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Major new study data demonstrates that the Onco*type* DX® test accurately predicts clinical breast cancer outcomes, bringing the total number of patients in prospective outcome studies to 50,000

- *Multiple data presentations establish Oncotype DX as the only multi-gene breast cancer test with industry-leading level of prospective outcomes evidence*
- *Next-generation sequencing (NGS) study showcases Genomic Health's scientific leadership in generating and analysing "big data"*

GENEVA, Switzerland, [14 December 2015] – Genomic Health today announced results from multiple Onco*type* DX® breast cancer test studies at the 38th CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) reconfirming that the Onco*type* DX test accurately predicts clinical outcomes, including risk of recurrence and breast cancer survival, in patients with early-stage invasive breast cancer. Data include results from the Surveillance, Epidemiology, and End Results (SEER) program of the U.S. National Cancer Institute (NCI)[1]; complete results from a multi-center study from Clalit Health Services[2], the largest health services organisation in Israel; and an additional analysis from the **T**rial **A**ssigning **I**ndividua**L**ized **O**ptions for Treatment (**Rx**), or TAILORx[3], led by the ECOG-ACRIN Cancer Research Group.

"The data from the SABCS meeting this year have confirmed the importance of genomic testing for women with early breast cancer to help define treatment, and importantly to define women who can safely avoid chemotherapy," said Dr. Alison Jones, breast cancer expert at specialist cancer treatment centre Leaders in Oncology Care (LOC) in London. "Chemotherapy has huge personal implications for the women concerned and is also really important from the perspective of health care providers - in terms of quality, cost and efficiency. Onco*type* DX is available to appropriate patients in the UK and is a major step forward."

Norman Wolmark, M.D., chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP), said: "Consistent with results from the NSABP and SWOG clinical validation studies of

Onco*type* DX, the new multiple prospective outcomes studies provide additional strong evidence of the test's ability to accurately predict prospective outcomes regardless of age, tumour size and grade. This is a significant milestone in genomics reconfirming the undeniable clinical value of Onco*type* DX when selecting patients for chemotherapy treatment."

Evidence in over 44,500 patients shows that the Oncotype DX test accurately predicts patient outcomes; Patients with Recurrence Score® results less than 18 have excellent breast cancer survival at five years

SEER is the premier source of cancer statistics in the United States, collecting incidence and cancer survival data for 30 percent of all U.S. cancer patients. A large population-based observational study based on the SEER registry of more than 40,000 node-negative and 4,500 node-positive patients who received the Onco*type* DX test in clinical settings showed Breast Cancer Specific Mortality (BCSM) at five years was less than half a percent in node negative disease and one percent in node positive disease (up to three positive nodes), when the Recurrence Score results are less than 18.

Another important finding was that mortality increased with increasing Recurrence Score results ($p<0.001$), underscoring the accuracy of the Onco*type* DX test in predicting real-world patient outcomes. BCSM increased slightly among patients with intermediate Recurrence Scores results of 18-30, and more than tenfold in patients with high Recurrence Score results equal to or greater than 31. Analyses that included patient age, tumour size and grade showed that the Recurrence Score provided information beyond those standard measures ($p<0.001$).

Three additional large international studies reinforce the test's ability to predict clinical outcomes, reconfirming worldwide value of Oncotype DX in guiding treatment

A study from Clalit Health Services analysed medical records of 2,028 patients with node-negative and node-positive disease with micrometastases across nine medical centers in Israel. The Onco*type* DX test was used in clinical practice in all the patients to assign treatment with or without chemotherapy. Results showed that the 996 women with low Recurrence Score results less than 18 who were largely treated with hormonal therapy alone (98 percent) had excellent outcomes with less than one percent chance of distant recurrence or breast cancer specific mortality at five years. In addition, the 812 patients with intermediate Recurrence Score results of 18 to 30, who were treated 28 percent of the time with chemotherapy, had only slightly higher rates of distant recurrence (3.2 percent) and breast cancer specific mortality (1.1 percent) at five years.

Separately, the initial results of TAILORx, that were recently published in *The New England Journal of Medicine* were presented again at SABCS along with an additional analysis of the correlation of the Onco*type* DX test single gene scores with clinicopathological measures. Key findings, previously

reported, demonstrated that trial participants with Recurrence Score results of less than 11 who received hormonal therapy alone had less than a one percent chance of distant recurrence at five years.

Similar findings regarding prospective outcomes for patients tested with Onco*type* DX were recently reported at the European Cancer Congress by the German Women's Healthcare Study Group (WSG)[4]. The planB study, conducted in more than 90 centers across Germany, is one of Europe's largest contemporary adjuvant breast cancer trials and analysed outcomes in more than 2,500 patients.

Next-generation sequencing gene discovery reveals opportunity for liquid biopsy to help guide late-recurrence treatment decisions

Also presented at the 2015 SABCS, a gene discovery study[5] conducted by the NCI cooperative group, SWOG, identified a number of new genes and pathways that may be important in early breast cancer recurrence or response to chemotherapy. The study also showed that the biology of late recurrence was very different than the biology for early recurrence. This is a particularly important finding because it provides an opportunity for a new technology like liquid biopsy – which may be better suited to predict late recurrence based on evolution of the tumour – to help guide duration of hormonal therapy and to track cancer progression and drug resistance.

About the Oncotype DX test

The Onco*type* DX breast cancer test 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 recognising the value of the test, which is incorporated in all major international clinical guidelines. Most recently, the National Health Service (NHS) in England agreed to an access programme for the Onco*type* DX breast cancer test. Other European countries that reimburse the test include Switzerland, Ireland, Greece and Spain. To learn more about the Onco*type* DX test, visit: www.OncotypeDX.com

About Genomic Health

Genomic Health, Inc. is a world-leading provider of genomic-based diagnostic tests that inform treatment decisions and help to ensure each patient receives appropriate treatment for early stage cancer. The company applies 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 screening and surveillance, through diagnosis and treatment selection. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.co.uk.

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 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 ability of test results to change treatment decisions; the risks and uncertainties associated with the regulation of the company's tests; the results of clinical studies; the applicability of clinical study results to actual outcomes; 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 quarterly report on Form 10-Q for the quarter ended September 30, 2015. 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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[1] Shak et al: "Breast cancer specific survival in 38,568 patients with node negative hormone receptor positive invasive breast cancer and Oncotype DX recurrence score results in the SEER database" (Poster session 5, P5-15-01)

[2] Stemmer et al: "Real-life analysis evaluating 1594 N0/Nmic breast cancer patients for whom treatment decisions incorporated the 21-gene recurrence score result: 5-year KM estimate for breast cancer specific survival with recurrence score results ≤30 is >98%" (Poster session 5, P5-08-02)

[3] Sparano et al: "Prospective trial of endocrine therapy alone in patients with estrogen receptor positive, HER2-negative, node-negative breast cancer: Results of the TAILORx low risk registry" (Poster session 2, P2-08-01)

[4] Gluz et al: "Clinical impact of risk classification by central/local grade or luminal-like subtype vs. Oncotype DX®: First prospective survival results from the WSG phase III planB trial" (Abstract #1937 presented at ECC2015)

[5] Albain et al: Molecular predictors of outcome on adjuvant CAF plus tamoxifen (T) vs T in postmenopausal patients (pts) with ER+, node+ breast cancer – transcriptome expression analysis of the phase III trial SWOG-8814 (General session 3, S3-02)