As more therapeutic regimens are emerging for ovarian cancer patients, it will become increasingly important to be able to determine the prognosis and response to treatment to stratify patients for appropriate therapy and new clinical trials. We therefore evaluated the novel ovarian cancer marker B7-H4 as a prognostic marker in tissue lysate and serum.

As reported previously (1), we have developed a sensitive ELISA for B7-H4 (DD-O110) and showed that the B7-H4 level in serum is elevated in ovarian cancer patients, when compared to normal controls and patients with benign gynecological diseases. Furthermore, the results indicate that B7-H4 may complement CA125, thus, increasing the sensitivity and specificity of the ovarian cancer detection.

In this study, serum samples from 84 patients with ovarian carcinoma were collected prior to each chemotherapy cycle, and were assessed for the levels of the tumor marker CA125 and B7-H4. The age median was 57 years (22 - 80 years, 57 + 11.1 with CI 95%). Seventy-three patients were treated with the adjuvant chemotherapy regimen CBDCA/CFA or Taxol/CBDCA following surgery. The Taxol-weekly (Tw) regimen was administered in 11 patients with recurrent disease. Forty-two patients died within two years of follow-up while forty-two patients survived; 21 of the surviving patients were classified as free of disease progression.

A cut-off point of 1.1 ng/ml (95th percentile of B7-H4 in healthy women, n = 344) was selected to categorize patients as B7-H4 positive or B7-H4 negative. Of the patients with 2 year disease-free survival, more than 50% had levels below the cut-point and no patient had levels in the highest quartile (4.2-46.0 ng/ml B7-H4). In contrast, B7-H4 was positive in 90% of patients who died or had a recurrence within 2 years of diagnosis, and 33% of these patients had B7-H4 concentrations in the highest quartile. Notably, seven of the patients with poor outcomes had positive B7-H4 levels, despite the fact that their CA125 levels were below the accepted cut-point of 35 U/ml.

These data suggest that the level of B7-H4 correlates with disease outcome in ovarian cancer patients undergoing therapy and may provide a means for determining the appropriate course of treatment for the patients.