Contact:

Senomic Health LIFE, CHANGING.

Media:
Hazel Davis
Media consultant
Genomic Health
07832234312
hazeldavis@gmail.com

Five-year outcomes results from European 'PlanB' study show that breast cancer patients with low Oncotype DX® Recurrence Score® results can be spared chemotherapy despite having high-risk disease by traditional measures

• Study confirms the test's ability to accurately predict clinical outcomes, reinforcing unique value of Oncotype DX as the only multi-gene breast cancer test with prospective outcomes evidence in more than 50,000 patients

GENEVA, Switzerland, [March 11, 2016] – Genomic Health today announced the presentation of new, five-year results from a large outcomes study with the Oncotype DX test at the 10th European Breast Cancer Conference (EBCC-10)¹. Results from the PlanB study showed that 94 percent of women with high risk early stage breast cancer and Recurrence Score results of 11 or less, who were treated with hormonal therapy alone, were still alive and disease-free five years after diagnosis.

PlanB is the first study which provides prospective data with the Oncotype DX breast cancer test in patients with high clinical risk of recurrence including those with node-positive disease (one to three nodes). The study was conducted by the West German Study Group (WSG) in 93 centres across Germany and is one of Europe's largest contemporary adjuvant breast cancer trials.

"Our study shows the unique value of adding biological information provided by the Oncotype DX test in order to identify low-risk breast cancer patients - among patients with 0-3 involved lymph nodes - who can safely be spared the toxicity and side effects of chemotherapy without compromising outcomes," said Prof. Nadia Harbeck, WSG Scientific Director and Head of the breast center at University of Munich (LMU). "This is especially important for patients who would be considered as intermediate to high risk of recurrence based on traditional clinical parameters. These results confirm previous retrospective studies with Oncotype DX as well as the prospective TAILORx trial which already provided results for the node-negative population."

The PlanB study enrolled more than 3,100 patients who were considered candidates for chemotherapy by traditional parameters. Participants with Recurrence Score results of 11 or less were offered

hormonal therapy alone, and patients with Recurrence Score results of 12 or higher were randomised to different chemotherapy regimens.

In women with Recurrence Score results of 11 or less who were treated with hormonal therapy alone, five-year disease free survival (DFS) was estimated as 94 percent after a median follow-up of 55 months. Patients with Recurrence Score results of 12 to 25 who were treated with adjuvant chemotherapy also had high DFS rates (94 percent) while in patients with Recurrence Score results above 25, who had also received chemotherapy, DFS rates were 84 percent.

Further analysis from PlanB shows that Recurrence Score results provided independent value in addition to traditional clinical-pathological markers such as tumour grade and size.

"Value in health care depends on results and outcomes, which are vital to the patient. Results from this study clearly show the benefit of a personalised approach to breast cancer treatment," said Denis Horgan, executive director of the European Alliance for Personalised Medicine (EAPM). "We hope to see more healthcare systems across Europe provide access to molecular diagnostics that are supported by a high level of scientific evidence and proven clinical utility."

These new PlanB study results with five year outcomes provide information beyond the three year outcomes published recently in the <u>Journal of Clinical Oncology</u>. The findings are consistent with conclusions of the Trial Assigning IndividuaLized Options for Treatment (Rx), or TAILORx, published in <u>The New England Journal of Medicine</u>. They add to an unprecedented body of evidence which now includes prospective outcomes in more than 50,000 patients across four large independently run international studies and provide unequivocal evidence supporting the expert clinical practice guidelines on the utility of Oncotype DX in node-negative and node-positive early breast cancer beyond the standard measures used alone for many years.

About the Oncotype DX test

The Onco*type* DX breast cancer test 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. Other European countries that reimburse the test include Switzerland, Ireland, Greece and Spain. To learn more about the Onco*type* DX test, visit: www.OncotypeDX.com

About Genomic Health

Genomic Health, Inc. is a world-leading provider of genomic-based diagnostic tests that inform treatment decisions and help to ensure each patient receives appropriate treatment for early stage cancer. 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 screening and surveillance, through diagnosis and treatment selection. The company is based in Redwood City, California with European headquarters in Geneva, Switzerland. For more information, please visit, www.GenomicHealth.co.uk.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating the company's beliefs regarding its liquid biopsy platform and the timing of a liquid biopsy test; the company's intent to continue its investments in DCIS, prostate cancer and international markets; the company's full year 2015 results; the attributes and focus of the company's product pipeline; the ability of any potential tests the company 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 not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the risks and uncertainties associated with the regulation of the company's tests; 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; the risks of competition; 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 year ended December 31, 2015. 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 and Recurrence Score are trademarks or registered trademarks of Genomic Health, Inc. All other trademarks and service marks are the property of their respective owners.

¹Abstract no: 8 LBA. "Prospective WSG Phase III PlanB trial: Clinical outcome at 5-year follow up and impact of 21 Gene Recurrence Score result, central/local-pathological review of grade, ER, PR and Ki67 in HR+/HER2- high risk node-negative and –positive breast cancer", Friday, Plenary session: oral and late breaking abstracts, 09.45-11.15 hrs, Elicium.