New Oncotype DX® Real-world Evidence Shows for the First Time the Practice-changing Impact of TAILORx Results

- *Data obtained in real-life setting from more than 800 patients with node-negative or node-positive early-stage breast cancer highlight the test's impact on clinical practice with chemotherapy-sparing effect*
- *Publication of landmark TAILORx study results led to greater reduction in chemotherapy recommendations*

MADISON, Wis., May 14, 2020 – Exact Sciences Corp. today announced results from a prospective clinical survey of the Oncotype DX Breast Recurrence Score® test, accepted at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting, published online in the ASCO meeting library, and expected to be published in the *Journal of Clinical Oncology* meeting's proceedings. The findings, consistent with previous studies, further support the unique value of the test in guiding chemotherapy treatment decisions. Results also highlight the practice-changing impact of the landmark TAILORx study[1], which showed that the Oncotype DX® test identifies the vast majority of women with node-negative disease who receive no substantial benefit from chemotherapy (approximately 80%), as well as the important minority (with a Recurrence Score result of 26-100) for whom chemotherapy can be life-saving.

The survey results[2,3] at ASCO20 summarise physicians' treatment decisions pre- and post-Recurrence Score results in hospitals across Latin America. A total of 647 patients (20% with one to three positive nodes) were enrolled during routine care at 14 community and academic sites in Argentina, Colombia, Mexico, and Peru, while an additional 155 patients (34% with one to three positive nodes) were treated at the largest public breast cancer hospital in Brazil.

The analysis conducted in Argentina, Colombia, Mexico, and Peru included patients treated before and after the June 2018 publication of TAILORx. Overall, the findings revealed a 36% net decrease in chemotherapy recommendations among patients with node-negative disease and a 46% decrease in those with node-positive disease. Importantly, the decrease in chemotherapy recommendations in node-negative disease was greater following the publication of TAILORx results and went from 28% to 36%.

Of the 155 patients treated in Brazil between August 2018 and April 2019, 70% were classified as having high-risk disease based on traditional clinical parameters, and the majority had tumours larger than 2 centimeters. A total of 151 of the 155 patients (97%) were initially recommended chemotherapy

[1] Sparano J et al. NEJM, 2018
[2] Gomez H et al. Abstract #e12539, ASCO 2020.
[3] Mattar A et al. Abstract #e12518, ASCO 2020.

in addition to hormonal therapy based on clinical and pathological features. Based on their Recurrence Score results, 104 of the 151 patients (69%) were spared chemotherapy and received hormonal therapy alone instead.

Results from this public hospital show that clinical and pathological features did not adequately identify patients most likely to benefit from chemotherapy. Testing also led to economic benefits and potential savings, suggesting that the Oncotype DX test should be incorporated in the Brazilian public health system.[4]

"Our findings highlight the unique value of the Oncotype DX test and the practice-changing impact of the TAILORx results to select patients for chemotherapy and to avoid overtreatment as well as undertreatment," said Dr. Henry Gómez, lead study author and Head, Breast Cancer Multidisciplinary Team, Oncosalud - AUNA, Lima, Peru. "Overall, the availability of Recurrence Score results led to substantial reductions in chemotherapy use and allowed us to tailor treatment plans more accurately and use resources more effectively."

These results add to the substantial real-world evidence available for the Oncotype DX test, which reflects its growing adoption, particularly since the publication of TAILORx. This landmark study has positively influenced treatment guidelines and is having an important impact on global reimbursement and standard use of the test. More than 1 million patients around the world have used the test to inform their treatment decision.

"These data align with the findings from a similar survey in the UK which looked at using the Oncotype DX test in node positive early breast cancer patients. The results showed a net decrease in chemotherapy recommendations by over 60% [5]," said Andrew Paramore, Director of Medical Affairs, Exact Sciences UK Ltd "As we continue to generate evidence showing the unique value of our test, we look forward to continuing to work with the relevant UK authorities to make it available to a broader patient group".

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

[4] Mattar A et al. Abstract #e19380, ASCO 2020.
[5] Battisti et al. Poster: P007, St. Gallen International Breast Cancer Conference 2019.

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

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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