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New real-world evidence confirms value of the Oncotype DX® test in clinical practice for patients with early-stage breast cancer

- *Studies presented at ESMO further demonstrate the test's ability to change chemotherapy treatment decisions by more precisely identifying patients who will or will not benefit from chemotherapy*
- *Findings underscore the value of the test in both node negative (N0) and node positive (N+) disease*
- *The Oncotype DX test is named as the only "preferred" test for chemotherapy decision-making by the US National Comprehensive Cancer Network (NCCN)*
- *The Oncotype DX test continues to be available on the National Health Service for patients in the UK with node negative breast cancer*

LONDON, [October 22, 2018] – Results from two prospective decision impact studies^{1,2}, presented at the [ESMO 2018 Congress](#), October 19-23 in Munich, Germany, further support the utility of the Oncotype DX Breast Recurrence Score® test to optimise chemotherapy recommendations in patients with early-stage, hormone-receptor positive, HER-2 negative breast cancer with or without lymph node involvement. These new results add to the body of data supporting the Oncotype DX test, which includes multiple validation studies demonstrating its unique ability to predict chemotherapy benefit along with prospective long-term patient follow-up of more than 70,000 patients both with N0 and N+ disease³⁻⁸, showing that the test accurately predicts clinical outcomes.

The first study¹ presented at ESMO is research from Ireland assessing the impact of the Oncotype DX test on treatment decisions in routine clinical practice for early breast cancer patients whose disease has spread to the lymph nodes (one to three positive nodes). Overall, access to the test's results led to a change in physicians' recommendations to patients. From the 74 patients with Recurrence Score® results included in the analysis, the study found that in 64% of cases, oncologists reported that the test's result substantially changed treatment recommendations. In particular, testing with Oncotype DX led to a 27% overall reduction in chemotherapy recommendations.

“These new results strengthen published findings from our PlanB study and show the unique value of adding genomic information provided by the Oncotype DX test to better target chemotherapy. Oncotype

DX identifies patients who can safely be spared chemotherapy toxicity and side effects. Furthermore, we have to be concerned about a relevant proportion of patients who seem to be undertreated if the risk of recurrence is evaluated using only traditional clinical parameters,” said Prof. Ulrike Nitz, head of the breast cancer/senology unit at the Bethesda Hospital, Moenchengladbach, Germany. “The use of the Oncotype DX test allows us to tailor treatment plans more accurately to suit the needs of individuals, and to use resources more effectively.”

Also presented at ESMO, results of another real-life, decision-impact study² from France and Italy including both N0 and N+, early-stage breast cancer patients showed that treatment recommendations changed for 35% of patients included in the study based on Recurrence Score results, and that using the test to guide treatment decisions resulted in a relative net reduction in chemotherapy recommendations of 43%. These changes in treatment recommendations would be even greater in patients with N0 disease applying decision-making criteria (Recurrence Score groups) based on results from the [recently published](#) landmark TAILORx study.³

TAILORx - the largest randomised adjuvant breast cancer treatment trial ever conducted - definitively confirmed the value of the Oncotype DX test for guiding adjuvant chemotherapy decisions in patients with early-stage, node-negative breast cancer. In particular, results demonstrate that the test provides definitive evidence about the magnitude of chemotherapy benefit based on prospective long-term patient follow up, identifying the vast majority of women who receive no substantial benefit from chemotherapy, as well as the important minority of women for whom chemotherapy can be life-saving. Thus, the test can greatly reduce both over- and undertreatment with chemotherapy.

This was recently acknowledged by Germany’s health technology assessment body - the Institute for Quality and Efficiency in Health Care (IQWiG) - which [concluded](#) that only the Oncotype DX test has sufficient evidence to guide breast cancer adjuvant chemotherapy decisions based on the TAILORx study results.

In a further international endorsement, the US National Comprehensive Cancer Network has categorised Oncotype DX as the only “preferred” test for chemotherapy treatment decision-making for node-negative, early stage breast cancer patients in its 2018 updated guidelines for treatment.

“There is a wealth of evidence from around the world to demonstrate that the Oncotype DX test is a crucial tool in guiding decisions on clinical care for breast cancer patients,” said Steve Ogram, UK Managing Director, Genomic Health. “Over the summer, the world’s biggest adjuvant breast cancer treatment trial – TAILORx – drew on 10,000 cases to definitively confirm that Oncotype DX is the only test that reduces both undertreatment and overtreatment with chemotherapy. Assessment bodies in Germany and the United States have endorsed the test. Today’s findings add to the compelling case for the National Institute for Health and Care Excellence to confirm its recommendation of Oncotype DX as

and Exchange Commission, including the risks set forth in the company's annual report filed on Form 10-Q for the year ended June 30, 2018. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Breast Recurrence Score, Recurrence Score, Oncotype DX AR-V7 Nucleus Detect, Oncotype DX DCIS Score, Oncotype DX Genomic Prostate Score, and Oncotype IQ are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

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¹ Hassan A. et al, Abstract #208P, presented at ESMO 2018

² Barni et al, abstract #194P, presented at ESMO 2018

³ Sparano et al. New Engl J Med. 2018

⁴ Sparano et al. New Engl J Med. 2015

⁵ Nitz et al. Breast Cancer Res Treat. 2017

⁶ Stemmer et al. npj Breast Cancer. 2017

⁷ Roberts et al. Breast Cancer Res Treat. 2017

⁸ Shak et al. ESMO 2016

⁹ Ferlay J et al, Eur J Cancer. 2013

¹⁰ Paik et al. J Clin Oncol. 2006

¹¹ Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. Lancet. 2012