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DEVELOPMENTAL THERAPEUTICS: MOLECULAR
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Phase I and pharmacokinetic study of VEGF Trap administered subcutaneously (sc) to patients (pts) with advanced solid malignancies

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Abstract

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Background: Vascular Endothelial Growth Factor (VEGF) Trap is a potent angiogenesis inhibitor that binds VEGF-A 100- to 1000- fold more tightly than monoclonal antibodies ($K_d < 1\text{pM}$) and inactivates all circulating and tissue VEGF-A isoforms plus placental growth factor. VEGF Trap is comprised of portions of the human VEGF receptor VEGFR1 (Flt-1) and VEGFR2 (KDR) extracellular domains fused to human IgG1 Fc.

Methods: In this phase I trial, successive cohorts of pts with relapsed or refractory solid tumors received a single sc dose of VEGF Trap, followed 4 weeks later by 6 weekly doses. Pts without disease progression subsequently entered a long-term extension study. Study endpoints included safety, pharmacokinetics, and immunogenicity. Anti-tumor activity was assessed by CT scan. **Results:** A total of 30 pts have been treated across 6 dose levels to date: 0.025, 0.05, 0.1, 0.2, 0.4 and 0.8 mg/kg. Drug-related grade 3 AEs have included hypertension (HTN; $n=4$), proteinuria ($n=1$), and afebrile neutropenia ($n=1$). Other than HTN, No dose-related pattern of adverse events (AEs) has emerged. However, the maximum tolerated dose has not yet been reached, and no pts have died due to an AE. No pts have developed anti-VEGF Trap antibodies, including 14 pts treated for ≥ 4 mos. Free plasma VEGF Trap levels associated with anti-tumor activity in animal models were approached at, but not below, the 0.8 mg/kg dose level. Objective partial or complete responses have not yet been achieved, but 14 of 24 evaluable pts, including 5 of 6 pts treated with 0.8 mg/kg, maintained stable disease (SD) for at least 10 weeks and entered the extension study. **Conclusions:** VEGF Trap has a favorable safety and tolerability profile and does not appear to elicit an antibody response. Consistent with previous findings with an anti-VEGF antibody, VEGF Trap may be associated with dose-dependent hypertension. Five of 6 evaluable pts treated with 0.8 mg/kg, compared with 9 of 18 evaluable pts who

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received lower doses, maintained SD at the end of the 10-week study. Evaluation of higher dose levels is ongoing.

Author Disclosure

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