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Title: Randomized phase II trial of weekly ixabepilone with or without biweekly bevacizumab for platinum-resistant or refractory ovarian/fallopian tube/primary peritoneal cancer

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Objectives: Ixabepilone is a microtubule-stabilizing agent that may retain activity in paclitaxel-treated patients. The goal of this multi-center randomized phase II study was to assess the activity and safety of ixabepilone with bevacizumab compared to ixabepilone alone in patients with platinum-resistant/refractory ovarian, fallopian tube, or primary peritoneal cancer. An exploratory objective was to examine the role of prior treatment with bevacizumab and tumor expression of class III ß-tubulin (TUBB3) by immunohistochemistry as a predictive biomarker.

Methods: Participants were randomly assigned to receive ixabepilone 20 mg/m2 days 1, 8, 15 with (IXA+BEV) or without (IXA) bevacizumab 10 mg/kg days 1, 15 every 28 days. Patients were stratified by receipt of prior BEV. The primary endpoint was progression-free survival (PFS). Overall survival (OS), safety, and response rates served as secondary endpoints.

Results: A total of 78 patients were randomized from March 2017-July 2020. Among 76 evaluable patients who received IXA+BEV (n = 39) compared to IXA (n = 37), the objective response rate was 33% (n = 13) versus 8% (n = 3) (P = 0.004), with clinical benefit durable at 6 months in 37% (n = 14) and 3% (n = 1) (P< 0.001). The addition of BEV significantly improved both PFS (median 5.5 vs 2.2 months, HR = 0.33, 95% CI 0.19-0.55, P < 0.001) [Fig. 1a] and OS (median 10.0 vs 6.0 months, HR = 0.52, 95% CI 0.31-0.87, P = 0.006) [Fig. 1b]. Both regimens were well-tolerated. TUBB3 expression did not predict response in either arm. Subgroup analyses revealed minimal effect of prior BEV on response to IXA+BEV [Fig. 1c/d].

Conclusions: IXA+BEV is a well-tolerated, effective combination for treatment of platinum/taxane-resistant ovarian cancer that extends both PFS/OS relative to IXA monotherapy. Prior receipt of BEV should not preclude use of IXA+BEV. TUBB3 is not a predictive biomarker for response to IXA+BEV.