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Effect of Oncotype® DX Colon Cancer Test Results on Treatment Recommendations in Patients with Stage II Colon Cancer: Preliminary Results

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Background: The Oncotype DX® Colon Cancer Recurrence Score (RS) has been clinically validated as an independent predictor of individual recurrence risk in stage II colon cancer patients following surgery. As a result, physicians have been ordering the Oncotype DX assay for stage II colon cancer patients since January 2010, yet no data exist on the assay's impact on adjuvant treatment planning in practice. We performed a survey to characterize the impact of the assay on adjuvant treatment recommendations in stage II colon cancer.

Methods: U.S. medical oncologists (N=277) who ordered Oncotype DX for ≥3 patients with stage II colon cancer were contacted and asked to complete a web-based survey regarding the single most recent stage II colon cancer patient for whom the assay was ordered. The survey was developed through cognitive interviews with four medical oncologists, and the protocol was institutional review board approved.

Results: As a planned preliminary analysis, we analyzed surveys from 92 eligible physicians. Physicians were more often in community (85%) than academic or other practices, and had a median of 14.5 years (range, 2-40) of practice experience. The median patient age was 62 years (range, 34–81). 84% of patients had T3 disease. Patients had ≤8, 9-11 and ≥12 nodes examined 2%, 14% and 84% of the time and 36% had comorbidities. Of the 60 patients tested for MMR/MSI, 9 (15%) were MMR-D or MSI-high and 37 (62%) were MMR-P or MSI-low; 14 (23%) unknown. Median RS was 20 (range, 1-77). Before obtaining the RS, chemotherapy was planned in 38 (41%) patients, observation in 35 (38%), and there was no recommendation in 19 (21%). For the 73 patients with pre-assay recommendations, recommended treatment changed after obtaining the RS for 23 patients (32%), including changes from chemotherapy to observation and vice-versa.

Discussion: These preliminary findings indicate that for stage II colon cancer patients, treatment recommendations were changed by RS results approximately one-third of the time. Final results will be reported to include accrual through December 2011.