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Genomic Health Launches Oncotype SEQ™ Liquid Biopsy Mutation Panel

Genomic Health Provides Unique New Option for Non-invasive Tumor Assessment in Later-stage Disease, Transforming Cancer Care Across the Patient Journey

REDWOOD CITY, Calif., June 14, 2016 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced the commercial launch of Oncotype SEQ™ Liquid Select, the first of several non-invasive liquid biopsy tests that the company plans to deliver through its Oncotype IQ™ Genomic Intelligence Platform. Oncotype SEQ is a blood-based test that uses next-generation sequencing to identify and assess actionable genomic alterations in a panel of 17 select genes to inform the treatment of stage IV solid tumors, including lung, breast, colon, melanoma, ovarian, and gastrointestinal stromal tumors.

The test is designed to provide clinically actionable information focused on genomic markers that have either been included in National Comprehensive Cancer Network (NCCN®) guidelines or associated with sensitivity or resistance to relevant FDA-approved therapies. The test can also match eligible patients with actively enrolling Phase II-IV clinical trials specific to their tumor type.

"As the world's leading provider of genomic-based cancer diagnostic tests, we are uniquely positioned to make a significant impact in the field of liquid biopsy with Oncotype SEQ, the newest clinically actionable test in our Oncotype IQ portfolio," said Phil Febbo, M.D., chief medical officer, Genomic Health. "This blood-based test will provide oncologists with important genomic information reported in a manner that will allow efficient interpretation and identification of potential treatment options. With our unique and extensive experience in the commercialization and reimbursement of advanced diagnostics, Genomic Health is leveraging its world-class channel to expand the delivery of precision medicine to physicians and patients beyond the research setting."

By analyzing cell-free DNA (cfDNA) isolated from a patient's blood through a simple blood draw, Oncotype SEQ examines tumor-derived genomic alterations that are associated with malignant transformation and response or resistance to therapy. Using unique bioinformatics methodology, the test detects the four major types of variants with very high sample-level sensitivity and specificity. The comprehensive Oncotype SEQ report provides physicians with important molecular alterations information in a streamlined format that facilitates interpretation and connection to potential treatment options.

"Liquid biopsy assesses cancer changes through a simple blood draw, a desirable choice for many patients, as it is a minimally invasive way to capture tumor genomic alterations and heterogeneity with the potential to be more cost- and time-efficient," said Lee Schwartzberg, M.D., chief, Division of Hematology Oncology, University of Tennessee. "Oncotype SEQ has robust analytical performance representative of the targeted patient population tested. Armed with this clinically meaningful information, Oncotype SEQ will allow physicians to be more effective and efficient in exploring treatment and clinical trial options for late-stage cancer patients."

The initial phase of the targeted launch will be focused on select clinics for the treatment of stage IV lung cancer patients. Liquid biopsy is a particularly viable option for lung cancer patients due to the difficulty and risk associated with lung tissue biopsy and the number of clinically actionable alterations. With successful analytical validation results being submitted for presentation, Genomic Health has launched a global, multi-center clinical concordance study as part of the company's goal to establish further evidence to support reimbursement.

By delivering insights into targeted therapy options, Oncotype SEQ Liquid Select is designed to address the needs of more than 350,000 patients who recur or present with late-stage disease each year in the United States alone. Oncotype SEQ will be performed at Genomic Health's CLIA-certified laboratory using the company's proprietary cfDNA sequencing platform.

About Oncotype SEQ™ Liquid Select
Oncotype SEQ Liquid Select is a blood-based mutation panel that uses next-generation sequencing to identify and assess 17 genes with well-known clinically actionable molecular markers that have either been included in National Comprehensive Cancer Network (NCCN®) guidelines or associated with sensitivity or resistance to relevant FDA-approved therapies in cancers of the lung, breast, colon, skin, ovaries, and gastrointestinal stromal tumors. The panel is comprehensive, covering all currently approved actionable drugs and actively enrolling Phase II-IV clinical trials as options for patients on the basis of their genomic alterations. For more information, please visit, www.OncotypeSEQ.com.

About Genomic Health
Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of cancer, 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 600,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests. 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.

This fact sheet contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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: our ability to develop and commercialize new tests and expand into new markets domestically and internationally; the risk that we may not obtain or maintain sufficient levels of reimbursement, domestically or abroad; competition; unanticipated costs or delays in research and development efforts; the regulation of our tests; the applicability of clinical study results to actual outcomes; our business model; our ability to obtain capital when needed; and the other risks and uncertainties set forth in our filings with the Securities and Exchange Commission, including the risks set forth in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016. 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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