Medicare Establishes Final Local Coverage Determination (LCD) for Use of the Oncotype DX® AR-V7 Nucleus Detect™ Test in Patients with Metastatic Castrate Resistant Prostate Cancer Effective December 10

October 29, 2018

Medicare coverage supports clinical utility of the Oncotype DX AR-V7 Nucleus Detect test, providing 25,000 Medicare patients with coverage

SAN DIEGO and REDWOOD CITY, Calif., Oct. 29, 2018 /PRNewswire/ -- Epic Sciences, Inc. (Epic) and Genomic Health, Inc. (Nasdaq: GHDX) announced today that Palmetto GBA, a Medicare Administrative Contractor that assesses molecular diagnostic technologies, has issued a positive final local coverage determination (LCD) for the Oncotype DX® AR-V7 Nucleus Detect™ test. The final LCD recommends Medicare coverage for use of the test effective December 10, 2018, throughout the United States to help determine which patients with metastatic castrate resistant prostate cancer (mCRPC) may benefit from continued androgen receptor signaling inhibitor (ARSi) therapy, such as enzalutamide, abiraterone and apalutamide, as well as those who are resistant who may benefit from chemotherapy.

An estimated 50,000 men in the United States with advanced prostate cancer, of which approximately 25,000 have Medicare coverage, could benefit from knowing their AR-V7 status prior to selecting further treatment. The Oncotype DX AR-V7 Nucleus Detect test is a circulating tumor cell-based liquid biopsy test that is commercially available in the United States through Epic's partnership with Genomic Health. The final LCD is posted to the Medicare Coverage Database on the Centers for Medicare and Medicaid Services (CMS) website.

The test, commercially launched by Genomic Health on February 28, 2018, is supported by three clinical utility studies including two multicenter validation studies. Results from a Memorial Sloan Kettering Cancer Center-led validation study were published online on June 28, 2018, in *JAMA Oncology*, establishing the predictive benefit of the test. Additionally, new validation data from the PROPHECY study were presented on June 4, 2018, at the American Society of Clinical Oncology (ASCO) Annual Meeting.

"For men with advanced prostate cancer, these independent, blinded, multicenter studies demonstrated that the Oncotype DX AR-V7 Nucleus Detect test is a clinically validated and useful test that can predict therapeutic response and, through its use, extend life. Importantly, with this final Medicare LCD, approximately 50 percent of addressable patients in the United States can gain access to the test," said Murali Prahalad, Ph.D., President and CEO of Epic Sciences. "Receiving a positive, final LCD for the test less than a year after commercial launch speaks to the importance and impact that this test has in improving patient survival."

Prior to the Oncotype DX AR-V7 Nucleus Detect test, there was no clear consensus on the therapeutic sequencing after initial exposure to an ARSi therapy. The most challenging clinical decision in mCRPC is whether to start a second ARSi therapy or taxane chemotherapy. Detection of nuclear-specific AR-V7-positive circulating tumor cells as measured by the Epic Sciences approach indicates which patients are resistant to AR-targeted therapies, such as enzalutamide, abiraterone and apalutamide, as well as those who are likely to live longer when placed on chemotherapy rather than on ARSi therapy. Conversely, patients negative for nuclear-localized AR-V7 are likely to live longer with ARSi therapy than with chemotherapy.

The Oncotype DX AR-V7 Nucleus Detect test was developed using Epic's proprietary No Cell Left Behind® technology. Epic is delivering a portfolio of blood-based tests that are predictive of drug response in cancer and are clinically proven, personalized and focused on improving patient survival and healthcare economics worldwide.

About the Oncotype DX® AR-V7 Nucleus Detect™ Test

Designed by Epic Sciences and based on results from multiple studies led by Memorial Sloan Kettering Cancer Center, the Oncotype DX AR-V7 Nucleus Detect test is the first and only liquid biopsy test of its kind that can potentially prolong the lives of men with metastatic castration-resistant prostate cancer (mCRPC) by helping their physician identify the most effective treatment. Through a blood draw, the test detects AR-V7 protein in the nucleus of circulating tumor cells utilizing Epic Sciences' No Cell Left Behind® platform to accurately identify patients who are resistant to androgen receptor (AR)-targeted therapies and who should instead switch to chemotherapy. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralized, CLIA-certified laboratory in San Diego and is offered exclusively by Genomic Health. To learn more about the Oncotype DX AR-V7 Nucleus Detest test, visit www.OncotypeIQ.com and watch this video.

About Epic Sciences

Epic Sciences, Inc. is developing novel diagnostics to personalize and advance the treatment and management of cancer. Epic Sciences' mission is to enable the rapid and non-invasive detection of genetic and molecular changes in cancer throughout a patient's journey. The company was founded on a powerful platform to identify and characterize rare cells, including circulating tumor cells. Epic Sciences *No Cell Left Behind*® technology helps match patients to therapies and monitor for drug resistance, so that the best treatment path can be chosen at every clinical decision point. Epic Sciences has partnered with Genomic Health to commercialize the Oncotype DX® AR-V7 Nucleus Detect™ test, which helps with therapeutic decisions between taxane chemotherapy or androgen-directed therapeutics in metastatic castrate-resistant prostate cancer. Today, we partner with leading pharmaceutical companies and major cancer centers around the world. Epic Sciences' goal is to increase the success rate of cancer drugs in clinical trials and improve patient outcomes by providing physicians real-time information to guide treatment choices. Epic Sciences is headquartered in San Diego.

Further information is available on the Company's website, www.epicsciences.com. Stay in touch on Linkedin, on Twitter @EpicSciences or on Facebook.com/EpicSciences.

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 900,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype DX® AR-V7 Nucleus Detect™ test. The company is based inRedwood 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.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the benefits of the Oncotype DX AR-V7 Nucleus Detect test to physicians, patients and payors. 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 finalization of a local coverage determination for the test; the ability of the test to obtain Medicare reimbursement coverage throughout the United States; the risk that the company may not obtain or maintain sufficient levels of reimbursement; the results of clinical studies; the applicability of clinical study results to actual outcomes; the ability of the test results to change treatment decisions and improve patient outcomes; the risks and uncertainties associated with the regulation of the company's tests; the risks of competition; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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