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Large study shows older breast cancer patients have worse outcomes

Results highlight need for tools to help identify patients who may benefit from chemotherapy

LONDON, [October 10, 2016] – Results from a large-scale observational study[1], presented at the European Society for Medical Oncology (ESMO) annual meeting, October 7 – 11 in Copenhagen, Denmark, showed outcomes disparities in breast cancer-specific mortality between patients 70 years or greater and those under 70 with a higher breast cancer mortality for the older patients.

Following up on the work of the multinational TEAM study[2], which reported worse outcomes for older patients with hormone-receptor-positive (HR+) breast cancer, this study examined Oncotype DX® Breast Recurrence Score® results in patients 70 years and greater versus those under 70. It then evaluated breast cancer-specific mortality in both groups.

In the study, Recurrence Score results were provided to the National Cancer Institute's SEER registry, the premier source of cancer statistics in the United States, and linked to breast cancer cases. Over 207,320 eligible patients were identified among those with node-negative, HR+ breast cancer diagnosed between 2004 and 2011. The results showed that mortality was indeed higher in patients over 70 who were either not tested with Oncotype DX, or had a Recurrence Score result greater than 18. Patients age 70 or older also had much lower reported chemotherapy use, supporting continued examination of the often reported issue of under-treatment of the elderly.

Last year, the European Registration of Cancer Care (EURECCA) study[3], a large-scale international comparison of the treatment of elderly patients with non-metastatic breast cancer, showed that there are substantial differences in the use of surgery, hormone therapy and chemotherapy between European countries. According to the study authors, this is due to a lack of evidence for the treatment of older patients with breast cancer.

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[1] Shak S. et al., abstract #146 O, presented at ESMO 2016
[2] Van de Water W. et al., JAMA 2012
[3] Derks M. et al., abstract #1808 presented at ECC 2015

"The results presented at ESMO reveal disparities in Oncotype DX testing use and patient outcomes, showing poor breast cancer specific survival in untested patients and in those with intermediate and high Breast Recurrence Score results, contrary to the general perception that older women tend to have only low-risk disease," said Steven Shak, M.D., chief scientific officer, Genomic Health. "These new data reinforce the specific value of examining tumor biology with Oncotype DX in older women and add to unprecedented evidence that the Recurrence Score provides critical information to improve treatment approaches and outcomes in breast cancer patients."

Professor Etienne Brain, President of the International Society of Geriatric Oncology, said: "In our modern world, researchers are continually working to refine and streamline breast cancer treatment, including the use of tools such as genomic testing that aim at improving the assessment of prognosis, and the prediction of treatment benefit. It is concerning that cancer diagnoses in older patients are rising as the population ages and life expectancy increases, and yet, their treatments and outcomes are inequitable compared to younger patients.

"This landmark study provides insightful data which stress the importance of addressing and improving the care for older patients, including the use of tools that lead to a more personalised treatment strategy for this vulnerable patient group."

Additional data solidify utility of Oncotype DX in node-positive breast cancer patients

Two posters were also presented at ESMO providing further evidence in over 7,300 patients that Oncotype DX accurately predicts outcomes and has important clinical utility in node-positive disease.

In the first study[4] from Clalit Health Services (Israel), medical records of more than 700 patients with micro metastases and node-positive disease who were tested between January 2008 and December 2011 were examined to verify treatment given, and subsequent outcomes. The results showed that use of chemotherapy was aligned with Recurrence Score results, and that patients with Recurrence Score results of less than 18, the vast majority (92.9%) of whom were treated with hormonal therapy alone, had very good outcomes with low rates of distant recurrence after a median follow-up of 5.9 years.

Another analysis of the SEER registry[5] looked at breast cancer-specific survival (BCSS) in more than 6,700 patients with node-positive disease. The results showed that 5-year BCSS was excellent in patients with Recurrence Score results less than 18 and micrometastases, one, or two positive nodes. Survival worsened with increasing number of lymph nodes involved and higher Recurrence Score results.

[4] Stemmer S. et al., abstract #147 PD, presented at ESMO 2016
[5] Miller D.P. et al., abstract #150 PD, presented at ESMO 2016

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. In France, Oncotype DX is available through a funding mechanism for genomic tests. To learn more about the Oncotype DX test, visit: www.OncotypeDX.co.uk

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 UK headquarters in London. For more information, please visit, www.GenomicHealth.co.uk 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 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 June 30, 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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