

New Data and Society Guidelines Support Value of Oncotype DX Breast Recurrence Score® Test in Guiding Neoadjuvant Treatment Decisions for Newly Diagnosed Patients

- *Study results presented at ASCO20 showed that the Recurrence Score® results on core biopsies predict the likelihood of response to neoadjuvant chemotherapy*
- *Results are particularly relevant in the context of the Covid-19 pandemic which is causing the delay of elective surgeries across health systems worldwide*

MADISON, Wis., May 29, 2020 – Exact Sciences Corp. today announced results from three studies of the Oncotype DX Breast Recurrence Score® test, presented at the virtual [2020 American Society of Clinical Oncology \(ASCO\) Annual Meeting](#). The findings highlight the value the Oncotype DX® test can provide by personalising and improving neoadjuvant treatment decisions (i.e., prior to surgery) in women with hormone receptor positive, HER2-negative breast cancer.

“As health systems across the world respond to the Covid-19 pandemic, decisions are being made that are resulting in the postponement of both screening and diagnostic oncology services as well as elective surgery,” said Dr Emilio Alba, Director of the Medical Oncology Units at the Hospital Universitario Virgen de la Victoria in Malaga, Spain. “This new evidence shows that the Oncotype DX test may be used to inform neoadjuvant therapy while awaiting surgery, therefore helping us to overcome some of the unique challenges we are currently facing in managing breast cancer patients.”

One study¹ presented at ASCO20 included 76 women treated with neoadjuvant chemotherapy from the Young Women’s Breast Cancer Study, a multi-center prospective group of women diagnosed with breast cancer at age 40 or younger. The Oncotype DX test was performed on tumor specimens from core biopsies obtained from the patients prior to surgery. Results revealed that patients with a higher Recurrence Score result were more likely to achieve a pathologic complete response (pCR; no residual invasive tumour) with chemotherapy. Most pathologic complete responses were achieved in patients with a Recurrence Score result of 26 and above. In contrast, only two patients with a Recurrence Score of 0-25 achieved pCR, and both had results between 21-25. These findings are consistent with previously published neoadjuvant studies in older breast cancer patients.

A second study² was conducted in Spain and prospectively analysed a group of 63 patients who received neoadjuvant chemotherapy after the Oncotype DX test was performed on tumour specimens from core biopsies. The analysis also showed a strong correlation between pCR and Recurrence Score result. In particular, the Recurrence Score result was the most significant predictor of pCR when compared to

¹ Sella T. et al, Abstract #514, ASCO 2020

² Morales S. et al, Abstract #e12630, ASCO 2020

other factors such as Ki67 (a classic prognostic factor), estrogen receptor status and initial tumour size. None of the patients with a Recurrence Score result of 0-25 achieved a pCR.

In the third study³, the Oncotype DX test was performed prior to surgery and patients with Recurrence Score results 0-30 received neoadjuvant endocrine therapy without chemotherapy. After four months of treatment, data from 142 patients showed that 97% of them had a clinical response or stable disease, suggesting that patients with a Recurrence Score result <31 can safely be offered neoadjuvant endocrine therapy alone with minimal risk of progression of disease.

The new data presented at ASCO20 add to existing evidence^{4,5,6} and reinforce the value of the Oncotype DX test in light of recent Covid-19 pandemic recommendations.^{7,8} Core biopsy specimens represent 14% of the overall Oncotype DX Breast Recurrence Score test volume, and they have a testing success rate of more than 98%.⁹

About Oncotype DX

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, and the Oncotype DX AR-V7 Nucleus Detect[™] test helps determine which patients with metastatic castration-resistant prostate cancer (mCRPC) are resistant to androgen receptor (AR)-targeted therapies. The Oncotype DX AR-V7 Nucleus Detect test is performed by Epic Sciences at its centralised, CLIA-certified laboratory in San Diego and offered exclusively by Exact Sciences. 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 tests, visit www.OncotypeIQ.co.uk

³ Al-Saleh K. et al, Abstract #594, ASCO 2020.

⁴ Iwata H, et al. *Breast Can Res Treat.* 2019.

⁵ Pivot X, et al. *Oncologist.* 2015.

⁶ Kantor O, et al. *Ann Surg Oncol.* 2019.

⁷ Dietz JR, et al representing the COVID-19 Pandemic Breast Cancer Consortium. *Breast Can Res Treat.* 2020

⁸ <https://www.esmo.org/guidelines/cancer-patient-management-during-the-covid-19-pandemic/breast-cancer-in-the-covid-19-era>.

⁹ Exact Sciences. Data on File.



About Exact Sciences Corp.

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter solutions providing 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 take on some of the deadliest cancers and improve patient care. Exact Sciences unites visionary collaborators to help advance the fight against cancer. For more information, please visit the company's website at www.exactsciences.com, follow Exact Sciences on Twitter [@ExactSciences](https://twitter.com/ExactSciences), or find [Exact Sciences](https://www.facebook.com/ExactSciences) on Facebook.

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