

## Reporter Backgrounder: Oncotype DX<sup>®</sup> For Early-stage Breast Cancer

### Moving Away from One-size-fits-all Treatment in Early-stage Breast Cancer

Not every breast cancer patient needs the same treatment. While chemotherapy and/or radiation can be effective for some patients, not all benefit in the same way. In fact, **only 4 percent of early-stage breast cancer patients actually benefit from chemotherapy**<sup>1</sup>. Physicians are increasingly using genomic testing such as the Oncotype DX Breast Recurrence Score to improve their understanding of each patient's individual tumor biology and determine the most appropriate treatment after surgery.



### What is the Oncotype DX Breast Recurrence Score?

The Oncotype DX Breast Recurrence Score is a multi-gene test that has been shown to predict both the likelihood of chemotherapy benefit and the risk of disease recurrence in early-stage invasive breast cancer. The test can help patients and their doctors determine the chances that the disease will recur and whether or not the cancer will respond to treatment, thereby enabling them to personalize their course of care. The Oncotype DX Breast Recurrence Score is the only genomic test validated to predict chemotherapy benefit, and it is included in all major breast cancer treatment guidelines worldwide. As a result, it is generally accepted as standard of care for patients with early-stage, hormone receptor-positive, invasive breast cancer (Stage I-IIIa). New studies involving more than 50,000 patients showed that the Oncotype DX Breast Recurrence Score accurately predicts clinical outcomes<sup>2</sup>.

### How Does the Test Work?

- The test is performed on tumor tissue sample previously obtained during the original surgery. There is *no* additional procedure.
- The test analyzes the activity of specific genes which can influence how a cancer is likely to grow and respond to treatment.
- The doctor receives the Recurrence Score result which is a number between 0 and 100 that corresponds to the risk of distant recurrence within 10 years and likelihood of chemotherapy benefit.
- A lower score means that cancer is less likely to come back and that chemotherapy is less likely to provide benefit. A higher score suggests greater risk that cancer will come back and that chemotherapy is likely to be beneficial.

<sup>1</sup>Paik S, Tang G, Shak S, et al. Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. *J Clin Oncol.* 2006; 24(23): 3726-34.

<sup>2</sup>Sparano J, ESMO 2015; Stemmer SM, ESMO 2015; Glitz O, ESMO 2015; Shak S, 2015 SABCS

\*ASCO and NCCN are registered trademarks of the American Society of Clinical Oncology (ASCO) and National Comprehensive Cancer Network (NCCN), respectively. ASCO and NCCN do not endorse any product or therapy.

## Data and Guidelines Support Using the Test as Standard of Care

- The Oncotype DX Breast Recurrence Score is supported by multiple rigorous clinical validation studies and four prospective outcome studies confirming the test's ability to provide additional and independent value beyond the currently used measures for determining breast cancer recurrence risk.
- More than 25 decision impact studies conducted in more than 10 countries demonstrate that the Oncotype DX Breast Recurrence Score changes treatment decisions in more than 30 percent of patients with the majority moving away from chemo.
- Included in all major international clinical guidelines including: ASCO®, NCCN® in the U.S., and St. Gallen, ESMO and NICE in Europe.
- The Oncotype DX Breast Recurrence Score is the only multi-gene breast cancer test with prospective outcomes in more than 50,000 patients, providing the highest level of evidence supporting the test's clinical utility.
- Results from one of the largest-ever adjuvant breast cancer trials – TAILORx – showed 99% of women with a low Breast Recurrence Score result were free of breast cancer recurrence after five years of hormone therapy alone. The findings from this trial, sponsored by the National Cancer Institute, were published in *The New England Journal of Medicine*.

## Is It Covered by Insurance?

- All major U.S. insurance carriers cover the Oncotype DX Breast Recurrence Score for eligible patients with early-stage invasive breast cancer, including Medicare, Aetna, CIGNA, United Healthcare, Kaiser Permanente, Anthem/WellPoint, Humana, Blue Cross Federal, and many others.