

New Analysis Reinforces Cost-Effectiveness of the Oncotype DX Breast Recurrence Score[®] Test in Node-Positive Early-Stage Breast Cancer

- *Improved quality of care and significant cost savings using the test to guide adjuvant chemotherapy treatment*
- *Analysis based on first results from the independent RxPONDER study which identified the majority of women with one to three positive nodes who receive no benefit from chemotherapy*

Geneva, May 20, 2021 – Exact Sciences today announced results from a health economic analysisⁱ of the Oncotype DX Breast Recurrence Score[®] test, accepted at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting and published online in the ASCO meeting library. This analysis shows the positive impact of initial results from the RxPONDER trialⁱⁱⁱ on the test's cost-effectiveness in postmenopausal women with one to three positive lymph nodes.

Based on this updated model, adding data from RxPONDER leads to further cost-savings and potentially improved outcomes by avoiding short- and long-term adverse effects of chemotherapy without increased distant recurrence risk. The findings showed that chemotherapy can be spared for the majority of postmenopausal women, those with Recurrence Score[®] results 0-25, increasing expected cost-savings without compromising patient outcomes and resulting in 50% greater cost-savings compared to the pre-RxPONDER scenario. The impact on cost-effectiveness was examined based on the list price for the test in the UK.ⁱⁱⁱ The potentially practice-changing impact of RxPONDER in the real-life setting may yield even greater savings, which are currently being investigated in multiple European studies.

Approximately 25% of patients diagnosed with HR-positive, HER2-negative early breast cancer have a tumour that has spread to their lymph nodes and two out of three are postmenopausal.^{iv} The vast majority of these patients currently receive chemotherapy,^v although approximately 80% of them could be expected to have Recurrence Score results of 0 to 25.^{vi}

Initial results from the RxPONDER trial, which was led by the independent SWOG Cancer Research Network and sponsored by the National Cancer Institute, were presented at the end of 2020. The findings indicated that postmenopausal women with up to three positive nodes and Recurrence Score results 0-25 were not observed to benefit from chemotherapy and may thus avoid the associated side effects of the treatment. Importantly, no chemotherapy benefit was observed regardless of the number of affected nodes, tumour grade, or size. The first trial results also concluded that premenopausal patients with a Recurrence Score result 0-25 derived a 2.9% benefit from chemotherapy on distant recurrence at five years.

These potentially practice-changing results, together with the foundational TAILORx results^{vii} in node-negative, early stage breast cancer, further elevate the test to standard of care, supporting its inclusion in guidelines as well as its reimbursement and adoption on a global scale. The National Comprehensive Cancer Network[®] (NCCN[®])^{viii} recently updated its guidelines for breast cancer and recognised the Oncotype DX Breast Recurrence Score test as the only test that can be used for prediction of chemotherapy benefit in early-stage breast cancer patients with one to three positive axillary lymph nodes, including micrometastases.^{ix} The Oncotype DX[®] test is now the only test classified as “*preferred*” with the highest level of evidence for node-negative and postmenopausal node-positive (one to three positive nodes) patients.

In addition, the Oncotype DX test is incorporated in the node-negative and postmenopausal node-positive NCCN treatment algorithms with a recommendation of “*strongly consider*,” using cutoffs defined by the TAILORx and RxPONDER trials to select patients for chemotherapy treatment.

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About the Oncotype DX[®] and Oncotype MAP[™] Portfolio of Tests

The Oncotype DX portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumour in order to optimise cancer treatment decisions. In breast cancer, the Oncotype DX Breast Recurrence Score test is the only test that has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the Oncotype DX Breast DCIS Score[™] test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. In prostate cancer, the Oncotype DX Genomic Prostate Score[®] test predicts disease aggressiveness and further clarifies the current and future risk of the cancer prior to treatment intervention. For patients with advanced and metastatic cancer, the company offers the Oncotype MAP[™] Pan-Cancer Tissue test, a rapid, comprehensive tumor profiling panel, which provides results in three to five business days and allows physicians to understand a patient’s tumour profile and recommend actionable targeted therapies or clinical trials. With more than 1 million patients tested in more than 90 countries, the Oncotype DX tests have redefined personalised medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX and Oncotype MAP tests, visit www.OncotypeIQ.com/en.

About Exact Sciences Corp.

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter answers to give people the clarity to take life-changing action, earlier. Building on the success of the Cologuard[®] and Oncotype DX tests, Exact Sciences is investing in its product pipeline to support patients throughout their cancer diagnosis and treatment. Exact Sciences unites visionary collaborators to help advance the fight against cancer. For more information,

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ⁱ Berdunov V. et al. Abstract #534, ASCO 2021.

ⁱⁱ Kalinsky, K. et al. Oral Presentation: [GS3-00]. San Antonio Breast Cancer Symposium; December 2020.

ⁱⁱⁱ NICE[®] Diagnostics Guidance DG34, December 2018. www.nice.org.uk/guidance/dg34 (accessed May 13, 2021)

^{iv} Heer E. et al., The Lancet 2020.

^v Zhang et al., Breast Can Res Treat 2020.

^{vi} Bello et al., Ann Surg Ocol. 2018.

^{vii} Sparano et al. New Engl J Med. 2018.

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^{ix} NCCN Guidelines: Breast Cancer, version 3.2021