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Genomic Health unveils a wealth of data for the Oncotype DX® breast cancer test, reinforcing its value in improving patient outcomes and leading to more cost-effective management

- *15 featured abstracts at the 15th St Gallen International Breast Cancer Conference underscore the growing adoption of the company's cutting-edge genomic test to identify those patients who will benefit from chemotherapy after breast cancer surgery*
- *New real world evidence highlights the significant impact in reducing the burden of unnecessary chemotherapy for patients and its associated costs for healthcare systems*
- *Additional data solidify utility of Oncotype DX in patients with node-positive disease*

GENEVA, Switzerland, [March 17, 2017] – Genomic Health today announced the presentation of 15 abstracts for the Oncotype DX® breast cancer test at the [15th St Gallen International Breast Cancer Conference](#) in Vienna, Austria. This test uses state-of-the-art genomic analysis techniques to uncover the unique footprint of each patient's tumour and generates a Recurrence Score® result which predicts the likelihood that the patient's cancer will return and whether chemotherapy is likely to provide benefit.

The presentations underline the substantial real world evidence which is now available for Oncotype DX and reflect the growing adoption of the test across Europe to personalise and improve the quality of clinical decisions leading to better patient outcomes and more cost-effective treatment.

Data highlights include:

- A pooled analysis of eight international studies including over 2,500 patients which assessed the impact of the Oncotype DX test on treatment decisions in routine clinical practice. The results showed that the average net reduction in chemotherapy use following testing was 42%.¹
- A detailed budget impact assessment comparing the genomic tests available in Germany. The analysis identified Oncotype DX as the test associated with the highest reduction in chemotherapy use because it appropriately classifies more patients at low risk than other tests, resulting in a potential net budget saving for sick funds of EUR 4,001 per patient tested.²
- A study from France which looked at the test utilisation in real-life clinical practice in 827 patients, including those with high-risk disease by traditional parameters. The results demonstrated that the use of Oncotype DX in France reduced the use of chemotherapy by 35%.^{3,4}

“The traditional criteria used for making chemotherapy clinical decisions may result in substantial overtreatment and toxicity with unnecessary costs for healthcare systems. The decision to initiate a course of chemotherapy should be as informed as possible. From a health service perspective, it is costly and resource-intensive but the toll for the patient can be even greater,” said Prof. Joseph Gligorov, Breast Cancer Expert Center, APHP-Tenon Hospital, Paris. “The new evidence presented for the Oncotype DX test highlights the impact it is having across Europe to drive a step-change in the quality of treatment decisions. These results, based on real-world clinical practice, indicate that molecular testing provides clinically meaningful information in addition to classical pathological parameters for a significant proportion of patients and support its broader use and public reimbursement.”

Every year in Europe, over 490,000 new cases of breast cancer are diagnosed.⁵ It is the most common cancer in women and affects many of them during their years dedicated to working and raising a family. An average of 20% of breast cancer cases in Europe occur in women when they are younger than 50 years old; and 37% occur at age 50–64. While chemotherapy is routinely offered, research shows that less than 10% of patients with early-stage breast cancer actually benefit from it.⁶

Additional data support the use of Oncotype DX in patients with node-positive breast cancer

Several posters were also presented at the St Gallen International Breast Cancer Conference providing further evidence that Oncotype DX accurately predicts outcomes and has important clinical utility in patients whose breast cancer has spread to their lymph nodes.

- An analysis based on the Surveillance, Epidemiology, and End Results (SEER) registry program of the National Cancer Institute (NCI) looked at breast cancer-specific survival (BCSS) in more than 6,700 patients. The results showed that five-year BCSS was excellent in patients with Recurrence Score results less than 18 and micro metastases, 1-3 positive nodes. Survival worsened with increasing number of lymph nodes involved and higher Recurrence Score results.⁷ These findings in node positive disease were recently updated and published in [*Breast Cancer Research and Treatment*](#).
- A study from Clalit Health Services (Israel) including over 700 patients showed that those with micro metastases and one to three positive nodes with Recurrence Score results of less than 18, the vast majority (92.9%) of whom were treated with hormonal therapy alone, had very good outcomes with low rates of distant recurrence after a median follow-up of 5.9 years.⁸
- A systematic review was conducted across seven international studies including more than 9,000 patients with node-positive disease. These studies consistently identified patients with a low number of positive nodes (1-3) and low Recurrence Score results who had good clinical outcomes.⁹
- A pooled analysis of seven international studies including a total of 385 patients with 1-3 positive lymph nodes showed that testing with Oncotype DX significantly impacted treatment decisions (43% change on average), resulting in a net reduction in chemotherapy use, similar to that seen in studies of node-negative breast cancer.¹⁰
- A study from Spain which assessed the impact of the test on treatment decisions in 217 patients found that among the 71 patients with lymph node positive breast cancer, there was a 72% reduction in chemotherapy use. For the group of 146 patients with lymph node negative disease, the reduction in chemotherapy was 26%.¹¹

“The momentum for genomic testing is building as healthcare systems across the world recognise its value to patients and society”, said Steven Shak, M.D., chief scientific officer, Genomic Health. “These latest presentations clearly highlight the impact of Oncotype DX in reducing chemotherapy usage and driving more cost-effective treatment, as well as its value in providing doctors with confidence that their patients will receive the quality care they deserve.”

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 recognising the value of the test, which is incorporated in all major international clinical guidelines. Following assessment and recommendation by NICE in 2013, the Oncotype DX test is now widely available to patients across the UK. In France, Oncotype DX is available through a funding mechanism for innovative diagnostics. Other European countries that reimburse the test include Switzerland, Ireland, Greece and Spain. To learn more about the Oncotype DX test, visit: www.OncotypeDX.com

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 700,000 cancer patients worldwide. Genomic Health is expanding its test portfolio to include additional liquid and tissue-based tests. 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](https://twitter.com/GenomicHealth), [Facebook](#), [YouTube](#) and [LinkedIn](#).

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 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 quarterly report on Form 10-Q for the year ended December 31, 2016. 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, Recurrence Score, DCIS Score, Oncotype SEQ, and Oncotype IQ 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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¹ Millen S, P233, St. Gallen 2017

² Nabieva N, P241, St. Gallen 2017

³ Curtit E, P114, St. Gallen 2017

⁴ Gligorov J, P115, St. Gallen 2017

⁵ Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F.

GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide : IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: <http://globocan.iarc.fr>, accessed on 08/02/17,

⁶ Paik et al. *J Clin Oncol*. 2006 ; Early Breast Cancer Trialists' Collaborative Group (EBCTCG) et al. *Lancet*. 2012.

⁷ Shak S, P225, St. Gallen 2017

⁸ Stemmer S, P251, St. Gallen 2017

⁹ Mamounas E., P226, St. Gallen 2017

¹⁰ Braybrooke J, P203, St. Gallen 2017

¹¹ Gasol Cudos A, P211, St. Gallen 2017