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Updated St. Gallen International Breast Cancer Guidelines reinforce important role of genomic testing in treatment of early breast cancer

- *Oncotype DX[®] test endorsed for guiding treatment decisions on adjuvant chemotherapy both in node-negative and in node-positive disease*
- *Gene expression signatures recommended for the first time as preferable to standard pathology, when adequate reproducibility is not granted*

LONDON, United Kingdom, [July 12, 2017] – Genomic Health today announced that the 15th St. Gallen International Breast Cancer Conference Expert Panel endorsed the use of genomic tests in early-stage breast cancer and recognised the Oncotype DX Breast Recurrence Score[®] test for its prognostic ability as well as its value in guiding treatment decisions on adjuvant chemotherapy for patients with early-stage, endocrine sensitive, invasive breast cancer.

In particular, Oncotype DX[®] was the only test supported by a majority of panelists (58.6 percent) for its value in providing information that can help physicians “decide to omit chemotherapy” in patients with node positive disease (up to three nodes). The guidelines, which are reviewed bi-annually, have been recently published online in the [Advance Access section](#) of *Annals of Oncology* and will appear in a future print issue.

“We are pleased that this expert panel once again recognised the value of the Oncotype DX test. An extensive body of clinical evidence highlights the unique ability of our test to identify both patients who can be spared chemotherapy and – importantly - those who will clearly benefit from it, while providing a positive impact on healthcare systems,” said Calvin Chao, Vice President of Global Medical Affairs at Genomic Health. “In addition to these updated guidelines, it is encouraging to see recently published data reinforcing that there is a spectrum of biology in breast cancer and growing evidence from all research groups on the importance of more precise estimates of risk and chemotherapy benefit as provided by the Oncotype DX individualised Recurrence Score result.”

The Oncotype DX Breast Recurrence Score test is incorporated in all major international guidelines, including NICE, St. Gallen International Breast Cancer Expert Panel, ESMO, ASCO and NCCN. The

test was also included in the [8th edition](#) of the American Joint Committee on Cancer (AJCC) criteria for breast cancer staging, which will be effective in January 2018. This is particularly significant since AJCC has, for the first time, added molecular markers to staging criteria and identified Oncotype DX as the only multigene test that can be used to determine formal staging of breast cancer patients along with hormonal status (ER, PR), and HER2 status.

Breast cancer is the most common cancer in European women¹ and affects many of them during their years dedicated to working and raising a family. While chemotherapy is routinely offered, research shows that less than 10 percent of patients with early-stage breast cancer actually benefit from it.² 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. 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.³

About Oncotype DX

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. 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.co.uk

About Genomic Health

Genomic Health, Inc. is a world's leading provider of genomic-based diagnostic tests that address both the overtreatment and optimal treatment of cancer. 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 750,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests, including the recently launched Oncotype SEQ[®] Liquid Select[™] test. The company is based in Redwood City, California with UK headquarters in London. For more information, please visit, www.GenomicHealth.co.uk and follow the company on Twitter: [@GenomicHealth](#), [Facebook](#), [YouTube](#) and [LinkedIn](#).

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements relating to the ability of any potential tests Genomic Health, Inc. may develop to optimize cancer treatment and the ability of the company to develop and commercialize additional tests in the future. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially, and reported results should

¹ <http://eco.iarc.fr/EUCAN/Country.aspx?ISOCountryCd=968>, last accessed on 21/06/17

² Paik et al. *J Clin Oncol*. 2006 ; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. *Lancet*. 2012.

³ Loncaster J et al., *Eur J Surg Oncol* 2017

not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the results of clinical studies and their impact on reimbursement and adoption; the applicability of clinical study results to actual outcomes; the company's ability to develop and commercialize new tests and expand into new markets domestically and internationally; 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; unanticipated costs or delays in research and development efforts; the company's ability to obtain capital when needed 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 yearly report on Form 10-K for the quarter ended March 31, 2017. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

NOTE: The Genomic Health logo, Oncotype, Oncotype DX, Oncotype IQ, Oncotype DX Breast Recurrence Score, Recurrence Score, and Breast Recurrence Score are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

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