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New data show important role of genomic testing in treatment of older breast cancer patients

- *Many patients 70 years or older had low rates of breast cancer recurrence and excellent survival when treated based on the biology of their tumor*

GENEVA, Switzerland, [June 6, 2017] – Genomic Health announced results from an analysis of patients with hormone-receptor-positive (HR+), early-stage breast cancer at the American Society for Clinical Oncology (ASCO) annual meeting, June 2 – 6, in Chicago, Illinois. New data[1] show that using the Oncotype DX Breast Recurrence Score® test to identify the right patients to treat with chemotherapy, can benefit patients 70 years or greater, similar to the outcomes reported for younger patients.

In the study, from Clalit Health Services, Israel, medical records of 458 elderly, and 2052 younger patients were examined. Using the patients' Oncotype DX Breast Recurrence Score results, the researchers compared given treatment and subsequent outcomes. The findings showed a similar distribution of Recurrence Score results between the age groups and that within each Recurrence Score result group (low, intermediate and high) there was no statistically significant difference in clinical outcomes between older and younger patients.

"This research provides insightful data which stress the importance of addressing and improving the care for elderly patients, including the use of tools that help us predict the likelihood of distant breast cancer recurrence, and the need for chemotherapy," said Prof Salomon Stemmer, Lead Investigator of the study, Department of Oncology, Davidoff Center, Rabin Medical Center affiliated to Tel Aviv University, Israel.

Previously, the European Registration of Cancer Care (EURECCA) study[2], a large-scale international comparison of the treatment of elderly patients with non-metastatic breast cancer, showed that there are substantial differences in outcomes, and the use of surgery, hormone therapy and chemotherapy between

[1] Stemmer S. et al., abstract #543, presented at ASCO 2017
[2] Derks M. et al., abstract #1808 presented at ECC 2015

European countries. The investigators called for more studies, such as the Clalit study, in order to improve treatment approaches and outcomes in elderly patients with breast cancer.

Real-world evidence confirms Oncotype DX Breast Recurrence Score ability to accurately predict clinical outcomes

Also presented at ASCO was an analysis[3] of the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI), including over 49,000 patients, which found that in those patients with Recurrence Score results of less than 18, chemotherapy use was uncommon (3-8%) and five-year breast cancer-specific survival (BCSS) rate was high (>99%). In the group with Recurrence Score results of 18-25, chemotherapy was administered more often (29%), and five-year BCSS rate was 99%, regardless of chemotherapy use (in both the chemotherapy-treated and the non-chemotherapy-treated patients).

These data, based on real-world clinical practice, confirm the test's ability to accurately predict long-term clinical outcomes, highlighting the unique value of Oncotype DX as the only multi-gene breast cancer test with prospective outcome evidence in over 60,000 patients.

"The results presented at ASCO once again reinforce the value of examining tumor biology with Oncotype DX in specific patient populations, such as older women, and add to unprecedented evidence that the Breast Recurrence Score test provides critical information to improve treatment approaches and outcomes in breast cancer patients," said Steven Shak, M.D., Chief Scientific Officer, Genomic Health.

Additional data demonstrate the value of the Oncotype DX Breast Recurrence Score test in selecting patients for chemotherapy treatment

Results of chemotherapy treatment from the prospective PlanB study[4] were presented at ASCO in an oral session. Findings for the group of HER2-negative, early breast cancer patients with high clinical risk and intermediate-to-high Recurrence Score results, showed a similar five-year disease-free survival for chemotherapy regimens with, and without, an anthracycline, indicating that avoiding an anthracycline may be an important option. In addition, the PlanB Recurrence Score results were consistent with previous chemotherapy trials (NSABP-B28, PACS-01) showing the strong prognostic impact of the Breast Recurrence Score test in chemotherapy-treated patients. Trials evaluating new agents in patients with high Recurrence Score results are warranted.

PlanB, one of the largest contemporary adjuvant breast cancer trials in Europe, is the first prospective study with the Oncotype DX test to report full results. The trial was conducted by the West German Study Group (WSG) and registered more than 3,100 patients who were considered candidates for chemotherapy by traditional parameters including those with node-positive disease (up to three nodes).

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[3] Miller D. et al., abstract #537, presented at ASCO 2017
[4] Harbeck N. et al., abstract #504, presented at ASCO 2017

Previously presented findings from PlanB demonstrated that women with low Recurrence Score results could be effectively treated with hormonal therapy alone, and had five-year disease-free survival of 94%.

About Oncotype DX

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. Healthcare systems across Europe are recognizing the value of the test, which is incorporated in all major international clinical guidelines. Following assessment and recommendation by NICE in 2013, the Oncotype DX test is now widely available to patients across the UK. In France, Oncotype DX is available through a funding mechanism for genomic tests. Other European countries that reimburse the test 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 a world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of cancer. 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 750,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests. 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 U.S. Private Securities Litigation Reform Act of 1995, including statements relating to the ability of any potential tests Genomic Health, Inc. may develop to optimize cancer treatment and the ability of the company to develop and commercialize additional tests in the future. 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 and their impact on reimbursement and adoption; the applicability of clinical study results to actual outcomes; the company's ability to develop and commercialize new tests and expand into new markets domestically and internationally; 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; unanticipated costs or delays in research and development efforts; the company's ability to obtain capital when needed 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 yearly report on Form 10-K for the quarter ended March 31, 2017. 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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