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German Federal Joint Committee (G-BA) Issues Exclusive Nationwide Reimbursement Decision for Oncotype DX Breast Recurrence Score® Test

Reimbursement Decision Follows IQWiG's Recommendation
Based on TAILORx Study Results

GENEVA, Switzerland, June 21, 2019 -- Genomic Health announced today that the German Federal Joint Committee (G-BA) issued a positive reimbursement decision for the Oncotype DX Breast Recurrence Score® test during its plenary meeting session on June 20. According to the decision, Oncotype DX® will be the only multigene test reimbursed by statutory sick funds with wide national coverage, for use in all patients with primary node-negative, hormone receptor-positive, HER2-negative early-stage breast cancer when a decision for or against chemotherapy cannot be made based on clinical and pathological parameters alone. The G-BA decision will become effective following its publication by the Ministry of Health in the Federal Gazette (*Bundesanzeiger*).

This decision follows the conclusion of the German Institute for Quality and Efficiency in Health Care (IQWiG) that only the Oncotype DX test has sufficient evidence to guide breast cancer adjuvant chemotherapy decisions based on results from the landmark TAILORx study[1]. Results from a recently published[2] subset analysis of TAILORx confirm the original findings from the trial, showing that only the Breast Recurrence Score® test can assess the expected benefit of chemotherapy and that clinical and pathological features generally only provide prognostic information.

"Breast cancer is the most commonly diagnosed cancer among women in Germany. Patients should only receive chemotherapy with all its side effects if they are going to get a substantial benefit," said Renate Haidinger, President of the German Breast Cancer Association. "A gene expression test, such as Oncotype DX, can play a critical role in making this decision and we look forward to educating patients in Germany about its value and availability through reimbursed access."

"The decision of the G-BA is an important step forward to personalised care for German breast cancer patients," said Prof. Ulrike Nitz, head of the breast cancer unit at Bethesda Hospital,

[1] Sparano et al. New Engl J Med. 2018
[2] Sparano et al. New Engl. J Med. 2019

Moenchengladbach, Germany. “Oncotype DX provides best available information about an individual patient’s response to chemotherapy. It allows us to target treatment much more effectively and should be routinely used for all eligible patients.”

Healthcare systems across Europe are recognising the value of the test, which is incorporated in all major international clinical guidelines, including St. Gallen, ESMO and NICE in Europe, and ASCO and NCCN in the U.S. In addition to Germany, the Oncotype DX Breast Recurrence Score test is currently reimbursed by public healthcare systems in seven other European countries, including the United Kingdom, Ireland, Spain and Switzerland. Nearly one million patients around the world have used the test to inform their treatment decision.

“We welcome the G-BA decision, which represents the culmination of several years of work and dedication to our mission of improving the quality of treatment decisions for cancer patients worldwide,” said Torsten Hoof, senior vice president, international, Genomic Health. “We look forward to working with sick funds in Germany to facilitate quick and equitable access throughout the country and to continuing to work with the relevant authorities to make Oncotype DX available to patients on a wider scale in Western Europe and around the world.”

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[3] 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.[4,5] The Oncotype DX test is designed to facilitate personalised 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: www.OncotypeIQ.com

About Genomic Health

Genomic Health, Inc. is the world’s leading provider of genomic-based diagnostic tests that help optimise cancer care. With its Oncotype IQ® Genomic Intelligence Platform, the company is applying its state-of-the-art scientific and commercial expertise and infrastructure to translate significant amounts of genomic data into clinically-actionable results for treatment planning throughout the cancer patient’s journey, from diagnosis to treatment selection and monitoring. The Oncotype IQ portfolio of genomic tests and services currently consists of the company’s flagship line of Oncotype DX gene expression tests that have been used to guide treatment decisions for more than one million cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based

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[3] 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

[4] Paik et al. J Clin Oncol. 2006

[5] Early Breast Cancer Trialists’ Collaborative Group (EBCTCG) et al. Lancet. 2012

tests, including the recently launched Oncotype DX® AR-V7 Nucleus Detect™ test. The company is based in Redwood City, California with international headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.com and follow the company on Twitter: @GenomicHealth, Facebook, YouTube and LinkedIn.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the benefits of the Oncotype DX Breast Recurrence Score test to physicians, patients and payors; the results of the TAILORx study including its implications on clinical treatment decisions; the ability of the Oncotype DX Breast Recurrence Score test to improve patient outcomes; and the ability of the company to expand commercial access and increase utilisation of its Oncotype DX Breast Recurrence Score test globally. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the results of clinical studies; the applicability of clinical study results to actual outcomes; the ability of the test results to change treatment decisions and improve patient outcomes; the risks and uncertainties associated with the regulation of the company's tests; the risk that the company may not obtain or maintain sufficient levels of reimbursement, domestically or abroad, for its existing tests and any future tests it may develop; the risks of competition; and the other risks set forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's annual report filed on Form 10-Q for the year ended March 31, 2019. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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