June 24, 2025

Bio-Techne and USP Announce Collaboration to Accelerate Monoclonal Antibody and Gene Therapy Product Development

MINNEAPOLIS, June 24, 2025 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) today announced a distribution agreement with the U.S. Pharmacopeia (USP) that enables the Company to sell USP monoclonal antibody (mAb) and recombinant adeno-associated virus (AAV) reference standards with its analytical solutions, including the Maurice system, to support monoclonal antibody and gene therapy development around the world.

More than 160 antibody therapies against nearly 100 targets and range of diseases have been approved worldwide. Maintaining consistent mAb quality is vital for their efficacy. The need for consistency is becoming increasingly more important as mAb patent protections expire, and biosimilar versions of these therapies become available. This leads to a greater need for manufacturers to rigorously test critical quality attributes throughout mAb development and manufacturing processes to demonstrate product safety and effectiveness.

Separately, gene therapy, which relies on recombinant AAV to deliver gene edits into cells, is one of the fastest-growing sectors in the biopharmaceutical industry. The exceptional growth of these groundbreaking treatments offers cures to previously incurable genetic diseases; however, challenges persist in the development and commercialization processes, including low yields, scalability hurdles, high costs, and analytical complexities. USP reference standards help solve these challenges by providing well-characterized benchmarks for analytical testing, ensuring accuracy, reliability, and regulatory compliance in product development and quality control.

Importantly, both USP mAbs and AAV reference standards provide stringent materials that can be used with Bio-Techne's leading analytical instruments, such as the MauriceFlex™ system. By combining these standards with the Company's rapid, easy-to-use, and multi-functional analytics, therapy manufacturers can achieve reliable, efficient, and integrated characterization for purity, charge, size, and identity applications for complex biologics, from development through product release.

"We are excited about our work with USP. This marks a significant milestone in advancing our commitment to providing cutting-edge tools and solutions to the scientific community," said Will Geist, President of Bio-Techne's Protein Sciences Segment. "This relationship underscores our dedication to supporting advancements in biotherapeutic development and ensuring the highest standards of quality and safety for patient care."

"We are thrilled to engage Bio-Techne as an authorized distributor, which enables USP to expand access of our solutions within the scientific community and beyond, ensuring that safe and quality therapeutic products reach the market for the benefit of patients worldwide,"

said Fouad Atouf, Ph.D., Senior Vice President, Global Biologics for USP. "Through working with Bio-Techne, USP is reinforcing its commitment to addressing the most prevalent quality issues with innovative solutions, leveraging our robust framework of science-based quality standards for pharmaceutical manufacturers."

Addressing quality challenges is essential to ensure the safety and quality of biotherapeutics. Both USP and Bio-Techne have a long history of developing solutions to support mAbs and are applying their know-how to solving analytical challenges in AAV-based gene therapies. The ability to purchase USP reference standards from Bio-Techne further simplifies the method development process, enabling customers to assess system suitability and other critical criteria for charge and size based analytical assays on the Maurice system.

About Bio-Techne

Bio-Techne Corporation (NASDAQ: TECH) is a global life sciences company providing innovative tools and bioactive reagents for the research and clinical diagnostic communities. Bio-Techne products assist scientific investigations into biological processes and the nature and progress of specific diseases. They aid in drug discovery efforts and provide the means for accurate clinical tests and diagnoses. With hundreds of thousands of products in its portfolio, Bio-Techne generated approximately $1.2 billion in net sales in fiscal 2024 and has approximately 3,100 employees worldwide. For more information on Bio-Techne and its brands, please visit http://www.bio-techne.com or follow the Company on social media at Facebook, LinkedIn, Twitter or YouTube.

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