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Secondary Analysis of Landmark TAILORx Results, Published in *The New England Journal of Medicine*, Affirms Unique Ability of Oncotype DX Breast Recurrence Score® Test to Predict Chemotherapy Benefit, Guiding Adjuvant Therapy with Even Greater Precision

- *Additional detail in patients age 50 or younger presented in oral session at 2019 American Society of Clinical Oncology (ASCO) Annual Meeting*
- *TAILORx continues to elevate Oncotype DX® test to a new global standard with increasing utilisation and reimbursement*

GENEVA, Switzerland, June 4, 2019 -- Results from a new analysis of the Trial Assigning IndividuaLised Options for Treatment (Rx), or TAILORx, confirm the original, definitive conclusions reported last year with additional detail on clinical risk, focusing on patients with early-stage breast cancer who are age 50 years or younger. These findings, published in *The New England Journal of Medicine* and presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, showed that stratifying patients by clinical risk (tumour size and histologic grade) alone does not predict chemotherapy benefit. Clinical risk provides prognostic information that is complementary to the Oncotype DX Breast Recurrence Score® test and may help identify younger women who benefit from more effective therapy.

"We're pleased to see leading authorities, including *The New England Journal of Medicine* and ASCO, continue to recognise the significant result and impact of TAILORx one year after it established that the Oncotype DX test definitively identifies the vast majority of women with early-stage breast cancer who receive no benefit from chemotherapy, and the important minority for whom chemotherapy can be life-saving," said Steven Shak, M.D., Chief Scientific Officer, Genomic Health. "The additional insight from this new analysis confirms young women with breast cancer are not all the same and indicates that they should be treated individually based on the biology of their disease, as determined by the Oncotype DX test and an assessment of their clinical risk."

A secondary objective of TAILORx, the largest ever breast cancer treatment trial, sponsored by the National Cancer Institute (NCI), and led by the ECOG-ACRIN Cancer Research Group, was to evaluate whether clinical risk provides additional prognostic or predictive information to the Recurrence Score® results. Of 9,427 women in TAILORx with a Recurrence Score result and clinical risk information, 70 percent were determined to be low clinical risk (tumour ≤3 cm and low grade, ≤2 cm and intermediate

grade, or ≤1 cm and high grade) and 30 percent were identified as high clinical risk (not meeting low clinical risk criteria). While clinical risk provided additional prognostic information across all Recurrence Score groups, disease free survival and distant recurrence free interval rates were similar with and without chemotherapy in the entire Recurrence Score 11-25 group irrespective of clinical risk.

"Last year TAILORx established the highest level of evidence and unprecedented precision supporting use of the Oncotype DX Breast Recurrence Score test to guide adjuvant chemotherapy treatment for women with early-stage breast cancer," said lead author Joseph A. Sparano, M.D., Associate Director for Clinical Research at the Albert Einstein Cancer Center and Montefiore Health System in New York, and Vice Chair of the ECOG-ACRIN Cancer Research Group. "With this new analysis, it is clear that women ages 50 or younger with a Recurrence Score result between 16 and 20 and low clinical risk do not need chemotherapy. Furthermore, the Oncotype DX test in combination with clinical risk factors could identify premenopausal women with higher clinical risk who may benefit from ovarian function suppression and more aggressive anti-oestrogen therapy."

The ground-breaking TAILORx results presented during the Plenary Session at the 2018 ASCO Annual Meeting and simultaneously published in *The New England Journal of Medicine* are elevating the Oncotype DX test to a new global standard of care with increasing, and more consistent, use of the test by physicians worldwide for all medically eligible patients. Additionally, important guidelines globally distinguish Oncotype DX from other 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 strong and highest level of evidence from TAILORx, as well as National Comprehensive Cancer Network (NCCN) guidelines, which were updated last fall to categorise Oncotype DX as the only "preferred" test for chemotherapy treatment decision-making for patients with node-negative, early-stage breast cancer. The landmark TAILORx study is also having an important impact on global reimbursement of the Oncotype DX test, including in Germany. Following the German Institute for Quality and Efficiency in Health Care's (IQWiG's) positive assessment, the German Federal Joint Committee (G-BA) is expected to make a decision on Oncotype DX reimbursement at its plenary meeting on June 20.

About early-stage breast cancer and the Oncotype DX test

Oncotype DX is the only genomic test validated for its ability to predict the likelihood of chemotherapy benefit as well as risk of recurrence in early-stage breast cancer. Breast cancer is the most common cancer in European women[1] and affects many of them during their years dedicated to working and raising a family. While chemotherapy is routinely offered, research shows that only a minority of patients with early-stage breast cancer actually benefit from it.[2,3] The Oncotype DX test is designed to

[1] Ferlay J et al, Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. 2018 Available from: https://gco.iarc.fr/today/home
[2] Paik et al. J Clin Oncol. 2006
[3] Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. Lancet. 2012

facilitate personalised clinical decisions by providing information about the biology of an individual breast cancer, with the potential to deliver financial benefits for healthcare systems.

To learn more about the Oncotype DX test, visit: www.OncotypeIQ.com

About Genomic Health

Genomic Health, Inc. is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care. With its Oncotype IQ® Genomic Intelligence Platform, the company is applying its state-of-the-art scientific and commercial expertise and infrastructure to translate significant amounts of genomic data into clinically-actionable results for treatment planning throughout the cancer patient's 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 one million 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 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 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, including in Germany. 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 March 31, 2019. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.