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New long-term evidence from large study reinforces value of the Oncotype DX Breast Recurrence Score® test to guide adjuvant chemotherapy treatment, confirming TAILORx conclusions

- *Real-world evidence from more than 80,000 patient study shows that this test can optimise outcomes by more precisely identifying patients who will or will not benefit from chemotherapy*

GENEVA, Switzerland, [December 10, 2018] – Long-term outcomes data from a large population-based study[1], presented at the 2018 San Antonio Breast Cancer Symposium® (SABCS), further support the 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.

Real-world evidence from a more than 80,000 patient study, based on an analysis of data from the Surveillance, Epidemiology, and End Results (SEER) registry programme of the National Cancer Institute (NCI), confirmed that the Oncotype DX Breast Recurrence Score® result is predictive of chemotherapy benefit in patients with node-negative disease (p=0.009), with no chemotherapy benefit with Recurrence Score® results less than 26. In patients with node-negative disease and Recurrence Score results less than 26 not treated with chemotherapy, the Breast Cancer Specific Survival (BCSS) was greater than 96 percent at nine years. In patients with node-positive disease not treated with chemotherapy and Recurrence Score results less than 18, BCSS was greater than 97 percent at nine years.

"This updated analysis reflects our experience with the Oncotype DX® test in routine clinical practice and is consistent with findings from multiple clinical trials, including the TAILORx study", said Dr Antonio Llombart, chairman of the Medical Oncology Service at the University Hospital Arnau de Vilanova in Valencia, Spain. "The results continue to show the unique value of adding genomic information provided by the test to better target chemotherapy."

[1] Hortobagyi et al. Poster: P3-11-02. San Antonio Breast Cancer Symposium. December 2018.

Importantly, the new real-world evidence reinforces the paradigm established by the TAILORx study, which provided definitive information on how to treat women with node-negative early-stage breast cancer based on their Oncotype DX Breast Recurrence Score results. TAILORx - the largest randomised adjuvant breast cancer treatment trial ever conducted - identified the vast majority of women (Recurrence Score result up to 25) who receive no substantial benefit from chemotherapy, as well as the important minority (Recurrence Score result 26-100) for whom chemotherapy can be life-saving. Thus, the Oncotype DX test can greatly reduce both over- and undertreatment with chemotherapy.

The test's clinical utility and the importance of the TAILORx results are underlined in leading international breast cancer treatment guidelines. Most recently, the National Comprehensive Cancer Network (NCCN) updated its guidelines for invasive breast cancer chemotherapy treatment and classified Oncotype DX as the "preferred" multi-gene test and the only one to be predictive of chemotherapy benefit.[2] Separately, Germany's health technology assessment body - the Institute for Quality and Efficiency in Health Care (IQWiG) - recommended the Oncotype DX test in September 2018 as the only multi-gene test to add benefit for decision making.[3,4]

"The practice-changing precision made possible by the Oncotype DX test can lead to improved quality of care and breast cancer survival, as well as reduced waste of healthcare resources by directing chemotherapy only to patients who have a high likelihood of deriving substantial benefit," said Torsten Hoof, Senior Vice President International, Genomic Health. "As we continue to generate evidence showing the unique value of our test, we look forward to continuing to work with the relevant authorities to make it available to patients on a wider scale."

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[5] 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.[6,7]

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.

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[2] https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
[3] IQWiG, press release, "Biomarker tests in breast cancer: New study data indicate advantage for certain patients," 5 September 2018. https://www.iqwig.de/en/press/press-releases/biomarker-tests-in-breast-cancer-new-study-data-indicate advantage-forcertain-patients.10059.html
[4] IQWiG, Addendum D18-01, Biomarker bei Mammakarzinom, 5 September 2018.
[5] Ferlay J et al, Eur J Cancer. 2013
[6] Paik et al. J Clin Oncol. 2006
[7] Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. Lancet. 2012

Healthcare systems across Europe are recognising 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 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 950,000 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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