January 31, 2019

ExoDx® Prostate(IntelliScore) (EPI) Recommended in National Comprehensive Cancer Network Guidelines for Prostate Cancer Early Detection

MINNEAPOLIS, Jan. 31, 2019 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ:TECH) today announced the National Comprehensive Cancer Network (NCCN) decision to include EPI as a recommended test in their Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Prostate Cancer Early Detection (Version 1.2019).

The updated treatment algorithm includes EPI testing prior to a first prostate biopsy or after a negative biopsy to assist patients and urologists in further defining the probability of high-grade cancer and in reaching a joint decision to either proceed with a prostate biopsy or continue monitoring.

The NCCN Guidelines are the recognized clinical standard for cancer care by clinicians and payors in the United States. The guidelines are developed and revised by a panel of expert physicians from 28 leading U.S. cancer centers. The panel revises recommended practice guidelines according to current clinical evidence and advances in cancer care.

The EPI test has been studied in over 5,000 patients in the intended use population, men over 50 with a PSA result between 2 and 10. Strong results supporting the clinical diagnostic validity of the EPI test were confirmed in two large peer reviewed clinical studies published in JAMA Oncology 2016; 2(7):882-889 and European Urology 2018; 74(6):731-738. Since the EPI test's national launch at the end of 2017, it has been ordered by more than 1100 practicing urologists in the US.

By using EPI to help assess a patient's risk for high grade prostate cancer, urologists are better equipped to guide men in deciding whether an invasive prostate biopsy and related complications can be safely avoided or deferred. The US Preventative Services Task Force (USPSTF) reported there are serious side effects from biopsies including infection, diminished sexual function, incontinence, pain, hospitalization and even death. USPSTF also noted biopsies can drive treatment of low grade disease and the associated complications of treatment with no overall survival benefit for the patient.

"When we acquired ExosomeDx we knew it could be a platform that could transform the rapidly growing field of Liquid Biopsy," stated Chuck Kummeth, President and CEO of Bio-Techne. "We also felt the synergies of ExosomeDx melded remarkably well with our ACD platform (Tissue Biopsy) and our Immunotherapeutic tools like Cell Culture. The ExosomeDx team has worked extremely hard these past few years towards the news we are announcing today. These new guidelines are critical in our efforts to broaden insurance coverage, including Medicare coverage, which we are pursuing with professional rigor. Inclusion in the guidelines will also broaden patient access to the EPI test by affirming its value in men evaluating whether to proceed with a prostate biopsy. Men over 50 with an inconclusive PSA level between 2 and 10 have another course of diagnosis before yielding to a painful and risky prostate biopsy."

Kummeth continued, "This is the first diagnostic test of many using both urine and blood derived exosomes that we will seek approval for over the coming years. Our exosome driven diagnostics platform is unique in the liquid biopsy field and is positioned to become true standard of care for diagnosing, treating and monitoring cancers as well as other diseases. Our diagnostic products will enable physicians to take a more targeted and precise approach in their treatment strategies and thus improve patient outcomes while lowering overall healthcare costs."

Forward Looking Statements:

Our press releases may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act. Such statements involve risks and uncertainties that may affect the actual results of operations. The

following important factors, among others, have affected and, in the future, could affect the Company's actual results: the effect of new branding and marketing initiatives, the integration of new businesses and leadership, the introduction and acceptance of new products, the funding and focus of the types of research by the Company's customers, the impact of the growing number of producers of biotechnology research products and related price competition, general economic conditions, the impact of currency exchange rate fluctuations, and the costs and results of research and product development efforts of the Company and of companies in which the Company has invested or with which it has formed strategic relationships.

For additional information concerning such factors, see the section titled "Risk Factors" in the Company's annual report on Form 10-K and quarterly reports on Form 10-Q as filed with the Securities and Exchange Commission. We undertake no obligation to update or revise any forward-looking statements we make in our press releases due to new information or future events. Investors are cautioned not to place undue emphasis on these statements.

About Bio-Techne Corporation (NASDAQ: TECH)

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