decisions, ultimately leading them to more effective viral clearance process steps.”

About Cygnus Technologies, LLC

Cygnus Technologies, part of Maravai LifeSciences, is the biopharmaceutical industry’s partner in host cell protein (HCP) and other process-related impurity detection and analytics as well as in innovative viral clearance solutions. Cygnus helps companies developing therapeutic proteins, vaccines, antibodies, plasma derivatives and gene therapies to ensure the safety of biotherapeutics prior to human trials, regulatory approval and commercial release. For more information on Cygnus Technologies, please visit

www.cygnustechnologies.com

About Maravai

Maravai is a leading life sciences company providing critical products to enable the development of drug therapies, diagnostics and novel vaccines. Maravai’s companies are leaders in providing products and services in the fields of nucleic acid synthesis and biologics safety testing to many of the world’s leading biopharmaceutical, vaccine, diagnostics, and cell and gene therapy companies.

For more information about Maravai LifeSciences, visit www.maravai.com.

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