

Meeting Abstract: 2014 ASCO Annual Meeting I

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Enhancement of cetuximab-induced antibody-dependent cellular cytotoxicity (ADCC) with lenalidomide in advanced solid tumors: A phase 1 trial.

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Abstract

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Background: Antibody-dependent cellular cytotoxicity (ADCC) is one mechanism of action of monoclonal antibody therapy. ADCC occurs via the innate immune system's ability to recognize mAb coated cancer cells and activate effector cells. Lenalidomide is an immunomodulatory agent with capacity to stimulate T cell proliferation, activate natural killer cells, and effect immune cytokines including IL-2, IL-12, and interferon gamma (INF-g). Pre-clinical and clinical data demonstrate the ability of lenalidomide to increase ADCC activity of mAb therapy. This phase 1 trial evaluated the combination of cetuximab with lenalidomide to enhance ADCC activity in advanced colorectal (CRC) and head and neck squamous cell cancers (HNSCC). **Methods:** This phase 1 dose escalation (3+3) trial included pts with metastatic CRC or HNSCC. Treatment consisted of cetuximab 500 mg/m² IV every 2 weeks with lenalidomide orally days 1-21 every 28 days. Three dose levels of lenalidomide were



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evaluated (15, 20, and 25 mg). Correlative studies include measurement of ADCC using an in vitro chromium release assay, bioplex cytokine profiles, and Fc gamma receptor (FcR) polymorphisms. For ADCC assay, target cell line was HT29 (CRC KRAS WT cell line). **Results:** 22 pts were treated (19 CRC, 3 HNSCC); 20 pts had received prior cetuximab or panitumumab. Grade 3 fatigue was the only DLT. One partial response was observed and 7 patients had stable disease as best response. The recommended phase II dose is cetuximab 500 mg/m² with lenalidomide 25 mg daily. ADCC assay demonstrated increased cell lysis with increasing doses of lenalidomide, particularly with lenalidomide 25 mg. Patient with PR demonstrated increase in ADCC as well as upregulation of IL-2, IL-12, INF- γ with downregulation of FGF and VEGF. No high affinity FcR polymorphisms were identified. **Conclusions:** Cetuximab and lenalidomide are well-tolerated with minimal toxicity. There was evidence of anti-tumor activity and clinical efficacy. Correlative studies also demonstrate improved immunologic activity as demonstrated by ADCC assays with increasing doses of lenalidomide although no high affinity FcR polymorphisms were identified. [Clinical trial information: NCT01254617.](#)

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by trastuzumab, cetuximab and rituximab

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