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New data demonstrate that Oncotype DX® can help guide treatment decisions before breast cancer surgery enabling more personalised care, including avoidance of full mastectomy

Study shows test can identify patients who could be spared chemotherapy but who could still benefit from hormonal treatment that allows breast conserving surgery

LONDON, [December 12, 2016] – New data presented at the 2016 San Antonio Breast Cancer Symposium (SABCS) demonstrate that analysing tumor biology with the Oncotype DX test can identify patients unlikely to benefit from chemotherapy prior to breast cancer surgery (neoadjuvant setting) and guide treatment decisions without compromising outcomes.¹

Neoadjuvant systemic therapy such as chemotherapy and hormonal therapy can shrink tumor size and allow breast conserving surgery (BCS) in patients with large tumors who may otherwise need a full mastectomy. However, chemotherapy can be toxic and, in some patients, does not provide improved surgical outcomes over hormonal therapy. Identifying hormone receptor positive (HR+) patients who may not respond to chemotherapy is difficult using traditional parameters and some receive the treatment unnecessarily.

This prospective, multi-center study enrolled patients with HR+, HER2-negative, invasive breast cancer who were not suitable for BCS due to tumor size. The biology of their tumors was analysed using the Oncotype DX® Breast Recurrence Score™ on core biopsy specimens, with the aim of identifying patients in whom treatment with neoadjuvant hormonal therapy alone would achieve sufficient tumor shrinkage to allow BCS.

This pilot study showed that for patients with a Recurrence Score® result below 25, treatment with neoadjuvant hormonal therapy alone could be an effective treatment strategy to achieve BCS. Such patients could thus potentially avoid chemotherapy without reducing their chances of successful BCS.

“These data demonstrate that analysing tumor biology with Oncotype DX on initial core biopsies in the neoadjuvant setting could be a powerful strategy in guiding treatment decisions. Tumor shrinkage is

¹ Bear H.D. et al. Using the 21 gene assay from core needle biopsies to choose neoadjuvant therapy for breast cancer: A multicenter trial. San Antonio Breast Cancer Symposium. December 2016.

difficult to achieve in patients with HR+ breast cancer, even with chemotherapy. But if we can identify patients who are likely to respond well to hormonal therapy, we can maximise their chances of breast conserving surgery whilst limiting the impact of treatment side effects on their quality of life,” said Prof. Nigel Bundred, Professor in Surgical Oncology, University Hospital of South Manchester NHS Foundation Trust.

A decade of real-world evidence reinforcing Genomic Health’s leadership in individualising breast cancer treatment decisions

Two further analyses presented at SABCS demonstrated the extensive real-world data supporting the clinical utility of the Oncotype DX test amassed over more than a decade.

A study based on the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI), the premier source of cancer statistics in the United States, looked at breast cancer-specific mortality in patients with poorly differentiated tumors who were treated according to their Recurrence Score results.² Although these patients generally have a worse prognosis, the study demonstrates that Oncotype DX can identify a sizeable proportion of patients with low Recurrence Score results who can expect good outcomes without chemotherapy and its associated toxicity.

A summary of the evidence from over 10 years of clinical use in more than 50,000 patients confirmed the valuable role of Oncotype DX in identifying patients who can be treated safely with hormonal therapy and avoid the toxicity and quality of life impact of chemotherapy.³ These data underscore the value to both clinicians and patients of analysing tumor biology alongside traditional parameters to allow better informed treatment decisions and greater personalisation of treatment.

“These latest Oncotype DX data presentations further our understanding of breast cancer biology across the continuum of the disease. The data continue to show the additional value provided by Oncotype DX in its ability to stratify patients by risk as well as help clinicians predict patients who are likely to benefit from either neoadjuvant or adjuvant chemotherapy,” said Prof. Nigel Bundred.

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

² Petkov VI et al. SEER study of breast cancer-specific mortality in patients with poorly differentiated tumors treated based on recurrence score results. San Antonio Breast Cancer Symposium. December 2016.

³ Sing AP et al. Real world clinical experience and outcomes in patients with early-stage breast cancer (EBC) treated according to the 21-gene Recurrence Score (RS) result. San Antonio Breast Cancer Symposium. December 2016.

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 700,000 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](https://twitter.com/GenomicHealth), [Facebook](https://www.facebook.com/GenomicHealth), [YouTube](https://www.youtube.com/GenomicHealth) and [LinkedIn](https://www.linkedin.com/company/genomic-health).

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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, 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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