



Contact:

Media:

Federico Maiardi

Genomic Health

+41 79 138 1326

fmairdi@genomichealth.com

Oncotype DX[®] presentations at 2016 ASCO[®] annual meeting reinforce Genomic Health's leadership in optimising breast cancer treatment

Recent publication in Journal of Clinical Oncology demonstrates that Oncotype DX predicts late distant recurrence in breast cancer

GENEVA, Switzerland, [June 6, 2016] -- Genomic Health announced multiple data presentations with Oncotype DX[®] Breast Recurrence Score[™] at the recent [2016 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#). The presentations about the test included new results from the European PlanB outcomes study and four new analyses of the Surveillance, Epidemiology, and End Results (SEER) Registry of the U.S. National Cancer Institute (NCI) with more than 44,600 breast cancer patients.

Collectively, these data confirm the test's ability to accurately predict clinical outcomes, reinforcing the unique value of Oncotype DX as the only multi-gene breast cancer test with prospective outcomes evidence in more than 50,000 patients.

New results from European PlanB outcomes study presented at ASCO 2016

Clinical outcome results from the prospective PlanB trial, one of the largest contemporary adjuvant breast cancer trials in Europe, showed that patients with low Breast Recurrence Score results treated with hormonal therapy alone had 99 percent five-year overall survival.¹ The results are consistent with conclusions of the **Trial Assigning Individualized Options for Treatment (Rx)**, or TAILORx, published in [The New England Journal of Medicine](#), and previously-presented results from the SEER Registry.²

PlanB was conducted by the West German Study Group (WSG) in 93 centres across Germany and enrolled more than 3,100 patients who were considered candidates for chemotherapy by traditional parameters including those with node-positive disease (up to three nodes). The study used the Oncotype

¹ Gluz O. et al., J Clin Oncol 34, 2016 (suppl; abstr 556)

² Shak et al., Poster session 5, P5-15-01, Presented at SABCS 2015

DX Breast Recurrence Score results to identify patients who, despite high clinical risk, would be spared adjuvant chemotherapy.

“These new study results show that a low Recurrence Score result identifies patients who can be safely spared chemotherapy without compromising outcomes,” said Prof. Nadia Harbeck, WSG Scientific Director and Head of the breast center at University of Munich (LMU), Germany. “This is especially important for patients who would be considered as intermediate to high risk of recurrence based on traditional clinical parameters. The results confirm previous retrospective studies with Oncotype DX as well as the prospective TAILORx trial, which already provided results for the node-negative population.”

Results of SEER analyses presented at ASCO 2016

- In node-positive disease, the Breast Recurrence Score added considerable additional independent prognostic value for five-year breast cancer survival when reported separately for patients with micrometastases, one, two or three positive nodes.³
- In node-negative disease, worse breast cancer survival was observed in older patients (over age 70) who were tested and had an intermediate or high Breast Recurrence Score result, contrary to the general perception that older women tend to have favorable outcomes. Patients age 70 or older also had lower reported chemotherapy use, supporting continued examination of the often reported issue of under-treatment of the elderly.⁴
- The utilisation of Oncotype DX in clinical practice significantly varied based on age, race, socioeconomic status, marital status, insurance, tumor grade, tumor size ($p < 0.01$ for each) and geographic location. Patient age and geographic location were particularly strong factors that influenced test use. Overall, about 40 to 50 percent of women who met the guideline criteria for Oncotype DX had the test, underscoring the opportunity to bring precision medicine to more patients.^{5,6}

The National Cancer Institute’s SEER Registry, the premier source of cancer statistics in the United States, collects incidence and cancer survival data for 30 percent of all U.S. cancer patients.

Publication in Journal of Clinical Oncology demonstrates that Oncotype DX predicts late distant recurrence in breast cancer

Separately, the [*Journal of Clinical Oncology*](#), the official journal of the American Society of Clinical Oncology (ASCO), recently published results from a large study confirming the ability of Oncotype DX, in combination with quantitative estrogen-receptor (ER) expression, to accurately predict after five years

³ Roberts M. et al., J Clin Oncol 34, 2016 (suppl; abstr 6575)

⁴ Petkov V. et al., J Clin Oncol 34, 2016 (suppl; abstr 574)

⁵ Petkov V. et al., J Clin Oncol 34, 2016 (suppl; abstr 6552)

⁶ Cronin K. et al., J Clin Oncol 34, 2016 (suppl; abstr 6553)

of tamoxifen therapy the risk of late distant recurrence up to 15 years in patients with early-stage, hormone receptor-positive breast cancer. These findings suggest that the Oncotype DX test may help identify which patients are most likely to benefit from extended hormonal treatment with tamoxifen.

“Extending tamoxifen treatment for 10 years has been shown to be associated with better outcomes, but not all patients have the same risk of late distant recurrence - meaning cancer coming back after five years - and it is important to know a patient’s risk in order to better understand who will benefit the most from extended hormonal treatment,” said Norman Wolmark, M.D., chairman of the National Surgical Adjuvant Breast and Bowel Project (NSABP) Foundation, the organisation that carried out the study in conjunction with Genomic Health. “The results of this large study confirm that Oncotype DX helps better define who is at greatest risk of a late distant recurrence and who would likely derive the greatest benefit from extended tamoxifen therapy.”

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 recognising 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. Other European countries that reimburse the test include Switzerland, Ireland, Greece and Spain. To learn more about the Oncotype DX test, visit: www.OncotypeDX.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 600,000 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](https://twitter.com/GenomicHealth), [Facebook](https://www.facebook.com/GenomicHealth), [YouTube](https://www.youtube.com/GenomicHealth) and [LinkedIn](https://www.linkedin.com/company/GenomicHealth).

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 risks and uncertainties associated with the regulation of the company's tests; 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; the risks of competition; 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, 2016. 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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