Microbialtec Developed An E. coli Production Platform for A Variety of GMP Products

New York City, New York May 8, 2023 (<u>Issuewire.com</u>**)** - Microbialtec, the division of Creative Biogene, specialized in supplying customers with an overall microbiological research program: including sample collection, preservation methods, preliminary experiments and effect evaluation, experiments and data analysis. Creative Biogene is dedicated to assisting researchers in exploring the hidden mysteries between microbes and health, production and the environment to make better use of microbial resources. Recently, Microbialtec announced the release of its comprehensive services in the design, optimization, scale-up and GMP manufacturing of products based on all production strategies using E.coli to support microbial research.

E. coli is a powerful expression system for the production of proteins and plasmid DNA for clinical and commercial human use. Proteins can be made using well-characterized production systems that are relatively cost-effective and readily scale up by fermentation of rapidly growing cells in bioreactors.

Microbialtec provides comprehensive services in product design, optimization, scale-up and GMP manufacturing according to all production strategies using E. coli: soluble cytoplasm, soluble periplasm and inclusion bodies. cGMP E. coli production services include primary and working cell bank services from cell line production to cryogenic storage, fermentation batch/fed-batch and perfusion, single-use/single-use systems to provide higher quality and more flexible services, downstream purification technologies including homogenization, continuous centrifugation, filtration systems, and chromatographic purification systems.

Microbialtec has developed E. coli production platforms for a variety of GMP products that allow for easier interpretation of data and earlier use of optimized methods:

GMP plasmids are highly scalable to manufacture gram-to-kilogram quantities of plasmids for use as starting material for DNA vaccines, non-viral gene therapy, or viral vector production.

GMP Proteins has extensive experience in producing and purifying recombinant proteins for human use to meet customer needs.

Experience with multiple strategies (e.g., pegylation, chemical conjugation to extend half-life) in conjugating peptides, proteins, polysaccharides, and PEG to form recombinant proteins for use in humans.

Creative Biogene has extensive experience and extensive expertise in the use of E. coli to manufacture recombinant proteins, whole-cell vaccines, viral vaccines and live biotherapeutics. Microbialtec provides comprehensive solutions for biologic and small molecule pharmaceuticals, utilizing licensing processes and technologies that comply with international current Good Manufacturing Practice (cGMP) standards. By employing cGMP fermentation procedures, Microbialtec integrates quality into every stage of the manufacturing process, ensuring compliance with regulatory requirements for safety, product identity, quality and purity, and can provide batch systems of cGMP material produced in a range of microbial expressions.

"Creative Biogene offers expert cGMP manufacturing using E. coli and yeast, and our upcycling and manufacturing of our customers' biotherapeutic products is cGMP compliant." said Marcia Brady, the

marketing director of Creative Biogene, she also added, "Our licensed facility is ready to meet the relevant downstream processing and purification in cGMP."

About Microbialtec

As a division of Creative Biogene, Microbialtec platform has an experienced technical team involving molecular biology, medicine, bioinformatics, and statistical ecology. With 10 years of front-line scientific research experience, Creative Biogene supports customers with an overall microbiological research program and is capable to satisfy customized needs at affordable prices.

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