Exact Sciences receives regulatory approval for the Oncotype DX Breast Recurrence Score® Program in Japan

MADISON, Wis., August 16, 2021 – Exact Sciences Corp. (Nasdaq: EXAS) today announced that Japan's Ministry of Health, Labor and Welfare (MHLW) has approved the Oncotype DX Breast Recurrence Score® Program. The test helps guide chemotherapy treatment recommendations and provides risk of distant recurrence in patients with hormone receptor-positive, HER2-negative early-stage breast cancer with up to three positive lymph nodes. MHLW approval is a critical step in making Oncotype DX® accessible to breast cancer patients in Japan.

Breast cancer is the most common cancer in Japanese women, and more than 90,000 new breast cancer cases were diagnosed in Japan in 2020.[i] The Oncotype DX Breast Recurrence Score Program approved in Japan combines the Oncotype DX Breast Recurrence Score® test and software developed for the Japanese market. Exact Sciences plans to pursue coverage under Japan's universal healthcare insurance system and launch the test though its Japanese affiliate, Exact Sciences K.K.

"MHLW's approval of Oncotype DX is great news for breast cancer patients in Japan and reflects the powerful evidence backing the Oncotype DX test," said Kevin Conroy, chairman and CEO. "Our international team is enabling new areas of growth for our current advanced cancer tests and will accelerate access to future innovative tests for patients around the world."

The Oncotype DX test provides information allowing doctors and patients to personalize treatment plans with greater confidence.[ii] While chemotherapy is routinely offered, research shows that only a minority of patients with early-stage breast cancer will actually benefit.[iii] Oncotype DX is the only test validated to determine which patients will benefit from chemotherapy and provides critical information beyond traditional prognostic factors.[iv-viii] The test is supported by prospective outcomes data from the TAILORx[vii] and RxPONDER[viii] studies, which show that most patients with either node-negative or node-positive disease can be spared chemotherapy when decisions are guided by Oncotype DX.

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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 tumor 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. The Oncotype MAP® Pan-Cancer Tissue test is a rapid, comprehensive tumor profiling panel that aids therapy selection for patients with advanced, metastatic, refractory, or recurrent cancer. With more than 1 million patients tested in more than 90 countries, the Oncotype tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment.

About Exact Sciences Corp.

A leading provider of cancer screening and diagnostic tests, Exact Sciences relentlessly pursues smarter answers to give people 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 support patients throughout their cancer diagnosis and treatment. 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 concerning our expectations, anticipations, intentions, beliefs, or strategies regarding the future. These forward-looking statements are based on assumptions that we have made as of the date hereof and are subject to known and unknown risks and uncertainties that could cause actual results, conditions and events to differ materially from those anticipated. There can be no assurance that Oncotype DX Breast Recurrence Score® Program will receive coverage at an acceptable reimbursement rate, if at all, under Japanese universal healthcare insurance system or that we will be able to successfully launch the test in Japan. Therefore, you should not place undue reliance on forward-looking statements. Risks and uncertainties that may affect our forward-looking statements are described in the Risk Factors sections of our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, and in our other reports filed with the Securities and Exchange Commission. 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.

[i] Globocan 2020
[ii] Licata et al. *ESMO* 2020 187P
[iii] Early Breast Cancer Trialists' Collaborative Group (EBCTCG) *et al. The Lancet* 2012.
[iv] Paik et al. *J Clin Oncol*. 2006.
[v] Geyer et al. *npj Breast Cancer* 2018.
[vi] Albain et al. *Lancet Oncol.* 2010.
[vii] Sparano et al. *New Engl J Med*. 2018.
[viii] Kalinsky et al. *SABCS* 2020 Abstract GS3-00.