KDX SELECTS ACUPATH AS LAB FOR URO17™ FDA CLINICAL TRIAL

INNOVATIVE BLADDER CANCER BIOMARKER DEMONSTRATES COMPELLING CLINICAL UTILITY

PLAINVIEW, NY, UNITED STATES, November 3, 2020 /EINPresswire.com/ -- Acupath Laboratories, Inc., a leading provider of sub-specialized anatomic and molecular pathology services, and KDx Diagnostics, Inc., a leading developer of bladder cancer tests, today announced that KDx has selected Acupath to process urine specimens for a formal FDA trial that kicked off in Q3. First offered in July 2019 as an LDT (Laboratory Developed Test), Acupath was the first lab in the U.S. to offer URO17™, a cost-effective urinary biomarker that improves on and adds value to traditional non-invasive diagnostic screening tests.

Bladder cancer is the 6th most common cancer in the U.S., with 81,000 new cancer cases annually, and a 75% recurrence rate. One of the most common and inexpensive screening tests, urine cytology, is largely ineffective and pathologically subjective, with limited sensitivity and specificity.

The FDA trial currently underway will evaluate URO17™ in conjunction with urine cytology and UroVysion™ FISH (Abbott Molecular). Several prominent LUGPA (Large Urology Group Practice Association) practices from across the US are participating as trial sites.

“Since launching in July 2019, our clients and patients have benefitted from the clinical information provided by URO17™, which can serve as a valuable risk stratification tool, properly ruling in or out additional diagnostic tests”, said John Cucci, Acupath’s Chief Sales & Strategy

Officer. “We are excited about being chosen by KDx for the FDA trial, which possesses significant potential to addresses the deficiencies of current diagnostic tests.”

“We excited that a patient enrollment for our clinical study has initiated and that the Acupath is our partner in this endeavor. Following up on our recent Breakthrough Device designation by the FDA and CE marking for URO17™ test in Europe, we are moving ahead to obtain FDA clearance for this important test.” said Nam W. Kim, Ph.D., CEO of KDx.

“As one of the most expensive cancer to treat, accurate non-invasive test for bladder cancer has a significant unmet medical need. Studies continue to show high sensitivity and specificity of URO17™ in detecting bladder cancer through urine samples, confirming its clinical potential”. said Sholeh Jahanfard, President and COO of KDx.

About Acupath Laboratories, Inc.
Founded in 1998 and based in Plainview, NY (Long Island), Acupath is an in-network provider of sub-specialized anatomic pathology and molecular diagnostics, including the SARS-CoV-2 PCR test, delivering results in 24-36 hours after receipt at the lab.

About KDx Diagnostics Inc.
Founded in 2017, KDx is focused on developing diagnostic and prognostic tests to improve early detection and therapy decisions in cancer. KDx’ URO17™ bladder cancer test may be the most sensitive and specific for bladder cancer developed to date. KDx can develop tests based on the same biomarker for other platforms and sample types and plans to expand its product line both by offering new formats of the bladder cancer test as well as tests for other cancers. Additional information is available at www.URO17test.com.

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