

Clinical Trial Results: Clinical Validation Study

Prognosis for node-negative breast cancer patients was determined based on the probability of distant recurrence (DR) for this patient population in the validation study ABCSG-8. This study analyzed 1,047 node-negative samples using a prospectively defined analysis plan. The data shown are for post-menopausal women with hormone receptor-positive, node-negative, Stage I and II breast cancer that received 5 years of endocrine therapy.^{2†}

Probability of Distant Recurrence in the ABCSG-8² Clinical Validation Study

Prespecified Patient Risk Group	LOW RISK	INTERMEDIATE RISK	HIGH RISK
	3% [2–6%]	10% [7–14%]	16% [11–22%]

DRFS by Risk Group for Node-Negative Patients³

The ROR score classifies node-negative patients as low, intermediate, or high-risk based on prespecified thresholds that indicate probability of DR at 10 years. In the ABCSG-8 clinical validation study, the probability of DR at 10 years for low-risk, node-negative patients was 3% (95% CI: 2–6%), while the probability of DR at 10 years for high-risk patients was 16% (95% CI: 11–22%).

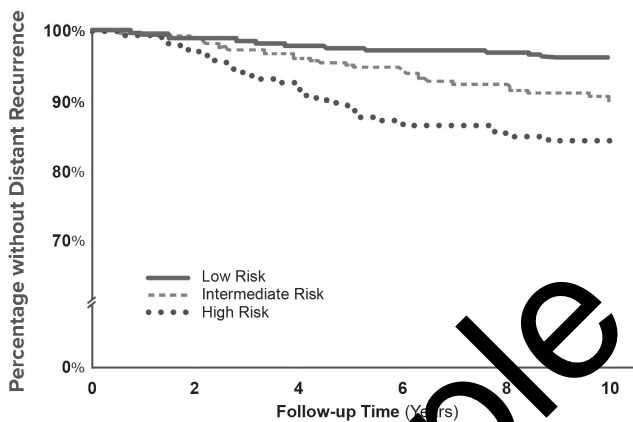


Table 1: Distribution of Node-Negative patients by 10-unit ROR score Range

ROR score Range	Number of Patients	Percent of Patients	10-year DR Risk (Empirical) with 95% Confidence Limits
1–10	7	0.7%	0% [N/A]
11–20	116	11.1%	1.8% [0%–4.3%]
21–30	155	14.8%	2.5% [0%–5.2%]
31–40	209	20.0%	5.1% [2.0%–8.1%]
41–50	183	17.5%	7.5% [3.3%–11.6%]
51–60	152	14.5%	12.1% [6.2%–17.6%]
61–70	116	11.1%	15% [7.6%–21.8%]
71–80	77	7.4%	12.3% [4.4%–19.6%]
81–90	28	2.7%	26.1% [7.3%–41.1%]
91–100	4	0.4%	33.3% [0%–70.0%]
Total	1,047	100%	

1. Wallden B, Storhoff J, Nielsen N, et al. Development and verification of the PAM50-based Prosigna breast cancer gene signature assay. *BMC Medical Genomics* 2015 Vol. 8 Issue 1, DOI: 10.1186/s12920-015-0129-6

2. Prosigna Package Insert

3. Ghant M, et al., on behalf of the Austrian Breast and Colorectal Cancer Study Group. Predicting distant recurrence in receptor-positive breast cancer patients with limited clinicopathological risk: using the PAM50 Risk of Recurrence score in 1478 postmenopausal patients of the ABCSG-8 trial treated with adjuvant endocrine therapy alone. *Annals of Oncology* 2014; 25(2):339-45

†See Package Insert for further information on therapy regimens and tested patient population. It is unknown whether these findings can be extended to other patient populations or treatment schedules.

Example - US ONLY