Phase 1 Open-Label, Ascending Dose Trial of AGEN1884, an anti-CTLA-4 Monoclonal Antibody, in Advanced Solid Malignancies:
Dose Selection for Combination With PD-1 Blockade

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BACKGROUND

CTLA-4 is a negative regulator of T cell activation and an attractive target for cancer immunotherapy. A phase 1 trial of Agenus’s anti-CTLA-4 antibody (AGEN1884) in advanced solid malignancies was conducted from May 2015 to July 2016 at a maximum tolerated dose (MTD) of 3 mg/kg.

METHODS

Patients (≥18 years old) with advanced solid tumors were treated in 5 cohorts (0.3–3 mg/kg) with 5–6 patients per cohort. In this single-arm, open-label trial, the primary objective was to establish the MTD while assessing DLTs and establishing a recommended phase 2 dose (RP2D). Secondary objectives included evaluating safety and dose–response relationships. The study was conducted in 3 phases: 1) Dose escalation, 2) expansion, and 3) safety.”

RESULTS

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