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Bio-Techne and Nonagen Bioscience Announce Exclusive Supply Agreement for Nonagen's Oncuria® Bladder Cancer Test

MINNEAPOLIS and LOS ANGELES, May 12, 2022 /PRNewswire/ -- Bio-Techne Corporation (NASDAQ: TECH) and Nonagen Bioscience today announced an agreement for R&D Systems, a Bio-Techne brand, to exclusively manufacture Nonagen Bioscience's Oncuria® bladder cancer diagnostic panel using xMAP Luminex® technology.

Oncuria is the first-of-its-kind multiplex protein-based urine test to provide early and accurate detection, therapy choice, and disease monitoring of bladder cancer. The Luminex-based multiplex assay panel combines Bio-Techne's high-quality reagents and over 40 years of industry-leading immunoassay experience with Nonagen's diagnostic expertise to create a powerful solution to advance bladder cancer treatment strategies. The partnership demonstrates Bio-Techne's commitment to supporting laboratory developed tests (LDTs) to bring clinical diagnostic tools to the market.

Nonagen Bioscience and Bio-Techne are targeting the last quarter of calendar 2022 to make Oncuria available as an LDT.

The US Food and Drug Administration (FDA) granted Oncuria a Breakthrough Device Designation in September 2021, for predicting response to Bacillus Calmette-Guérin (BCG) therapy, a first-line treatment for bladder cancer. The designation enables close collaboration with, and expedited review of the assay by the FDA. It also provides formal acknowledgement of Oncuria's utility and potential clinical benefit.

"We're excited to partner with Bio-Techne to make Oncuria available as a laboratory developed test (LDT), given their extensive biomarker discovery expertise," said Nonagen Bioscience CEO Charles Joel Rosser, MD, MBA. "Bio-Techne also shares our passion for translating research discoveries into innovative diagnostics, to improve the detection and management of cancer."

"We look forward to working with Nonagen to develop this game-changing immunoassay in the fight against bladder cancer," said Will Geist, President of Bio-Techne's Protein Sciences division. "Nonagen's deep experience in diagnostic and testing research is complementary to Bio-Techne's extensive immunoassay expertise and world-class manufacturing capabilities, creating an ideal partnership for this important bladder cancer detection assay."

About Bladder Cancer

As the 6th most common cancer in the United States[1] and a highly recurrent disease, bladder cancer is a major health concern that places an immense burden on healthcare

systems. Up to 77% of early-stage bladder tumors that are treated with current approaches (tumor resection and/or intravesical BCG or chemotherapy) will recur.[2] More than half of patients who receive BCG therapy as the first-line treatment for bladder cancer will fail to respond. In addition, in 20% of patients, the disease grows and extends during or after BCG therapy.[3,4]

This is where the exceptional sensitivity and rapid biomarker quantification capabilities of the Oncuria diagnostic assay are poised to play a vital role. The ability to quickly and accurately detect the presence of bladder cancer and monitor disease activity can help improve patient outcomes.

About Bio-Techne
Bio-Techne Corporation (NASDAQ: TECH) is a global life sciences company that provides 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. These products also aid in drug discovery efforts, and provide the means for accurate clinical tests and diagnoses. With thousands of products in its portfolio, Bio-Techne generated approximately $931 million in net sales in fiscal 2021. The company has approximately 2,700 employees worldwide. For more information on Bio-Techne and its brands, please visit www.bio-techne.com

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About Nonagen Bioscience
Nonagen Bioscience is a privately-held biotechnology company that is focused on globally reducing the burden of cancer with innovative diagnostics. As a physician-led company, Nonagen Bioscience is committed to bringing to the market best-in-class, noninvasive diagnostics for cancer detection, therapy choice, and disease monitoring, so patients can live better, longer lives. The Los Angeles-based company was founded in 2011 and is currently developing diagnostics for bladder, breast, and prostate cancers. Learn more at www.nonagen.com

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