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New analysis from German study group prospective trial shows minimal distant recurrence in patients with clinically high-risk breast cancer and low Oncotype DX Breast Recurrence Score® results following five years of hormone therapy alone

- *Additional large population-based study indicates not all young women under 40 years with node negative breast cancer have aggressive disease - excellent survival without chemotherapy reported at five years for patients with low Recurrence Score® results*

GENEVA, Switzerland, [September 11, 2017] – Genomic Health today announced new data presentations with the Oncotype DX Breast Recurrence Score® test at the European Society for Medical Oncology (ESMO) annual meeting in Madrid, Spain.

"The results presented at ESMO once again highlight the unique value of Oncotype DX® in providing critical information to personalize and improve the quality of treatment decisions in early breast cancer," said Calvin Chao, Vice President of Global Medical Affairs at Genomic Health. "These latest presentations reinforce our test's ability to accurately predict clinical outcomes and the value of examining tumor biology in specific patient populations, such as younger women and those with clinically high-risk breast cancer."

Distant recurrence results from prospective 'PlanB' study presented for the first time

New results from the PlanB trial[1], one of the largest contemporary adjuvant breast cancer trials in Europe, showed that patients with low Breast Recurrence Score® results (0-11) treated with hormonal therapy alone had very low rates of distant recurrence (distant disease-free survival: DDFS) after 60 months median follow-up. DDFS rates were comparable in patients with node-positive (up to three nodes) disease and in those with clinically high-risk node-negative disease at 97.9 and 97.7 percent respectively.

[1] Gluz O, et al. LBA11, Presented at ESMO 2017

In the study, the Recurrence Score result was the strongest independent predictor for DDFS in multivariable analysis ($p<0.001$), providing the greatest impact on prognosis and outperforming all the other factors, such as the traditional criteria of tumor size and tumor grade.

"These new study results show the unique value of adding biological information provided by the Oncotype DX test in order to identify low-risk breast cancer patients - among patients with 0-3 involved lymph nodes - who can safely be spared the toxicity and side effects of chemotherapy without compromising outcomes," said Dr Oleg Gluz, Scientific Coordinator of the West German Study Group that conducted the PlanB study. "This is especially important for patients who would be considered as intermediate to high risk of recurrence based on traditional clinical parameters. These results confirm previous retrospective studies with Oncotype DX as well as the prospective TAILORx trial."

The distant recurrence results presented at ESMO 2017 provide information beyond the five-year PlanB outcomes published recently in *Breast Cancer Research and Treatment*, which include disease-free survival (DFS) and overall survival (OS).

PlanB was conducted by the West German Study Group (WSG) in 93 centers across Germany and enrolled more than 3,100 patients who were considered candidates for chemotherapy by traditional parameters including those with node-positive disease. The study used the Oncotype DX Breast Recurrence Score results to identify patients who, despite high clinical risk, could be spared adjuvant chemotherapy.

Testing with Oncotype DX in women under 40 shows excellent survival with low Recurrence Score results and demonstrates important role of genomic testing in treatment of younger breast cancer patients

Breast cancer at a young age is generally associated with poor prognosis, more aggressive treatment, long-term toxicities, and unique psychosocial concerns[2]. In the study, Recurrence Score results were provided to the National Cancer Institute's population-based SEER registries, the premier source of cancer statistics in the United States, and linked to breast cancer cases. This analysis[3] looked at breast cancer specific survival (BCSS) in over 1,700 patients younger than age 40 with node-negative, HR+ breast cancer treated based on their Recurrence Score result.

Excellent five-year BCSS (100 percent) was observed in the 821 patients with Recurrence Score results less than 18, the vast majority of whom (83 percent) did not receive chemotherapy. Similarly, patients with Recurrence Score results up to 25 also had favorable five-year BCSS. An important minority (11 percent) of young women with high Recurrence Score results had poor outcomes despite chemotherapy use.

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[2] Paluch-Shimon S, et al. Breast. 2016;26:87-99
[3] Shak S, et al. 1451P, Presented at ESMO 2017

"This analysis provides important information for a small but greatly impacted group of patients with breast cancer, indicating that not all young women have aggressive tumor biology and poor prognosis", said Steven Shak, M.D., chief scientific officer, Genomic Health. "Genomic testing should be an important element of the treatment strategy to refine care decisions for younger breast cancer patients."

Head-to-head comparisons confirm genomic tests are not interchangeable, and reinforce the unique value of Oncotype DX in identifying the minority of patients who benefit from chemotherapy

A summary of head-to-head comparisons[4] presented at ESMO 2017 confirmed that the most common genomic tests in clinical use for early breast cancer (Oncotype DX, MammaPrint®, EndoPredict®, Prosigna® and Breast Cancer Index℠) risk-stratify patients differently and are not interchangeable - which carries implications for the potential use of adjuvant chemotherapy.

Oncotype DX data presentations at the congress also included an analysis[5] of over 600,000 Recurrence Score results collected globally, which revealed geographically highly consistent subgroup sizes with more than half of patients classified as low risk (Recurrence Score result less than 18). These findings mirror observations from prospective registry studies, including SEER and Clalit, as well as the TAILORx and PlanB prospective clinical trials, suggesting that tumor biology as characterized by Recurrence Score results does not vary by geography and supporting the generalizability of outcomes-study results across geographic regions.

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[6] and affects many of them during their years dedicated to working and raising a family. While chemotherapy is routinely offered, research shows that less than 10 percent of patients with early-stage breast cancer actually benefit from it.[7]

The Oncotype DX test is designed to facilitate personalized clinical decisions by providing information about the biology of an individual breast cancer, with the potential to deliver financial benefits for healthcare systems. This is supported by substantial real-world evidence showing that the test can reduce the number of women undergoing unnecessary chemotherapy by up to 60 percent.[8]

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, the Oncotype DX test is widely available to patients across the UK. In France, Oncotype DX is available

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[4] Varga S, et al., 187P, Presented at ESMO 2017
[5] Blohmer et al. 192P, Presented at ESMO 2017
[6] EUCAN. 2012. Available at: http://eco.iarc.fr/EUCAN/CancerOne.aspx?Cancer=46&Gender=2
[7] Paik et al. *J Clin Oncol.* 2006 ; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. *Lancet.* 2012.
[8] Loncaster J et al, Eur J Surg Oncol 2017

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, including addressing the overtreatment of the disease. 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 800,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests, including the recently launched Oncotype SEQ® Liquid Select™ 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 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 June 30, 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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