

Meeting Abstract: 2014 ASCO Annual Meeting I

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# Relationship of pharmacokinetics (PK), toxicity, and initial evidence of clinical activity with IMGN853, a folate receptor alpha (FR $\alpha$ ) targeting antibody drug conjugate in patients (Pts) with epithelial ovarian cancer (EOC) and other FR $\alpha$ -positive solid tumors.

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## Abstract

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**Background:** IMGN853 is a FR $\alpha$ -targeting ADC that comprises a FR $\alpha$ -binding antibody conjugated with the potent maytansinoid tubulin inhibitor, DM4. FR $\alpha$  is highly expressed on many solid tumors, particularly EOC, endometrial, non-small cell lung cancer, and clear cell renal cancer **Methods:** The phase I primary objectives are to determine the maximum tolerated dose and recommended phase 2 dose. The secondary objectives include evaluation of safety, PK, pharmacodynamics and preliminary efficacy. Analysis of PK data and the relationship with ocular toxicity, the dose limiting toxicity at 7.0 mg/kg total body weight (TBW) and initial evidence of clinical activity from patients in this ongoing study is described. **Results:** Thirty pts have been enrolled across 7 dose levels 0.15 to 7.0 mg/kg TBW



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(IV) every 21 days (Q3W). The occurrence of ocular toxicity was associated with high  $C_{max}$  ( $p=0.0004$  Fisher exact test) and high early exposure levels, (area under the curve in the first 24 hours ( $AUC_{0-24}$ ) ( $p=0.0001$ )). Covariate analysis indicated a correlation between weight and  $C_{max}$  (Pearson  $r=0.48$ ,  $p=0.02$ ). Preliminary evidence of clinical activity (CA125 CGIC response criteria, partial response (PR), SD > 6 cycles) was observed in 10/24 patients receiving doses > 3.3 mg/kg (TBW). There was evidence of a threshold exposure level for activity around  $AUC_{0-\infty} > 12,944$  (hr ug/ml). In patients with these exposure levels, clinical activity was observed in 5/6 serous or transitional EOC pts and 2/4 endometrial pts. The final clinical activity threshold may vary slightly as additional pts are enrolled. Based on these results, and PK modeling, dosing by adjusted ideal body weight (ADJ) was identified as a means to decrease PK variability due to body weight dependence. The phase I trial has been amended to evaluate this hypothesis.

**Conclusions:** Preliminary evidence of anti-tumor activity is encouraging, and results from the PK analysis suggest ADJ dosing should enable more pts to be treated within a clinically relevant therapeutic window. [Clinical trial information: IMGN853-0401 NCT01609556.](#)

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