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Norway's decision-making council for specialist health services (Nye Metoder) approves introduction of Oncotype DX® test to predict chemotherapy benefit for early breast cancer patients

- *First gene expression test in early breast cancer to achieve positive health technology evaluation outcome and a positive decision from Nye Metoder*

London, 27 August 2024 – Exact Sciences, a leading provider of cancer screening and diagnostic tests, today announced national approval for routine use of the Oncotype DX Breast Recurrence Score® test for eligible breast cancer patients in Norway.

The approval means that many patients with early breast cancer in Norway each year will have access to this innovative diagnostic test, the only test available which measures certain cancer related genes in the tumour and determines whether the individual is likely to benefit from chemotherapy or if they can avoid unnecessary chemotherapy side-effects.¹

The Oncotype DX test provides two pieces of information crucial for patients and their clinicians to make a fully informed chemotherapy treatment decision, 1) What is the risk of cancer recurrence without chemotherapy? 2) Would adding chemotherapy reduce the risk? Only the Oncotype DX test provides both pieces of information and can therefore directly determine if adding chemotherapy would reduce the risk of cancer recurrence.

The Oncotype DX test represents a major step forward in the treatment of breast cancer. Research shows that chemotherapy is effective in less than 10% of early-stage breast cancer cases², but it was previously not possible to identify who would benefit. It will now be possible for chemotherapy to be used in a much more targeted way, potentially sparing hundreds of women each year from debilitating side-effects such as hair loss, fatigue and nausea³, whilst ensuring that those who may benefit are not missed.

The approval follows an assessment by the Norwegian Institute of Public Health (NIPH) which concluded that the Oncotype DX test will be more effective and less costly compared to the traditional (non-genomic) approach to deciding who gets chemotherapy treatment.

The test has been approved in Norway for people with early-stage breast cancer whose cancer tests positive for hormone receptors and negative for HER-2 receptors, and who are postmenopausal with 1-3 positive lymph nodes.

Oncologist and head of the Norwegian Oncological Association Dr Daniel Heinrich says, "*Modern cancer treatment is becoming increasingly individualized, which is often called personalized. This often involves finding drugs that treat the individual patient's cancer in a more targeted way. But it is equally important to be able to define better and more accurately which patients need and can benefit from extensive treatment and those who can be managed with less intensive and thus less*

¹ Norwegian Institute of Public Health (NIPH) Single Technology assessment Oncotype DX Breast Recurrence Score test published October 2023 <https://www.fhi.no/en/publ/2023/Oncotype-DX-breast-cancer-recurrence-score-test/>

² EBCTCG. Lancet. 2012

³ Partridge et al. J Natl Cancer Inst Monogr. 2001.

side-effect-heavy treatment. Today, relatively large groups of patients with, for example, breast or bowel cancer are still treated with chemotherapy after surgery. Not all these people need this treatment and not everyone who receives it benefits from it. Tests such as the one approved today will help doctors to provide more accurate information and better recommendations to their patients, which is clearly beneficial for the individual, but not least also a benefit at the societal level, since the relationship between benefit of the treatment, costs and potential side effects is positively affected."

The test is supported by multiple randomized controlled trials, including the landmark TAILORx⁴ and RxPONDER⁵ studies, which demonstrated that most patients with either node-negative or node-positive early-stage breast cancer do not benefit from chemotherapy and can be reliably identified using the Oncotype DX test.

Matt Bull, Head of Northern Europe (UK, Ireland and Nordics) at Exact Sciences, added: *"We are delighted that node-positive breast cancer patients in Norway will now benefit from knowing their Recurrence Score[®] result. We are proud of the potential impact that the use of the Oncotype DX test will have for patients and their clinician, making informed chemotherapy treatment decisions to avoid both over- and under-treatment and, through this, offer resource optimization for the Norwegian health services. We are surprised that patients who are node-negative have not been included as the Oncotype DX test has significant value to offer for this patient group and the Norwegian health system. We look forward to engaging with the Decision Forum to provide further information so that this patient group can be reassessed."*

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About the Oncotype DX Breast Recurrence Score test

The Oncotype DX Breast Recurrence Score 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. The test was first made available to patients in 2004, and over 1,5 million patients around the world have benefited from it. It is incorporated in major breast cancer treatment guidelines, including those of the European Society for Medical Oncology (ESMO) and the St. Gallen International Breast Cancer Conference, as well as the American Society of Clinical Oncology (ASCO[®]) and the National Comprehensive Cancer Network (NCCN[®]) in the U.S.

To learn more about the test, visit: <https://www.oncotypeiq.com/en>

About Exact Sciences

A leading provider of cancer screening and diagnostic tests, Exact Sciences gives patients and health care professionals the clarity needed to take life-changing action earlier. Building on the success of the Cologuard[®] and Oncotype[®] tests, Exact Sciences is investing in its pipeline to develop innovative solutions for use before, during, and after a cancer diagnosis. For more information, visit <https://www.exactsciences.com>, follow Exact Sciences on X (formerly known as Twitter) [@ExactSciences](#), or find Exact Sciences on [LinkedIn](#) and [Facebook](#).

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⁴ Sparano et al. N Engl J Med. 2018

⁵ Kalinsky et al. New Engl J Med. 2021

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At this point in time, Cologuard is only available in the U.S.

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. 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.