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New Long-Term Outcomes Data Reconfirm Value of Oncotype DX Breast Recurrence Score® Test to Target Chemotherapy

- *Real-world evidence reinforces TAILORx treatment paradigm and standard of care use for Oncotype DX® test*
- *Importance of tailoring chemotherapy use and differences between tests acknowledged by leading international breast cancer specialists*

GENEVA, Switzerland, March 25, 2019 -- New data recently presented at the 16th St. Gallen International Breast Cancer Conference further support the utility of Oncotype DX Breast Recurrence Score® test to optimise chemotherapy recommendations in patients with early-stage breast cancer with or without lymph node involvement.

An updated analysis[1] of the Clalit Health Services registry, the largest health services organisation in Israel, examined medical records of more than 1,300 patients with node negative breast cancer applying the Recurrence Score cut point determined by the landmark TAILORx study[2]. The findings showed that use of chemotherapy was aligned with Recurrence Score results and that patients with Recurrence Score results up to 25, the vast majority of whom were treated with hormonal therapy alone, had excellent outcomes at ten years with low rates of distant recurrence.

"This important analysis with long-term follow up is based on our experience with the Oncotype DX® test in routine clinical practice and is consistent with findings from multiple clinical trials, including the TAILORx study", said Prof. Salomon Stemmer, lead investigator of the study, Department of Oncology, Davidoff Center, Rabin Medical Center affiliated to Tel Aviv University, Israel. "These results continue to show the unique value of adding genomic information provided by the test to better target chemotherapy."

Another piece of research presented at the congress is real-world evidence[3] from a study in more than 80,000 patients, based on an analysis of data from the Surveillance, Epidemiology, and End Results (SEER) registry programme of the National Cancer Institute (NCI). The findings confirmed that the Oncotype DX Breast Recurrence Score® result is predictive of chemotherapy benefit in patients with

[1] Stemmer et al. Poster: P249, St. Gallen International Breast Cancer Conference. March 2019
[2] Sparano et al. New Engl J Med. 2018
[3] Winer et al. Poster: P246, St. Gallen International Breast Cancer Conference. March 2019

node-negative disease (p=0.009), with no chemotherapy benefit in patients with Recurrence Score results up to 25. In patients with node-negative disease and Recurrence Score results up to 25 not treated with chemotherapy, the Breast Cancer Specific Survival (BCSS) was greater than 96 percent at nine years. In patients with node-positive disease not treated with chemotherapy and Recurrence Score results less than 18, BCSS was greater than 97 percent at nine years.

Importantly, the new real-world evidence reinforces the paradigm established by the TAILORx study, which provided definitive information on how to treat women with node-negative early-stage breast cancer based on their Oncotype DX Breast Recurrence Score results. TAILORx - the largest randomised adjuvant breast cancer treatment trial ever conducted - identified the vast majority of women (approximately 80 percent with Recurrence Score result up to 25) who receive no substantial benefit from chemotherapy, as well as the important minority (Recurrence Score result 26-100) for whom chemotherapy can be life-saving.

The important role of genomic testing to optimise patient outcomes in early-stage breast cancer was discussed in a debate[4] between leading international breast cancer specialists during the recent St. Gallen International Breast Cancer Conference. The experts presented several case studies showing that genomic testing adds value beyond clinical pathological factors and agreed that there are substantial differences between the available tests.

Prof. Joseph Gligorov from the Breast Cancer Expert Center of the APHP-Tenon Hospital in Paris, who participated in the panel discussion, commented: "Only a test such as Oncotype DX that has been specifically developed to be predictive of chemotherapy benefit can identify the right treatment for the right patient. The practice-changing precision made possible by such a test can lead to improved quality of care and breast cancer survival, as well as reduced waste of healthcare resources by directing chemotherapy only to patients who have a high likelihood of deriving substantial benefit."

Additional real-life data highlight value of Oncotype DX to personalise and improve the quality of clinical decisions

Also presented at the congress, results of two decision impact studies from the UK and the Czech Republic:

- UK clinical practice results[5] from 582 patients with node-positive disease (one to three positive lymph nodes) showed that chemotherapy recommendations changed in a significant proportion of patients following testing with Oncotype DX. In particular, the test allowed more than 60 percent of patients to be spared chemotherapy and its associated short and long-term side-effects. Conversely, it identified 23 patients who were initially advised to undergo only endocrine therapy, but whose treatment was changed to add chemotherapy based on their Recurrence Score

[4] Genomic Health Satellite Symposium: Optimising outcomes in early-stage breast cancer by tailoring the use of chemotherapy, St. Gallen International Breast Cancer Conference
[5] Battisti et al. Poster: P007, St. Gallen International Breast Cancer Conference

result. Without testing, these patients would not have received potentially life-saving chemotherapy treatment.

- A study from Czech medical centers[6] which looked at test utilisation in real-life clinical practice in 432 patients, including those with high-risk disease by traditional parameters. Results showed that testing with Oncotype DX led to a 78.4 percent reduction of chemotherapy recommendations, indicating a significant potential for overtreatment with chemotherapy when decisions are based on clinical pathological parameters alone.

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[7] 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.[8,9] The Oncotype DX test is designed to 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 belief that the Oncotype DX Breast Cancer test is unique in its ability to predict chemotherapy benefit in early-stage breast cancer; the company's belief that the Oncotype DX Breast Cancer test is cost effective and can reduce the cost of treatment in the United Kingdom and in various other health systems around the world; the applicability of study results to actual outcomes; and the ability of the company's tests to impact clinical practice.

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[6] Petrakova et al. Poster: P004, St. Gallen International Breast Cancer Conference
[7] Ferlay J et al, Eur J Cancer. 2013
[8] Paik et al. J Clin Oncol. 2006
[9] Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. Lancet. 2012

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 company's ability to increase usage of its tests; the company's ability to successfully commercialize its tests outside of the United States; the company's ability to compete against third parties; 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 and uncertainties associated with regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes; 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 September 30, 2018. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.