Contact

Media
Federico Maiardi
Genomic Health
+41 79 138 1326
fmaiardi@genomichealth.com

New validation shows Oncotype DX Breast Recurrence Score® test predicts clinical response to neoadjuvant hormonal therapy to improve surgical outcomes in certain patients with large tumors

Ten Oncotype DX® studies presented at the 40th San Antonio Breast Cancer Symposium

GENEVA, Switzerland, [December 11, 2017] – Genomic Health today announced highlights from new data presentations with the Oncotype DX Breast Recurrence Score® test at the 2017 San Antonio Breast Cancer Symposium (SABCS).

"These latest presentations further our understanding of breast cancer biology across the continuum of the disease and highlight the unique value of the Oncotype DX® test in providing critical information to personalize and improve the quality of treatment decisions in both the adjuvant and neoadjuvant settings," said Calvin Chao, Vice President of Global Medical Affairs at Genomic Health.

Analyzing tumor biology with Oncotype DX can help guide treatment decisions prior to breast cancer surgery

Neoadjuvant systemic therapy such as chemotherapy and hormonal therapy can shrink tumor size and allow breast conserving surgery (BCS) for patients diagnosed with hormone receptor positive (HR+) large tumors (≥2cm) who may otherwise be advised to undergo a mastectomy. However, chemotherapy comes with its many debilitating side effects and, in some patients, does not provide improved surgical outcomes over hormonal therapy. Identifying patients whose tumors may not respond to chemotherapy is difficult using traditional parameters and as a result some patients receive chemotherapy treatment in this setting, yet unfortunately they do not derive any benefit.

Core needle biopsy samples from approximately 300 postmenopausal patients with HR+, HER2-, node negative invasive breast cancer enrolled in the randomized Phase 3 NEOS study were analyzed to determine clinical response to six months of hormonal therapy before surgery based on Recurrence Score® results.

The analysis[1] showed that Recurrence Score results are significantly associated with clinical response to hormonal neoadjuvant therapy ($p<0.001$). Specifically, findings suggest that, for patients with a Recurrence Score result below 18, treatment with neoadjuvant hormonal therapy alone could be an effective treatment strategy. Such patients could thus potentially avoid chemotherapy without reducing their chances of successful BCS.

"This important validation study demonstrates that analyzing tumor biology with Oncotype DX in the neoadjuvant setting can help guide treatment decisions," said Prof. Hiroji Iwata, Principal Study Investigator, Department of Breast Oncology, Aichi Cancer Center Hospital, Nagoya, Japan. "In particular, patients with a low Recurrence Score result tend to have higher clinical response rate with neoadjuvant hormonal therapy, which makes it possible to shrink the tumor size and achieve breast conserving surgery leading to better cosmetic outcomes whilst limiting the impact of treatment side effects on their quality of life."

New results from large registry with 10-year follow up show excellent outcomes for patients with low Recurrence Score results treated with hormonal therapy alone

In this study[2] from Clalit Health Services, the largest health services organization in Israel, medical records of more than 1,500 patients with node negative breast cancer or with micro metastases tested between January 2006 and December 2009 were examined to verify given treatment and subsequent outcomes. The findings showed that use of chemotherapy was aligned with Recurrence Score results. Patients who had been diagnosed with HR+, node negative breast cancer and who had Recurrence Score results of less than 18, the vast majority of whom (98.2% or 632) were treated with hormonal therapy alone, had excellent outcomes with 10-year Kaplan Meier estimates of distant recurrence of 3.9% and breast cancer specific survival rate of 98.1%.

"This important analysis with long-term follow up shows that patients with low Recurrence Score results can be treated with hormonal therapy alone and indicates that withholding chemotherapy is possible in those with intermediate risk and Recurrence Score results up to 25," said Prof. Salomon Stemmer, Lead investigator of the study, Department of Oncology, Davidoff Center, Rabin Medical Center affiliated to Tel Aviv University, Israel. "The genomic information provided by the Oncotype DX test is important in order to identify patients who can be spared the toxicity of chemotherapy."

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[1] Yamamoto, Iwata et al. TransNEOS: Validation of the Oncotype DX Recurrence Score testing core needle biopsy samples from NEOS as predictor of clinical response to neoadjuvant endocrine therapy for postmenopausal ER+, HER2-negative breast cancer patients. Abstract: PD5-03. San Antonio Breast Cancer Symposium. December 2017.

[2] Stemmer et al. Real-life analysis evaluating >1000 N0/N1mi ER+ breast cancer patients for whom treatment decisions incorporated the 21-gene Recurrence Score result: Clinical outcomes with median follow up of >9 years. Abstract: P1-07-14. San Antonio Breast Cancer Symposium. December 2017.

New data reinforce specific value of examining tumor biology with Oncotype DX in older women

This analysis[3] from the prospective West German Study Group's (WSG) PlanB trial examined Oncotype DX Breast Recurrence Score results in patients aged 70 years and greater versus those under 70. It then evaluated disease free survival (DFS) in both groups. For patients with higher risk tumors (Recurrence Score result over 25) treated with chemotherapy, results showed comparable DFS rates regardless of which age bracket they were in.

The findings reinforce the value of the Oncotype DX Breast Recurrence Score test for older patients to identify more accurately those who would derive benefit from chemotherapy.

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[4] 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.[5]

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.[6]

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 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

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[3] Harbeck et al. No age-related outcome disparities according to 21-gene Recurrence Score groups in early breast cancer patients treated by adjuvant chemotherapy in the prospective WSG PlanB trial. Abstract: P1-06-06. San Antonio Breast Cancer Symposium. December 2017.

[4] EUCAN. 2012. Available at: http://eco.iarc.fr/EUCAN/CancerOne.aspx?Cancer=46&Gender=2

[5] Paik et al. *J Clin Oncol.* 2006 ; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. *Lancet.* 2012.

[6] Loncaster J et al, Eur J Surg Oncol 2017

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 September 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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