## **Contact:**

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



## Onco*type* DX<sup>®</sup> test available to guide treatment decisions for early breast cancer patients, through access scheme for NHS in England

- Multigene test developed by Genomic Health predicts likelihood of chemotherapy benefit and risk of disease recurrence in invasive breast cancer
- Access scheme follows NICE's exclusive recommendation

**[London, February 5, 2015]** Genomic Health UK announced that as of April 1, 2015, the Onco*type* DX test will be available, through an access scheme, as an option to help National Health Service (NHS) clinicians in England decide whether to prescribe chemotherapy in people with early breast cancer. The access scheme allows NHS hospitals to implement the National Institute for Health and Care Excellence's (NICE) <u>guidance</u>, which recommends only the Onco*type* DX multi-gene breast cancer test for assisting in chemotherapy treatment decisions for patients with early-stage, hormone receptor-positive, HER2 negative, invasive breast cancer.<sup>1</sup>

In setting up the access scheme, NHS England recognised the advantages of more targeted use of chemotherapy for patients, in line with NICE guidance. 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.

"The improved access to a test that allows for a better understanding of individual tumour biology is an important step forward to personalised care for UK breast cancer patients," said Professor Nigel Bundred, Professor in Surgical Oncology, University Hospital of South Manchester NHS Foundation Trust. "Having this knowledge can give us greater confidence in recommending a treatment plan best suited for an individual patient which decreases the complications of treatment without compromising survival. The Oncotype DX breast cancer test should be routinely used for all eligible patients throughout the country."

Criteria currently used for making chemotherapy treatment decisions in clinical practice may result in substantial overtreatment and unnecessary costs for the healthcare system. Research shows that less than 10% of patients with early-stage breast cancer actually benefit from chemotherapy<sup>2,3</sup> and almost a third of treatment recommendations for UK-based, early-stage breast cancer patients change after the use of the Oncotype DX test.<sup>4</sup>

"We welcome this decision, which represents the culmination of several years of work and dedication to our mission of improving the quality of treatment decisions for patients diagnosed with breast cancer,"

<sup>&</sup>lt;sup>1</sup> NICE diagnostics guidance [DG10]. Available at: <a href="http://www.nice.org.uk/guidance/DG10">http://www.nice.org.uk/guidance/DG10</a> Last accessed January 2015.

<sup>&</sup>lt;sup>2</sup> Paik S et al. J Clin Oncol 2006;24:3726-34

<sup>&</sup>lt;sup>3</sup> Early Breast Cancer Trialists' Collaborative Group (EBCTCG), et al. Lancet. 2012:379;432-444

<sup>&</sup>lt;sup>4</sup> Holt S, et al. Br J Cancer. 2013 Jun 11; 108(11):2250-8

said Dr Andrea Pithers, Genomic Health Group Country Manager, UK and Ireland. "With more than 3,500 women in the UK having already used the Onco*type* DX test to help guide their treatment decisions, the access scheme represents a pathway towards making the test routinely available for NHS patients where it will aid treatment decision-making. We will work with local hospitals to facilitate quick and equitable access throughout the country."

The Onco*type* DX breast cancer test is incorporated in major international guidelines including NICE, St. Gallen International Breast Cancer Expert Panel, ESMO and ASCO. Since it became available in 2004, nearly half a million breast cancer tests have been requested by more than 19,000 physicians in over 70 countries.

## **About Genomic Health**

Genomic Health, Inc. (NASDAQ: GHDX) is a world leading provider of genomic-based diagnostic tests that optimize treatment for early stage cancer. 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 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, <a href="https://www.GenomicHealth.co.uk">www.GenomicHealth.co.uk</a>. To learn more about Oncotype DX, visit: <a href="https://www.OncotypeDX.com">www.OncotypeDX.com</a>

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 and attributes of the company's tests to physicians and patients; the attributes and focus of the company's product pipeline; the company's belief that it is applying its infrastructure and expertise to lead the translation of genomic data into clinically-actionable results; and the applicability of clinical study results to actual outcomes. 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; the applicability of clinical study results to actual outcomes; our 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 quarterly report on Form 10-Q for the quarter ended September 30, 2014. 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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