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New St. Gallen International Breast Cancer Guidelines Recommend Oncotype DX Breast Recurrence Score® Test to Guide Chemotherapy for Node-Negative and Node-Positive Early-Stage Breast Cancer

- *Guidelines include TAILORx-defined cutoff of 26 for determining chemotherapy benefit in node-negative disease, and recommend that more women with limited nodal involvement may avoid chemotherapy*
- *Oncotype DX® test recommended based on prospective landmark TAILORx and German PlanB studies, recognized as key scientific and clinical research innovations of the past two years*
- *Genomic testing strongly endorsed by vast majority of panelists*

REDWOOD CITY, Calif., August 21, 2019 – Genomic Health today announced that, based on results from the prospective TAILORx[1] and PlanB[2] studies, the 16th St. Gallen International Breast Cancer Conference Expert Panel has recommended the Oncotype DX Breast Recurrence Score® test to guide chemotherapy treatment use for patients with hormone-receptor positive, HER-2 negative early-stage breast cancer with and without lymph node involvement (up to three positive nodes).

In particular, the panelists recognised the value of the landmark TAILORx study results and noted that women with node-negative cancers and Recurrence Score® results ≤25 do not need chemotherapy.[3] This group represents up to about 80% of patients who may be safely spared chemotherapy. The Breast Recurrence Score test also identifies those patients (with results of 26 to 100) who may receive a life-saving benefit from chemotherapy.

In the new guidelines, genomic testing with robust validation through prospective, randomised trials is preferred over clinical-pathological features "for basing the critical yes/no chemotherapy decision."[4] Results from a recently published subset analysis of the prospective, randomised TAILORx study[5]

[1] Sparano et al. *New Engl J Med*. 2018.
[2] Nitz et al. *Breast Cancer Res Treat*. 2017.
[3] Burstein et al. *Annals of Oncology*. 2019.
[4] Burstein Harold J. et. al. Annals of Oncology 2019
[5] Sparano et al. New Engl. J Med. 2019

showed that only the Breast Recurrence Score test is predictive of chemotherapy benefit; clinical and pathological features are only prognostic and do not provide predictive information.

"We are pleased that this expert panel once again recognised the unique value of the Oncotype DX test to guide chemotherapy treatment. An extensive body of clinical evidence supports the ability of the Recurrence Score to identify both patients who can be spared chemotherapy and, importantly, those who will clearly benefit from it," said Steven Shak, M.D., chief scientific officer, Genomic Health. "All major guidelines in the U.S. and Europe recommend Oncotype DX to help select patients for chemotherapy treatment, providing physicians with the highest level of evidence to support using the test as standard of care."

The new St. Gallen International Consensus guidelines, "Estimating the benefits of therapy for early stage breast cancer," were recently published online in the Advance Access section of *Annals of Oncology* and will appear in a future print issue.

The Oncotype DX Breast Recurrence Score test is incorporated in all major international guidelines. Recently, it was elevated to highest 1A level of evidence in the updated ESMO guidelines for early-stage breast cancer. Similar to the St. Gallen guidelines, the ESMO guidelines refer to TAILORx and PlanB results, which identify groups of patients – both in the node-negative and node-positive setting – for whom chemotherapy can be safely spared, thus underscoring the clinical utility that the Breast Recurrence Score test provides to guide chemotherapy treatment decisions.

Over the last several months, results of the TAILORx study have influenced positive treatment guideline updates distinguishing the Oncotype DX Breast Recurrence Score test from prognostic-only tests based on clinical evidence and the critical importance of predicting chemotherapy benefit. This includes the recent update to ASCO guidelines, which increased the proportion of women who can be effectively treated without chemotherapy based on the Recurrence Score results, highlighting the importance of testing all medically eligible early-stage breast cancer patients with the Breast Recurrence Score test. The National Comprehensive Cancer Network (NCCN) updated its guidelines in 2018 to categorise the Breast Recurrence Score test as the only "preferred" test for chemotherapy treatment decision-making for patients with node-negative, early-stage breast cancer. NCCN also classified the Breast Recurrence Score test as the only test that is predictive of chemotherapy benefit.

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 optimise 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, and the Oncotype DX AR-V7 Nucleus Detect™ test helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant to androgen

receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralised, CLIA-certified laboratory in San Diego and offered exclusively by Genomic Health. With more than 1 million patients tested in more than 90 countries, the Oncotype DX tests have redefined personalised medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com, 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 optimise 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 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 over 1 million cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the Oncotype DX® AR-V7 Nucleus Detect™ 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.

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; the results of the TAILORx study, including secondary analysis, and its implications on guiding clinical treatment decisions; the ability of the Oncotype DX Breast Recurrence Score test to improve patient outcomes; and the ability of the company to achieve additional global reimbursement coverage for its Oncotype DX Breast Recurrence Score test. 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; 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 sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks of competition; unanticipated costs or delays in research and development efforts; 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, 2019. 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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