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New real-world evidence confirms utility of the Oncotype DX® test in clinical practice for patients with early-stage breast cancer

- *Further demonstrates the test's ability to change clinical chemotherapy treatment decisions by more precisely identifying patients who will or will not benefit from chemotherapy hence targeting treatment more effectively*
- *Underscores the value of the test in both node negative (N0) and node positive (N+) disease*

GENEVA, Switzerland, [October 22, 2018] – Results from two prospective decision impact studies[1,2], presented at the ESMO 2018 Congress, October 19-23 in Munich, Germany, further support the utility of the Oncotype DX Breast Recurrence Score® test to optimise chemotherapy recommendations in patients with early-stage, hormone-receptor positive, HER-2 negative breast cancer with or without lymph node involvement. These new results add to the body of data supporting the Oncotype DX test, which includes multiple validation studies demonstrating its unique ability to predict chemotherapy benefit along with prospective evidence in more than 70,000 patients both with N0 and N+ disease[3-8], showing that the test accurately predicts clinical outcomes.

The first study[1] presented at ESMO is research from Ireland assessing the impact of the Oncotype DX test on treatment decisions in routine clinical practice for early breast cancer patients whose disease has spread to the lymph nodes (one to three positive nodes). Overall, access to the test's results led to a reduction in physician perception of tumour chemo-sensitivity. From the 74 patients with Recurrence Score® results included in the analysis, the study found that in 64% of cases oncologists thought the test's result substantially changed treatment recommendations. In particular, testing with Oncotype DX led to a 27% reduction in chemotherapy recommendations.

"These new results strengthen published findings from our PlanB study and show the unique value of adding genomic information provided by the Oncotype DX test to better target chemotherapy. Oncotype DX identifies patients who can safely be spared chemotherapy toxicity and side effects. Furthermore, we have to be concerned about a relevant proportion of patients who seem to be undertreated if the risk of recurrence is evaluated using only traditional clinical parameters," said Prof. Ulrike Nitz, head of the

breast cancer/senology unit at the Bethesda Hospital, Moenchengladbach, Germany. “The use of the Oncotype DX test allows us to tailor treatment plans more accurately to suit the needs of individuals, and to use resources more effectively.”

Also presented at ESMO, results of another real-life, decision-impact study[2] from France and Italy including both N0 and N+, early-stage breast cancer patients showed that treatment recommendations changed for 35% of patients included in the study based on Recurrence Score results, and that using the test to guide treatment decisions resulted in a relative net reduction in chemotherapy recommendations of 43%. These changes in treatment recommendations would be even greater in patients with N0 disease applying decision-making criteria (Recurrence Score groups) based on results from the recently published landmark TAILORx study.[3]

TAILORx - the largest randomised adjuvant breast cancer treatment trial ever conducted - definitively confirmed the value of the Oncotype DX test for precisely guiding adjuvant chemotherapy decisions in patients with early-stage, node-negative breast cancer. In particular, results demonstrate that the test provides definitive evidence about the magnitude of chemotherapy benefit based on prospective long-term patient follow up, identifying the vast majority of women who receive no substantial 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 over- and undertreatment with chemotherapy.

This was recently acknowledged by Germany’s health technology assessment body - the Institute for Quality and Efficiency in Health Care (IQWiG) - which concluded that only the Oncotype DX test has sufficient evidence to guide breast cancer adjuvant chemotherapy decisions based on the TAILORx study results.

Separately, the National Comprehensive Cancer Network (NCCN) recently updated their guidelines for invasive breast cancer chemotherapy treatment and categorised Oncotype DX as the only “preferred” test for chemotherapy treatment decision-making for patients with node-negative, early-stage breast cancer. In the updated NCCN guidelines, Oncotype DX continues to be distinguished as the only genomic test predictive of chemotherapy benefit.

“The momentum for genomic testing is building as healthcare systems across the world recognise its value to patients and society,” said Torsten Hoof, Senior Vice President International, Genomic Health. “There is evidently a clear need for a personalised approach as part of routine decision-making – not just in Europe but globally, and we look forward to continuing to work with the relevant authorities to make the Oncotype DX test available to patients on a wider scale.”

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[9] 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.[10,11]

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.

Healthcare systems across Europe are recognising the value of the test, which is incorporated in all major international clinical guidelines. Following assessment and recommendation by NICE, the Oncotype DX test is widely available to patients across the UK. In France, Oncotype DX is available through a funding mechanism for genomic tests. Other European countries where the test is reimbursed include Switzerland, Ireland, Greece and Spain.

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 optimize 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 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 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. 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.

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