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New Real-World Evidence Further Demonstrates the Clinical Utility of the Oncotype DX Breast Recurrence Score[®] Test, Beyond Clinical Risk Factors, in Guiding Chemotherapy Treatment Decisions in Patients with Early-stage Breast Cancer

- *Study in over 500 patients with node-negative or node-positive disease highlights impact of the test on treatment decisions, reducing potential over- and undertreatment and leading to a 23.5% net reduction in chemotherapy recommendations*
- *Publication shows that Recurrence Score[®] results do not correlate with clinical pathologic parameters*

GENEVA, October 2, 2020 – Exact Sciences today announced results from a prospective decision impact study¹ presented at the virtual [European Breast Cancer Conference](#) (EBCC-12), being held October 2-3. The findings are consistent with previous studies and further support the clinical utility of the [Oncotype DX Breast Recurrence Score[®] test](#) to optimise chemotherapy recommendations in patients with early-stage, hormone-receptor positive, HER-2 negative breast cancer with or without lymph node involvement.

The study was conducted between 2016 and 2019 in 15 certified breast cancer centers across Germany. The analysis presented at EBCC-12 includes 567 patients – 403 with node-negative (N0) disease and 167 with one to three positive nodes. Results showed that treatment recommendations changed for 33.5% of patients based on their Recurrence Score results, and that using the test to guide treatment decisions resulted in a net reduction in chemotherapy recommendations of 23.5%. These changes in treatment recommendations could well have been greater in patients with N0 disease if the decision-making criteria (Recurrence Score groups) based on results from the landmark TAILORx study, which was [published](#)² in 2018, had been applied at the time of the study.

“These important results show the value of the Oncotype DX[®] test to best select patients for chemotherapy and to avoid potential over- as well as undertreatment by adding genomic information and not relying only on traditional clinical parameters,” said Prof. Dr Marc Thill, lead study author and chief physician of the Clinic for Gynecology and Gynecological Oncology at the Agaplesion Markus

¹ Thill M, et al. [The REMAR (Rhein-Main-Registry)-Study: Prospective Evaluation of Oncotype DX[®] Assay in Addition to Ki-67 For Adjuvant Treatment Decisions in Early Breast Cancer]. Presented at EBCC-12; October 2, 2020.

² Sparano JA, Gray RJ, Makower DF, et al. Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer. *New Engl J Med.* 2018;379:111-121.

Krankenhaus in Frankfurt, Germany. “The use of this test allows us to tailor treatment plans more accurately to suit the needs of individual patients, and to use resources more effectively.”

Importantly, the analysis presented at EBCC-12 also revealed a weak correlation between centrally and locally performed Ki67 (a classic prognostic factor) and showed a broad range of Recurrence Score results for patients with grade 2 tumours, suggesting that grade does not predict the Recurrence Score result and that the test can provide relevant information for all patients. These findings are consistent with results from a [subset analysis](#)³ of the TAILORx study, which showed that only the Oncotype DX test can assess the expected benefit of chemotherapy, and that clinical and pathological features generally provide only prognostic information.

Evidence from routine clinical practice shows that Recurrence Score results do not correlate with clinical pathologic factors

In addition to the results presented at EBCC-12, a recently published retrospective analysis compared the Recurrence Score result with clinical parameters in 4,695 patients with node-negative or node-positive early-stage breast cancer for whom testing with the Oncotype DX test was performed in routine clinical practice in Germany.⁴ In this group of patients, 84% had a Recurrence Score result of 0-25, consistent with data from TAILORx.² The findings highlighted an overall high discordance of 45% between Ki67 and the Recurrence Score result classifications, and showed that a large proportion of patients with clinically high-risk features, such as high Ki-67 or high tumour grade, had low Recurrence Score results, suggesting they would not benefit from additional chemotherapy.

These latest 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.

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

³ Sparano JA, Gray RJ, Ravdin PM, et al. Clinical and genomic risk to guide the use of adjuvant therapy for breast cancer. *New Engl J Med.* 2019;380:2395-2405

⁴ Walter VP, Taran F-A, Wallwiener M, et al. Distribution of the 21-gene breast recurrence score in patients with primary breast cancer in Germany. *Geburtshilfe und Frauenheilkunde.* 2020;80:619-627.

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. 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.com/en

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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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 willingness of healthcare 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; data protection laws and rules affecting our performance of diagnostic tests, including the Oncotype DX test; the effects of changes in pricing, coverage and reimbursement for our products and services; recommendations, guidelines and quality metrics issued by various organizations such as the American Society of Clinical Oncology, the National Cancer Care Network, the European Society of Medical Oncology, the St Gallen Consensus, and national health technology assessment bodies regarding our products and services; our ability to successfully develop new

products and services and assess potential market opportunities; 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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