

Media:

Sally Herd
BCW
+44 2073006151
Sally.herd@bcw-global.com

New Evidence from Large Studies Highlights Value of Oncotype DX Breast Recurrence Score® to Guide Chemotherapy Treatment in Young Patients with Node-negative or Node-positive Early-stage Breast Cancer

- *TAILORx Study Featured in William L. McGuire Memorial Lecture Award at 2019 San Antonio Breast Cancer Symposium®*
- *New Publication of Long-term Data from Real-world Clinical Practice Confirms Conclusions of TAILORx*

MADISON, Wis., December 12, 2019 – Exact Sciences Corp. (NASDAQ: EXAS) today announced new outcomes data from two large population-based studies^{1,2} presented at the [2019 San Antonio Breast Cancer Symposium](#) (SABCS®). The real-world evidence suggests that use of the Oncotype DX Breast Recurrence Score® test in clinical practice is consistent with previous clinical validation studies including TAILORx, the largest ever breast cancer treatment trial. This landmark study was featured in the [William L. McGuire Memorial Lecture Award](#), which recognized Joseph A. Sparano, M.D., TAILORx study chair, for his leadership, collaboration and practice-changing achievements in breast cancer research.

“Last year, TAILORx established the highest level of evidence and unprecedented precision supporting the use of the Oncotype DX Breast Recurrence Score test to guide adjuvant chemotherapy treatment for women with early-stage breast cancer,” said Dr Sparano, associate director for clinical research at the Albert Einstein Cancer Center and Montefiore Health System in New York, and vice chair of the ECOG-ACRIN Cancer Research Group. “I am honoured to receive this prestigious award and pleased that the TAILORx results have been incorporated in major clinical practice guidelines and used to guide patient care around the world.”

Outcomes Data in Patients Age 50 or Younger Reinforce Ability of Oncotype DX® to Identify Those Who Can Be Treated with Hormone Therapy Alone

¹ Sammons S. et al. Poster : P3-08-10. San Antonio Breast Cancer Symposium; December 2019.

² Petkov V. I. et al. Poster : P3-07-01. San Antonio Breast Cancer Symposium; December 2019.

An analysis from the U.S. National Cancer Database in over 4,700 women age 40 or younger with node-negative disease showed a distribution of Recurrence Score® results consistent with existing clinical evidence, with as many as 80% of patients having low Recurrence Score results (0-25). Higher Recurrence Score results were associated with worse five-year overall survival.

Another analysis from the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI) provides real-world evidence of the value of the Oncotype DX® test in patients age 50 or younger with node-positive disease (up to three positive nodes). Results from more than 2,500 patients indicated a significant association between Recurrence Score results and breast cancer-specific mortality (BCSM), with five-year BCSM of less than 2% in young patients with Recurrence Score results 0-25 and no or unknown use of chemotherapy reported.

New Publication of Long-term Data from Real-world Clinical Practice Confirms Major Finding of TAILORx Study

Separately, the first reported 10-year outcomes data, including distant recurrence risk, from a large cohort of patients using the Recurrence Score results to guide treatment decisions in clinical practice were recently [published](#).³ This analysis from investigators working with Clalit Health Services, the largest health services organization in Israel, examined medical records of more than 1,300 patients with node-negative breast cancer and applied the Recurrence Score cut points established by the landmark [TAILORx study](#).⁴

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 10 years, with low rates of distant recurrence. For the group of patients with Recurrence Score results 11-25, there were no statistically significant differences in 10-year distant recurrence rates between patients who received chemotherapy and those treated with hormonal therapy alone. These results are consistent with the primary findings of the large TAILORx randomized clinical trial.

“The additional insight from the new analyses in young patients is consistent with, and further supports, the value of the Recurrence Score result in younger women,” said Steven Shak, M.D., chief medical officer, Exact Sciences. “We are pleased to see the publication of new real-world evidence that reinforces the paradigm established by the TAILORx study, which has influenced positive treatment guidelines updates over the past 18 months and is having an important impact on global reimbursement and standard use of the Oncotype DX test.”

³ Stemmer S. M. et al. *NPJ Breast Cancer*. 2019

⁴ Sparano J. A. et al. *New Engl J Med*. 2018

Additional Oncotype DX Presentations at 2019 SABCS Reinforce Value of the Test in Multiple Patient Populations Throughout Disease Continuum

- 732 patients with ER Positive, HER2-ve early breast cancer were tested with the Oncotype DX Breast Recurrence Score[®] assay between 2015 & 2018. These patients were matched to the Welsh Cancer Registry (Canis) to record their grade, size, nodal status and method of detection (screened vs non screened), to calculate the NPI & Predict score. The findings show a very weak correlation between the NPI and Predict scores and the Recurrence Score[®] result, leading to discordant results for large numbers of patients. Therefore, using NPI or predict to identify patients for testing means that some individual patients who would benefit from chemotherapy will be missed.

“From our findings we do not believe that clinical pathological features should be used to identify patients for genomic profiling” said Ms Marianne Dillon Consultant Breast Surgeon, Singleton Breast Care Unit, Swansea Bay Health Board.

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 optimize 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 centralized, 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 personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeIQ.com, www.MyBreastCancerTreatment.org or www.MyProstateCancerTreatment.org.

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 Cologuard and Oncotype DX, 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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Forward-Looking Statements

This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the “safe harbour” created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as “believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “seek,” “intend,” “plan,” “goal,” “project,” “estimate,” “anticipate” or other comparable terms. All statements other than statements of historical facts included in this news release regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding expected future operating results, anticipated results of our sales, marketing and patient adherence efforts, expectations concerning payer reimbursement, the anticipated results of our product development efforts and the anticipated benefits of our acquisition of Genomic Health, including estimated synergies and other financial impacts. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, the following: our ability to successfully and profitably market our products and services; the acceptance of our products and services by patients and healthcare providers; our ability to meet demand for our products and services; the willingness of health insurance companies and other payers to cover our products and services and adequately reimburse us for such products and services; the amount and nature of competition from other cancer screening and diagnostic products and services; the effects of the adoption, modification or repeal of any law, rule, order, interpretation or policy relating to the healthcare system, including without limitation as a result of any judicial, executive or legislative action; the effects of changes in pricing, coverage and reimbursement for our products and services, including without limitation as a result of the Protecting Access to Medicare Act of 2014; recommendations, guidelines and quality metrics issued by various organizations such as the U.S. Preventive Services Task Force, the American Cancer Society, and the National Committee for Quality Assurance regarding cancer screening or our products and services; our ability to successfully develop new products and services and assess potential market opportunities; our ability to effectively utilize strategic partnerships, such as through our Promotion Agreement with Pfizer, Inc., and acquisitions; our success establishing and maintaining collaborative, licensing and supplier arrangements; our ability to maintain regulatory approvals and comply with applicable regulations; expectations regarding our international expansion and opportunities; the potential effects of foreign currency exchange rate fluctuations and our efforts to hedge such effects; the possibility that the anticipated benefits from our acquisition of Genomic Health cannot be realized in full or at all or may take longer to realize than expected; the possibility that costs or difficulties related to the integration of Genomic Health’s operations will be greater than expected; the outcome of any litigation, government investigations, enforcement actions or other legal proceedings; and the other risks and uncertainties described in the Risk Factors and in Management’s Discussion and Analysis of Financial Condition and Results of Operations sections of our most recently filed Annual Report on Form 10-K and our subsequently filed Quarterly Reports on Form 10-Q. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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