August 13, 2019

Bio-Techne And Cygnus Technologies Announce Partnership For 3G CHO-HCP Assay

MINNEAPOLIS and SOUTHPORT, N.C., Aug. 13, 2019 /PRNewswire/ -- Bio-Techne Corporation and Cygnus Technologies, part of Maravai LifeSciences, announced today a strategic partnership for the quantification of Chinese hamster ovary host cell proteins (CHO-HCP) on the ProteinSimple™-branded Ella™ immunoassay platform. Under the terms of the agreement, Bio-Techne and Cygnus are introducing the co-developed third generation CHO-HCP assay in the proprietary Simple Plex™ immunoassay cartridge for customers in North America and Europe.

HCP measurements are critical quality-control steps in biopharmaceutical development because the presence of these impurities in the final product can potentially interfere with drug efficacy, induce an undesired immune response or impact drug stability. Regulatory authorities have provided recommendations for biopharmaceutical companies on the removal of HCPs. Biopharmaceutical manufacturers monitor HCPs to demonstrate reproducibility of their purification process, ensure HCP clearance and perform product lot release testing.

Cygnus Technologies' third generation CHO-HCP ELISA Kit has long been considered the gold standard in CHO-HCP impurity quantification. The antibody used in the kit has been evaluated for reactivity to more than 1,000 individual HCPs present in CHO strains by state-of-the-art antibody affinity extraction and mass spectrometry methods. The kit has been qualified with many drug substances and in-process samples, providing the specificity and sensitivity to detect CHO-HCP impurities with reproducibility that supports regulatory compliance.

The Ella platform allows users to perform high-quality immunoassays in 90 minutes with no manual intervention. This innovative immunoassay technology enables companies to decrease the iteration time and overhead burden of their process development.

Dave Eansor, president of Bio-Techne's Protein Sciences Segment, commented, "We are excited about this partnership as it provides the bioprocess community an automated platform-based approach for their impurity testing. Fast and efficient process development and monitoring is crucial for biopharmaceutical companies providing a safe and efficacious product in a cost-effective manner."

Ken Hoffman, founder and president of Cygnus Technologies, commented, "Many of our biopharma customers are developing more and more biotherapeutic drugs and the development of biosimilars is also on the rise. To keep up with a growing number of projects, process development and manufacturing quality control teams desire faster and higher throughput HCP impurity assays. Our partnership provides an automation solution for fast and efficient bioprocess impurity testing."

About Cygnus Technologies

Cygnus Technologies develops, manufactures and markets assay kits and related services that enable pharmaceutical and biotech companies to detect and identify host cell impurities in biotherapeutics, an important step in regulatory approval and quality control processes. With products, services and expert advice, Cygnus helps biopharmaceutical companies quickly move new therapeutics through the development and approval stages to market. With headquarters in Southport, N.C., Cygnus Technologies serves customers worldwide through a global network. Cygnus Technologies was acquired by Maravai LifeSciences in 2016.

About Bio-Techne Corporation (NASDAQ: TECH)

Contact: David Clair, Investor Relations
ir@bio-techne.com
646-227-1266

David Weber, Vice-President & Chief Commercial Officer
david.weber@maravai.com
650-292-2674

View original content to download multimedia:http://www.prnewswire.com/news-releases/bio-techne-and-cygnus-technologies-announce-partnership-for-3g-cho-hcp-assay-300900475.html

SOURCE Bio-Techne Corporation