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Genomic Health Announces Inclusion of Oncotype DX® in the 8th Edition of American Joint Committee on Cancer (AJCC) Criteria for Breast Cancer Staging

For the First Time, AJCC Adds Molecular Markers to Staging Criteria, Including Oncotype DX along with Estrogen Receptor (ER), Progesterone Receptor (PR), and HER2 Status

REDWOOD CITY, Calif., Dec. 22, 2016 /PRNewswire/ -- Genomic Health, Inc. (NASDAQ: GHDX) today announced that based on unparalleled clinical evidence, the American Joint Committee on Cancer (AJCC) incorporated the Oncotype DX® test in its recently published [Eighth Edition AJCC Cancer Staging Manual](#). Representing a rigorous, multi-disciplinary assessment, the updated criteria identify Oncotype DX as the only multi-gene test with Level I evidence to determine formal staging of breast cancer patients, based on clinical evidence in more than 63,000 patients.

"For the first time, AJCC has added molecular signatures to complement the traditional anatomic features of the disease, transitioning cancer diagnosis and care to truly personalized medicine," said Steven Shak, M.D., chief scientific officer, Genomic Health. "We believe this groundbreaking milestone will enhance physicians' ability to deliver the excellent patient outcomes demonstrated across multiple prospective studies of the Oncotype DX test."

Effective January 2018, the new AJCC Prognostic Stage Groups will add the Oncotype DX Breast Recurrence Score™, hormonal status (ER, PR), and HER2 status to nodal status, tumor size, and tumor grade for staging breast cancer. For patients with node-negative disease or micrometastases in the nodes, a low Oncotype DX Recurrence Score (RS < 11) classifies a patient as having the most favorable Prognostic Stage, regardless of tumor grade or tumor size (up to five centimeters).

As part of the implementation process, all AJCC partners, including the College of American Pathologists (CAP) and the National Comprehensive Cancer Network (NCCN), will develop and update protocols and tools to facilitate successful adoption of the required new staging system rules in 2018. The electronic version of the [Eighth Edition AJCC Cancer Staging Manual](#) is scheduled to be available the first quarter of 2017.

As stated in the AJCC publication¹, "Based on the best available evidence at this time, the Expert Panel determined that it was appropriate to incorporate multigene molecular profiling to incorporate the Oncotype DX score into staging for the subgroup of patients defined by Arm A of the TAILORx study. These patients should be staged according to the AJCC Prognostic Stage Groups. The findings for the ODX (Oncotype DX) test are supported by Level I Evidence (large-scale prospective clinical trial data)."

The results of the Trial Assigning Individualized Options for Treatment (Rx), or TAILORx, led by the ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) were published in *The New England Journal of Medicine* in 2015. Additionally, the *Eighth Edition AJCC Cancer Staging Manual* cites clinical outcomes data from tens of thousands of patients in the United States generated by the Surveillance, Epidemiology, and End Results (SEER) Registry program of the National Cancer Institute (NCI), demonstrating that patients with low Recurrence Scores have excellent breast cancer survival at five years.

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. The company's flagship product, the Oncotype DX breast cancer test, has been shown to predict the likelihood of chemotherapy benefit as well as recurrence in invasive breast cancer. Additionally, the test predicts the likelihood of recurrence in a pre-invasive form of breast cancer called DCIS. With more than 700,000 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 or www.MyBreastCancerTreatment.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 700,000 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 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 quarter ended September 30, 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 AJCC Cancer Staging Manual, 8th Edition, 2016



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