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NeoGenomics Launches FDA-Approved PTEN IHC Companion Diagnostic for Prostate Cancer

Available within NEO PanTracer™ Pro for prostate cancer and as a standalone test, PTEN IHC CDx identifies patients who may be eligible for TRUQAP®

FORT MYERS, Fla.--(BUSINESS WIRE)-- **NeoGenomics, Inc. (NASDAQ: NEO)**, a leading provider of oncology diagnostic solutions that enable precision medicine, today announced the launch of PTEN IHC CDx, the first immunohistochemistry (IHC) companion diagnostic test approved by the U.S. Food and Drug Administration (FDA) for patients with prostate adenocarcinoma. The test identifies PTEN protein loss, also known as PTEN deficiency, in patients who may be eligible for AstraZeneca's recently approved targeted therapy TRUQAP® (capivasertib).[1]

PTEN IHC CDx extends the company's reach into urologic oncology, where community practices manage the majority of patients with advanced prostate cancer. Performed by NeoGenomics' pathologists across its national oncology laboratory network, the test is available as a standalone order or as part of NEO PanTracer™ Pro for prostate cancer, a comprehensive molecular workup that combines CGP and cancer-type-directed IHC testing in a single order built to evolve with new treatment options.

"Clinicians treating this aggressive form of prostate cancer have long needed both a targeted therapy and a validated way to identify eligible patients," said Nathan Montgomery, Vice President, Medical Services, NeoGenomics. "With PTEN IHC CDx now integrated into NEO PanTracer Pro, community oncology practices have an FDA-approved companion diagnostic available through a single national laboratory partner, reflecting our commitment to providing the tools clinicians need for timely treatment decisions when new therapies become available."

Prostate cancer is the most common cancer in men in the United States, with more than 300,000 new cases and over 36,000 deaths annually.[2] Of the approximately 35,000 patients diagnosed each year with mAPMN/S prostate cancer (formerly mHSPC), about one in four – or approximately 8,750 patients – have PTEN-deficient tumors.[2,3] PTEN protein loss is detectable through a tissue-based test at the time of diagnosis.[4]

About PTEN IHC CDx

NeoGenomics' IHC companion diagnostic assay detects PTEN protein loss in prostate adenocarcinoma tissue using the VENTANA PTEN (SP218) RxDx Assay. Authorized by the FDA to identify patients with mAPMN/S prostate cancer who may be eligible for TRUQAP®,

the test is performed by NeoGenomics pathologists across its national oncology laboratory network. PTEN IHC CDx is available as a standalone order, delivering results in as few as one to two days, or as part of NEO PanTracer™ Pro for prostate cancer, a comprehensive molecular workup offered in a single coordinated order that integrates CGP with cancer-type-directed IHC and ancillary testing for prostate carcinoma. The test has been approved in New York State.

About NeoGenomics
NeoGenomics, Inc. is a premier cancer diagnostics company specializing in cancer genetics testing and information services. We offer one of the most comprehensive oncology-focused testing menus across the cancer continuum, serving oncologists, pathologists, hospital systems, academic centers, and pharmaceutical firms with innovative diagnostic and predictive testing to deliver timely, actionable insights that guide personalized care decisions. Headquartered in Fort Myers, FL, NeoGenomics operates a network of CAP-accredited and CLIA-certified laboratories for full-service sample processing and analysis services throughout the US and a CAP-accredited full-service sample-processing laboratory in Cambridge, England.

Forward Looking Statements
This press release includes forward-looking statements. These forward-looking statements generally can be identified by the use of words such as “anticipate,” “expect,” “plan,” “could,” “would,” “may,” “will,” “believe,” “estimate,” “forecast,” “goal,” “project,” “guidance,” “plan,” “potential” and other words of similar meaning, although not all forward-looking statements include these words. These forward-looking statements address various matters, including statements regarding the Company’s strategy, planned future operations and development plans and initiatives, as well as the timing, outcome and potential for its offerings to impact patients' ability to make timely treatment decisions, and the potential impact on clinical treatment and patient prognosis. Each forward-looking statement contained in this press release is subject to a number of risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statement. Applicable risks and uncertainties include, among others, the Company’s ability to successfully complete development of and to offer new types of tests, to execute on its strategic priorities and to otherwise implement its business plan, and the risks identified under the heading "Risk Factors" contained in the Company's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and the Company's other filings with the Securities and Exchange Commission.

We caution investors not to place undue reliance on the forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document (unless another date is indicated), and we undertake no obligation to update or revise any of these statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

Reference

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2. Zhang JY, Kong YY, Wang QF, et al. Prognostic value of PTEN in de novo diagnosed metastatic prostate cancer. Asian J Androl. 2022;24(1):50-55. doi:10.4103/aja.aja_39_21
3. Stopsack KH, Nandakumar S, Wibmer AG, et al. Oncogenic genomic alterations, clinical phenotypes, and outcomes in metastatic castration-sensitive prostate cancer. Clin Cancer Res. 2020;26(13):3230-3238. doi:10.1158/1078-0432.CCR-20-0168
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