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German Health Technology Assessment Body (IQWiG) Concludes Only Oncotype DX® Has Sufficient Evidence to Guide Breast Cancer Adjuvant Chemotherapy Decisions Based on Landmark TAILORx Study Results

Updated Assessment of Breast Cancer Gene Expression Profiling Tests for Clinical Use in Germany

Final German Federal Joint Committee (G-BA) Reimbursement Decision Expected by End of 2018

GENEVA, Switzerland, September 7, 2018 -- Genomic Health today announced the publication of an updated assessment of breast cancer gene expression profiling tests by the German Institute for Quality and Efficiency in Health Care (IQWiG). In their analysis, IQWiG concluded that, based on results from the TAILORx study[1], the Oncotype DX Breast Recurrence Score® test can support patients with primary node-negative, hormone-receptor-positive, HER2-negative breast cancer in the decision for or against chemotherapy.

IQWiG's technical assessment will inform the Federal Joint Committee (G-BA) official reimbursement procedure. In July 2018, the G-BA publicly stated that a final decision on reimbursement of breast cancer gene expression profiling tests is expected by the end of 2018.

"With IQWiG's recognition of the unique value the Oncotype DX test provides, we believe we are one step closer to ensuring reimbursed access to tens of thousands of breast cancer patients diagnosed in Germany each year as is the case in other countries around the world including the U.S., Canada, the UK, France, Spain and Switzerland," said Torsten Hoof, Senior Vice President International, Genomic Health. "We look forward to G-BA's final reimbursement decision later this year as we continue to see the impact of the landmark TAILORx study results on clinical practice around the world."

IQWiG's conclusion is based on results from TAILORx, the largest randomized adjuvant breast cancer treatment trial ever conducted that were recently published in *The New England Journal of Medicine*[1]. This independently-conducted, prospective, phase III study followed more than 10,000 women with node-negative, hormone-receptor positive (HR+), HER2-negative early breast cancer for an average of nine years.

Study results demonstrate that the Oncotype DX Breast Recurrence Score test provides definitive long-term evidence about the magnitude of chemotherapy benefit, identifying the vast majority of women with early-stage breast cancer who receive no significant benefit from chemotherapy, as well as the important

[1] Sparano et al. New Engl J Med. 2018 Jul 12;379(2):111-121

minority of women for whom chemotherapy can be life-saving. Thus, the test can greatly reduce both over- and undertreatment with chemotherapy.

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[2] 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.[3]

The Oncotype DX 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. This is supported by substantial real-world evidence showing that the test can reduce the number of women undergoing unnecessary chemotherapy by up to 60 percent.[4]

Healthcare systems across Europe are recognizing the value of the test, which is incorporated in all major international clinical guidelines. Following assessment and recommendation by NICE, the Oncotype DX test is widely available to patients across the UK. In France, Oncotype DX is available through a funding mechanism for genomic tests. Other European countries where the test is reimbursed include Switzerland, Ireland, Greece and Spain.

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 optimize 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 900,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid- and tissue-based 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.

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[2] EUCAN. 2012. Available at: http://eco.iarc.fr/EUCAN/CancerOne.aspx?Cancer=46&Gender=2
[3] Paik et al. *J Clin Oncol.* 2006; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. *Lancet.* 2012.
[4] Loncaster J et al, Eur J Surg Oncol 2017

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. 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, including the TAILORx study; 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 reimbursement, domestically or abroad, including in Germany with the Federal Joint Committee (G-BA), for the Oncotype DX Breast Recurrence Score test; 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 June 30, 2018. 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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