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**Evidence from UK hospitals supports the value of the Oncotype DX® test in avoiding unnecessary chemotherapy for patients with node-positive breast cancer**

- *Following use of the Oncotype DX test, recommendations for chemotherapy declined from 69.9% of patients to 27.7% of patients*
- *Real-life findings based on 582 breast cancer patients across 30 UK hospitals receiving the test as part of PONDx survey*
- *Data was presented today by researchers from The Royal Marsden NHS Foundation Trust at the 16th St. Gallen International Breast Cancer Conference*
- *"These data show that the Oncotype DX test provides valuable information in guiding treatment decisions for patients whose cancer has spread to the lymph nodes," said co-lead author Dr Sophie McGrath*

**LONDON,** [March 25, 2019] – A prospective decision impact survey[1] in UK clinical practice has shown that chemotherapy recommendations changed in a substantial proportion of patients with cancer detected in one to three lymph nodes following testing with the Oncotype DX Breast Recurrence Score® test. The findings were derived from information collected through the PONDx survey, which was conducted by physicians from various institutions including the Royal Marsden NHS Foundation Trust and allowed breast cancer patients with node-positive disease to access the Oncotype DX test in the UK.

The results show a substantial difference in the treatment recommended by oncologists after adopting the Oncotype DX test, with the test identifying both over-treatment and under-treatment of hormone receptor positive, HER2 negative breast cancer tumours. The findings are based on 582 patients at 30 institutions across the UK.

Before using the Oncotype DX test, chemotherapy was recommended for 407 patients (69.9%). However, after analysis of the tumour biology using the test, chemotherapy was suggested in 161 patients (27.7%) and given to 140 (24.1%), with the rest referred for less aggressive hormone therapy.

The test allowed 269 patients who had initially been recommended for chemotherapy – 66% of this subset - to avoid such therapy, including the associated short and long-term side-effects of the treatment.

[1] Battisti et al. Poster: P007, St. Gallen International Breast Cancer Conference

Conversely, the Oncotype DX test identified 23 patients who were initially advised to undergo only hormone therapy, but whose treatment was changed to add chemotherapy based on their Recurrence Score® result. Without testing, these patients may have been under-treated, potentially increasing their risk of breast cancer recurrence.

"This data shows that the Oncotype DX test provides valuable information in guiding treatment decisions for patients whose cancer has spread to the lymph nodes," said Dr Sophie McGrath, Consultant in Medical Oncology at The Royal Marsden NHS Foundation Trust. "Not all node-positive patients need to receive chemotherapy. It is in everybody's interests that chemotherapy is targeted effectively. The Oncotype DX test can help identify the high proportion of patients who can be treated with hormone therapy alone, as well as the small minority who are likely to derive significant benefit from chemotherapy."

The findings add to mounting evidence that the Oncotype DX test can improve the care of patients with node-positive breast cancer. The test is available on the NHS only for patients with node-negative or micrometastatic breast cancer under guidance drawn up by the National Institute for Health and Care Excellence (NICE). At present, node-positive breast cancer patients in the UK require private health insurance to access the test.

Stephen Ogram, UK Managing Director for Genomic Health, said: "Thousands of breast cancer patients across the UK have already benefited from the Oncotype DX test. This data underlines the case for widening availability to patients whose cancer has spread to the lymph nodes. Oncotype DX is the only test that predicts who truly needs adjuvant chemotherapy, helping to target treatment more effectively and alleviating pressure on already stretched NHS services."

***New long-term outcomes data reconfirm value of Oncotype DX Breast Recurrence Score® test to target chemotherapy***

Also presented at the St. Gallen International Breast Cancer Conference, new data further support the utility of the Oncotype DX test to optimise chemotherapy recommendations in patients with early-stage breast cancer with or without lymph node involvement:

- An updated analysis[2] of the Clalit Health Services registry, the largest health services organisation in Israel, examined medical records of more than 1,300 patients with node-negative breast cancer applying the Recurrence Score cut point determined by the landmark TAILORx study. The findings showed that use of chemotherapy was aligned with Recurrence Score results and that patients with Recurrence Score results up to 25, the vast majority of whom were treated with hormonal therapy alone, had excellent outcomes at ten years with low rates of distant recurrence.

[2] Stemmer et al. Poster: P249, St. Gallen International Breast Cancer Conference. March 2019

- Real-world evidence[3] from the nine-year follow up of more than 80,000 patients with Recurrence Score results included in the Surveillance, Epidemiology, and End Results (SEER) registry programme of the National Cancer Institute (NCI) confirm the TAILORx results. The breast cancer specific survival (BCSS) was greater than 96% in patients with node-negative disease and Recurrence Score results up to 25 not treated with chemotherapy. In patients with node-positive disease not treated with chemotherapy and Recurrence Score results less than 18, BCSS was greater than 97 percent at nine years.

***About TAILORx***

TAILORx - the largest randomised adjuvant breast cancer treatment trial ever conducted, comprising more than 10,000 patients, last year definitively confirmed the value of the Oncotype DX test for guiding adjuvant chemotherapy decisions in patients with early-stage, node-negative breast cancer. The study identified the majority of women (Recurrence Score result up to 25) who receive no substantial benefit from chemotherapy, as well as the important minority (Recurrence Score result 26-100) for whom chemotherapy can be life-saving. A further trial, RxPONDER, designed to determine the effect of chemotherapy in breast cancer patients with one to three positive nodes, who have a Recurrence Score result equal to, or less than, 25, is currently underway.

***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 UK 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 only a minority of patients with early-stage breast cancer actually benefit from it[5].

The Oncotype DX test is designed to facilitate personalised 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].

To learn more about the Oncotype DX test, visit: www.OncotypeIQ.co.uk

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[3] Winer et al. Poster: P246, St. Gallen International Breast Cancer Conference. March 2019

[4] Cancer Research UK. Available at : https://www.cancerresearchuk.org/health-professional/cancer-statistics/incidence/common-cancers-compared

[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

***About Genomic Health***

Genomic Health is the world's leading provider of genomic-based diagnostic tests that help optimise cancer care. 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 one million cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based tests, including the recently launched Oncotype DX® AR-V7 Nucleus Detect™ test. The company is based in Redwood City, California with international headquarters in Geneva, Switzerland and a UK office in London. For more information, please visit, www.GenomicHealth.co.uk and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

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