October 10, 2016

Multiple Oncotype DX® Presentations at ESMO 2016 Congress Reinforce Its Unique Clinical Utility with Prospective Outcomes Results in Over 63,000 Breast Cancer Patients

Two Large International Studies Underscore Ability of Oncotype DX to Identify Patients with Node-positive Breast Cancer Who Can Forego Chemotherapy and Its Side Effects
Studies across Four Countries Demonstrate Oncotype DX Results Significantly Change Treatment Decisions and Reduce Chemotherapy Use

REDWOOD CITY, Calif., Oct. 10, 2016 /PRNewswire/ -- Genomic Health, Inc. (Nasdaq: GHDX) today announced results from eight Oncotype DX® Breast Recurrence Score™ (RS) presentations at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen, Denmark, highlighting superior clinical evidence in identifying which patients with node-negative and node-positive invasive breast cancer should be treated with chemotherapy. Specifically, prospective clinical outcomes in more than 7,400 patients with node-positive invasive breast cancer from two independent studies show excellent survival in women with RS results less than 18.

"The ESMO presentations continue to reinforce that Oncotype DX provides unique and unsurpassed value beyond tumor size and tumor grade for invasive breast cancer patients with node-negative and certain patients with node-positive disease," said Steven Shak, M.D., chief scientific officer, Genomic Health. "With our level 1 evidence for predicting chemotherapy benefit and prospective outcomes now in over 63,000 patients from the TAILORx, Clalit, PlanB and SEER studies, it is clear that Oncotype DX is the only genomic test that can provide doctors with confidence that their patients will receive the quality care they deserve."

New data confirm Oncotype DX accurately predicts clinical outcomes in node-positive breast cancer patients
Two independent studies in more than 7,400 patients from the United States and Israel provide further evidence that Oncotype DX accurately predicts outcomes in patients with early-stage, node-positive invasive breast cancer. Specifically, an updated analysis of the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) Registry results from 6,768 patients who were treated based on RS results showed that in 3,919 patients with a RS of less than 18, breast cancer specific survival was excellent. Specifically, it was greater than 97 percent in patients with micrometastases, one, or two positive lymph nodes.

Similarly, results from a prospective study of more than 700 patients tested with Oncotype DX within Clalit Health Services, the largest health maintenance organization in Israel, showed that patients with micrometastases or one to three positive lymph nodes and a RS less than 18, the vast majority (92.9 percent) of whom were treated with hormonal therapy alone, had very good outcomes with low rates of distant recurrence (3.2 percent) and excellent breast cancer survival (> 99 percent) at five years.

"These two important updates add significantly to the growing body of evidence that Oncotype DX accurately predicts outcomes and aids treatment decision making in women with early-stage, node-positive breast cancer. Just as we have learned in node-negative disease, it is now increasingly evident that women with one to three positive nodes and the lower scores do extremely well without chemotherapy," said Kathy S. Albain, MD, FACP, FASCO, professor of medicine, Loyola University Chicago, Cardinal Bernardin Cancer Center, Maywood, IL. "While we are now completing accrual of the RxPONDER trial looking at whether chemotherapy adds to standard endocrine therapy in this group, getting the results will take several years. In the meantime, these data along with previously published results, provide extremely strong evidence to justify use of Oncotype DX in 1-3 node-positive disease. If the patient's tumor biology is that of a low Recurrence Score, chemotherapy simply does not add benefit, and its risks and costs can be avoided."

In addition, exploratory analyses of patients with RS results of 18 to 30 showed that the rate of distant recurrence were generally closer to lower risk patients with a RS less than 18. The group of patients with mid-range Recurrence Score results is also being studied in the Trial Assigning IndividuaLized Options for Treatment (Rx), or TAILORx, and the RxPONDER trial.

Oral presentation of additional SEER analysis reveals large disparities in survival and Oncotype DX testing in older patients

Following up on the results of the multinational TEAM study, which reported worse outcomes for older patients with hormone-receptor-positive (HR+) breast cancer, this study examined RS results in patients 70 years and older versus those under 70 years. The results showed that mortality was indeed much higher in older patients who were either not tested with Oncotype DX or had a RS result greater than 18. Patients age 70 or older also had lower reported chemotherapy use, supporting continued examination of the often reported issue of under-treatment of the elderly.

Oncotype DX reduces overtreatment of breast cancer and increases confidence in treatment decisions globally
Results from multiple international studies conducted in Canada, the Czech Republic, Italy and Spain reinforce the findings of more than 20 previous decision impact studies from around the world. Collectively, the results demonstrated that the RS increases confidence in treatment decisions and changes approximately 30 percent of treatment recommendations, resulting in a 22-24 percent reduction in use of chemotherapy in patients, including in those with node-positive disease.

About Oncotype DX®

The Oncotype DX® portfolio of breast, colon and prostate cancer tests applies advanced genomic science to reveal the unique biology of a tumor in order to optimize cancer treatment decisions. With more than 600,000 patients tested in more than 90 countries, the Oncotype DX tests have redefined personalized medicine by making genomics a critical part of cancer diagnosis and treatment. To learn more about Oncotype DX tests, visit www.OncotypeDX.com, www.mybreastcancertreatment.org and www.myprostatecancertreatment.org.

About Genomic Health

Genomic Health, Inc. (NASDAQ: GHDX) is the world's leading provider of genomic-based diagnostic tests that help optimize cancer care by addressing the overtreatment of the disease, one of the greatest issues in healthcare today. With its Oncotype IQ™ Genomic Intelligence Platform, the company is applying its world-class scientific and commercial expertise and infrastructure to lead the translation of clinical and genomic big data into actionable results for treatment planning throughout the cancer patient 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 600,000 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 assay. 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.

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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: our business model; the applicability of clinical study results to actual outcomes; our ability to develop and commercialize new tests and expand into new markets domestically and internationally; unanticipated costs or delays in research and development efforts; and the other risks and uncertainties set forth in our filings with the Securities and Exchange Commission, including the risks set forth in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

GHDX-B

Genomic Health®
LIFE, CHANGING.

Video - https://www.youtube.com/watch?v=vNkPtTOhCZY
Logo - http://photos.prnewswire.com/prnh/20130425/SF01493LOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/multiple-oncotype-dx-presentations-at-esmo-2016-congress-reinforce-its-unique-clinical-utility-with-prospective-outcomes-results-in-over-63000-breast-cancer-patients-300341606.html

SOURCE Genomic Health, Inc.