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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 personalizing 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 study[1] 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 tumor) 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.

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

A second study[2] was conducted in Spain and prospectively analyzed a group of 63 patients who received neoadjuvant chemotherapy after the Oncotype DX test was performed on tumor 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 other factors such as Ki67 (a classic prognostic factor), estrogen receptor status and initial tumor size. None of the patients with a Recurrence Score result of 0-25 achieved a pCR.

In the third study[3], 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 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 European women[10] 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.[11,12] The Oncotype DX test is designed to facilitate personalized clinical decisions by providing information about the biology of an individual breast cancer, with the potential to deliver financial benefits for healthcare systems.

To learn more about the Oncotype DX test, visit: oncotypeiq.com/en

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[2] Morales S. et al, Abstract #e12630, ASCO 2020
[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.
[10] Ferlay J et al, Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. 2018 Available from: https://gco.iarc.fr/today/home
[11] Paik et al. J Clin Oncol. 2006
[12] Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. Lancet. 2012

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, or find Exact Sciences on Facebook.

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 harbor" 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, expectations, 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, and the anticipated results of our product development efforts. 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. Actual results, conditions and events 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 actual results, conditions and events to differ materially from those indicated in the forward-looking statements include, among others, the following: uncertainties associated with the coronavirus (COVID-19) pandemic, including its possible effects on our operations and the demand for our products and services; our ability to efficiently and flexibly manage our business amid uncertainties related to COVID-19; 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 success of our efforts to facilitate patient access to Cologuard via telehealth; 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 for our 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 Society of Clinical Oncology, 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 enter into and 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; our ability to manage an international business and our 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 combination with 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 and the possibility of disruptions to our business during integration efforts and strain on management time and resources; 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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