November 28, 2017

Genomic Health and Cleveland Diagnostics Announce Strategic Collaboration to Develop and Commercialize New Prostate Cancer Tests

Global Licensing Agreement Provides Genomic Health with Exclusive Rights to Cleveland Diagnostics' Proprietary IsoPSA™ Technology

REDWOOD CITY, Calif. and CLEVELAND, Nov. 28, 2017 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX), the world's leading provider of genomic-based diagnostic tests, and Cleveland Diagnostics, Inc., a biotechnology company focused on developing next-generation diagnostics technology for the detection of cancers, today announced an exclusive licensing agreement to develop and commercialize new prostate cancer tests based on Cleveland Diagnostics' IsoPSA™ reagents and technology. Initial efforts under this agreement will focus on Genomic Health's development of a high-PSA (prostate-specific antigen) reflex test to accurately predict the presence of high-grade cancer (Gleason score $\geq$ 7) prior to prostate biopsy. The goal is to reduce unnecessary biopsies and optimize healthcare spending for the more than 4 million screened men who receive a PSA score between 2 and 10 each year in the United States.[i] Seventy five percent of all prostate biopsies performed are either negative or indicate a low likelihood of high-grade cancer, resulting in an unnecessary burden to patients and unnecessary costs to the U.S. healthcare system each year.[ii]

IsoPSA is a reagent that interrogates the entire spectrum of structural changes, or isoforms, of complex PSA, which Genomic Health intends to develop and commercialize as an in vitro diagnostic (IVD) blood-based test. Using Cleveland Diagnostics' proprietary solvent interaction analysis (SIA) technology platform, the IsoPSA assay can be integrated into the workflow of any urology laboratory practice to distinguish cancer-related PSA isoforms from benign isoforms to detect prostate cancer more precisely than standard PSA testing alone.

"Our research has shown that IsoPSA offers improved accuracy for identifying men at risk of high-grade disease, which will address one of the main limitations of standard PSA assays by reducing the over-diagnosis of low-grade, indolent cancers," said Eric L. Klein, M.D., chair of the Glickman Urological & Kidney Institute at Cleveland Clinic. "Use of IsoPSA is likely to reduce unneeded biopsies, for the benefit of both patients and clinicians."

A multi-center prospective trial of the IsoPSA reagent with the SIA technology led by Cleveland Clinic was recently published in *European Urology*. Results demonstrated significantly improved diagnostic accuracy over PSA in both determining whether a patient has prostate cancer and identifying patients at risk for high-grade disease, a critical distinction given the slow progression of many prostate cancers and the shift to active surveillance in properly selected patients. Specifically, at a cutoff selected to exclude the need for biopsy, the IsoPSA reagent demonstrated a 48 percent reduction in false-positive biopsies. At a cutoff selected to identity men at low risk of high-grade disease, the false-positive rate was reduced by 45 percent. A follow-up multicenter clinical study in more than 250 patients to further confirm this finding is currently underway and is expected to be completed in the first half of 2018.

"This strategic collaboration marks another important step forward in our mission to address additional unmet needs across the continuum of cancer, by adding a high-PSA reflex test to improve the diagnosis of prostate cancer with greater specificity while eliminating unnecessary biopsies," said Frederic Pla, Ph.D., chief business and product development officer, Genomic Health. "As we continue to expand our commitment to urology and leverage our commercial capabilities, we will soon have multiple tests to answer critical questions about prostate cancer treatment decisions from early diagnosis to late-stage disease. With the Oncotype DX Genomic Prostate Score™ for low- and intermediate-risk patients considering active surveillance, Oncotype DX AR-V7 Nucleus Detect™ for metastatic patients considering androgen receptor-therapy, and now the IsoPSA platform, Genomic Health is well positioned to be the diagnostic partner of choice in urology."

"With the rapid development of costly therapies for late-stage cancer in concert with diminishing healthcare system resources, patients, physicians and payers are increasingly focused on clinically actionable and affordable diagnostics - especially on tools that target early clinical decisions," said Arnon Chait, Ph.D., chief executive officer of Cleveland Diagnostics. "We look forward to collaborating with Genomic Health, a leader in advanced cancer diagnostics, to develop and bring to market a timely test with significant potential to reduce unnecessary procedures, while identifying patients who need further clinical intervention. Tests based on the IsoPSA reagents, with simple workflow and process integration into the lab offered by the SIA technology, promise to satisfy both goals of clinical efficacy and affordability in addressing this important clinical need."

The strategic collaboration will provide Genomic Health with broad exclusive global rights to develop and commercialize early- and late-stage cancer diagnostic tests based on Cleveland Diagnostics' proprietary IsoPSA reagent and SIA technology. Genomic Health is expected to begin additional development and clinical validation of the first high-PSA reflex test in 2018, with the aim of providing initial access to U.S. urology labs in 2020.

As part of the agreement, Genomic Health will make a convertible note investment in Cleveland Diagnostics in the principal amount of $2 million in the fourth quarter of 2017. The company will make a contingent additional payment of $5 million and a $3 million convertible note investment following positive results from a follow-on multicenter study, which is expected to be completed in the first half of 2018. Additional future payments are conditional and will be made as certain milestones are achieved over the next several years, in addition to royalties on test sales. These milestone payments are based on national reimbursement, certain annual net sales targets and additional licensing rights.

About Genomic Health
Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimize cancer care, including addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ® Genomic Intelligence Platform, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company's flagship line of Oncotype DX ® gene expression tests that have been used to guide treatment decisions for more than 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select™ test. The company is based in Redwood City, California, with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

About Cleveland Diagnostics
Cleveland Diagnostics is a Cleveland, Ohio, based biotechnology company with proprietary first-in-class technology and reagents to enable development of high efficacy and affordable tests that are focused on early detection and diagnostics of cancer and neurodegenerative diseases. Conducted as a simple add-on step prior to conventional immunoassays in the clinical lab, the SIA technology provides unparalleled access to interrogating disease-specific changes to the structure of protein biomarkers directly in a blood sample. With the potential to revolutionize the underperforming state of diagnostics at an early stage in both cancer and neurodegenerative diseases, Cleveland Diagnostics is dedicated to the development of a near-term pipeline of reagents for breast and other cancers, and for Alzheimer's disease. For more information visit www.cleveland-diagnostics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the company's beliefs regarding its future performance, including the company's ability to successfully develop and commercialize IVD tests based on the IsoPSA technology; the expected benefits and clinical utility of IsoPSA blood-based tests, the company's expectations regarding timing, geographic rollout and adoption of any such tests; the successful completion of clinical studies to validate the clinical utility of IVD tests based on the IsoPSA technology described in this press release; the company's belief that its exclusive license will allow it to accelerate adoption, reimbursement and access to a menu of prostate cancer tests; the company's ability to successfully submit the tests described in this release to the FDA and other required regulatory bodies for clearance or approval; the commercial performance of its tests; the attributes and focus of the company's product pipeline; the ability of any potential tests the company may develop to optimize cancer treatment; and the ability of the company to develop and commercialize, and collaborate with third parties to commercialize, additional tests in the future. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to the company's ability to execute its business model; the regulation of the company's tests or any tests offered through its commercial channel; the applicability of clinical study results to actual outcomes; the company's ability to develop, commercialize or collaborate to offer any new test, including IVD versions of IsoPSA prostate cancer tests, in new markets domestically and internationally; the risk that sufficient levels of reimbursement may not be obtained or maintained, domestically or abroad, for the company's tests or tests offered through its commercial channel; competition; unanticipated costs or delays in research and development efforts; the company's ability or the ability of its collaborators to obtain capital when needed to support the activities contemplated by the collaboration described in this press release; and the other risks and uncertainties set forth in Genomic Health's filings with the Securities and Exchange Commission, including the risks set forth in Genomic Health's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

[i] Drazer MW, Huo D, Eggener SE. National prostate cancer screening rates after the 2012 US Preventive Services Task

Force recommendation discouraging prostate-specific antigen-based screening. *Journal of Clinical Oncology*. 2015;33,2416-2423.

[ii] Pinsky PF, Crawford ED, Kramer BS, Andriole GL, Gelmann EP, Grubb R, Greenlee R, Gohagan JK. Repeat prostate biopsy in the prostate, lung, colorectal and ovarian cancer screening trial. *BJU International. 2017;* 99(4):775-9.

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