A Phase 1b Study of the Anti-Cancer Stem Cell Agent Demcizumab, Pemetrexed and Carboplatin in Patients with 1st Line Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

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Background
The regimen of DEM, PEM & carboplatin has been shown to have activity in NSCLC. However, the biomarker response to DEM is not well characterized. This study extends previous work that included immunogenicity testing and identifies novel targets for developing future treatment strategies.

Methods
This is an ongoing phase Ib dose escalation study of demcizumab plus pemetrexed and carboplatin in chemotherapy-naive patients with 1st-line NSCLC. Prior to enrollment, patients underwent screening to determine eligibility. The study endpoints include the determination of the safety profile maximum tolerated dose (MTD), immunogenicity, pharmacokinetics, antitumor activity, and biomarkers of notch signaling and CSCs in tumor. Patients received demcizumab (2.5 or 5 mg/kg), pemetrexed 500 mg and carboplatin AUC = 6 every 3 weeks for 5 cycles followed by maintenance demcizumab every 4 weeks (CONTINUOUS). Patients with clinical progression were treated up to known to have started. Two maintenance cycles of demcizumab were administered to patients who achieved complete remission. Patients were monitored with BNP and ECHO.