

German Health Technology Assessment Body (IQWiG) Concludes Only Oncotype DX® has Sufficient Evidence to Guide Breast Cancer Adjuvant Chemotherapy Decisions Based on Landmark TAILORx Study Results

September 7, 2018

Updated Assessment of Breast Cancer Gene Expression Profiling Tests for Clinical Use in Germany Final German Federal Joint Committee (G-BA) Reimbursement Decision Expected by End of 2018

REDWOOD CITY, Calif., Sept. 7, 2018 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced the publication of an <u>updated</u> <u>assessment</u> of breast cancer gene expression profiling tests by the German Institute for Quality and Efficiency in Health Care (IQWiG). In its analysis, IQWiG concluded that, based on results from the TAILORx study, the Oncotype DX Breast Recurrence Score[®] test can support patients with primary node-negative, hormone-receptor positive, HER2-negative breast cancer in the decision for or against chemotherapy.

IQWiG's technical assessment will inform the Federal Joint Committee (G-BA) official reimbursement procedure. In July 2018, the G-BA <u>publicly</u> <u>stated</u> that a final decision on reimbursement of breast cancer gene expression profiling tests is expected by the end of 2018.

"With IQWiG's recognition of the unique value the Oncotype DX test provides, we believe we are one step closer to ensuring reimbursed access to tens of thousands of breast cancer patients diagnosed in Germany each year as is the case in other countries around the world including the U.S., Canada, the UK, France, Spain and Switzerland," said Torsten Hoof, senior vice president international, Genomic Health. "We look forward to G-BA's final reimbursement decision later this year as we continue to see the impact of the landmark TAILORx study results on clinical practice around the world."

IQWiG's conclusion is based on results from TAILORx, the largest randomized adjuvant breast cancer treatment trial ever conducted, which were recently published in <u>The New England Journal of Medicine</u>. This independently-conducted, prospective, Phase III study followed more than 10,000 women with node-negative, hormone-receptor positive, HER2-negative early-stage breast cancer for an average of nine years.

Study results demonstrated that the Oncotype DX Breast Recurrence Score test provides definitive long-term evidence about the magnitude of chemotherapy benefit, identifying the vast majority of women with early-stage breast cancer who receive no significant benefit from chemotherapy, as well as the important minority of women for whom chemotherapy can be life-saving. Thus, the test can greatly reduce both overtreatment and undertreatment with chemotherapy.

About Oncotype DX®

The Oncotype DX® portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. The company's flagship product, the Oncotype DX Breast Recurrence Score® test, is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score® test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score® test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention. With more than 900,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.MyBreastCancerTreatment.org or www.MyBreastCancerTreatment.org or www.MyProstateCancerTreatment.org.

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 DetectTM test. The company is based irRedwood 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 Breast Recurrence Score 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 results of clinical studies, including the TAILORx study; 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 risk that the company may not obtain or maintain reimbursement, domestically or abroad, including in Germany with the Federal Joint Committee (G-BA), for the Oncotype DX Breast Recurrence Score test; 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 annual report filed on Form 10-Q for the year 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.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Breast Recurrence Score, Recurrence Score, Oncotype DX AR-V7 Nucleus Detect,

Oncotype DX DCIS Score, Oncotype DX Genomic Prostate Score, and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

GHDX-B



C View original content with multimedia:http://www.prnewswire.com/news-releases/german-health-technology-assessment-body-iqwig-concludes-only-oncotype-dx-has-sufficient-evidence-to-guide-breast-cancer-adjuvant-chemotherapy-decisions-based-on-landmark-tailorx-study-results-300708619.html

SOURCE Genomic Health, Inc.

Investors: Emily Faucette; Genomic Health; 650-569-2824; investors@genomichealth.com OR Media: Victoria Steiner; Genomic Health; 415-370-5804; media@genomichealth.com