Phase 1a/b Study of First-in-Class B7-H4 Antibody, FPA150, as Monotherapy in Patients with Advanced Solid Tumors

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Phase 1a: Study of Safety

- There were no Dose Limiting Toxicities (DLTs)
- Treatment-emergent serious adverse events (SAEs) were reported in 5 of 29 patients (17.2%) and were generally consistent with an advanced cancer population

- One patient with cholangiocarcinoma had a grade 5 SAE of acute kidney injury, not related to FPA150, in the setting of abruptly progressive disease
- No SAEs were considered related to FPA150
- FPA150-related adverse events (SAEs) were reported in 15 of 29 patients (52%)
- Grade 3/4 decreased lymphocytes count in one patient
- All other TRAEs were grades 1 or 2 with diarrhea in 5 patients (17.2%) and fatigue in 4 patients (13.8%) being the most frequent
- Median of 3 (range: 1-14) FPA150 injections and median of 44 days (range: 1-274) on treatment

Phase 1a: Safety Pharmacokinetics

- Typical monoclonal antibody PK profile with linear dose proportionality
- No Gr 4 TRAEs or SAEs related to FPA150
- One patient with cholangiocarcinoma had a grade 5 SAE of acute kidney injury, not related to FPA150
- There were no Dose Limiting Toxicities (DLT)

RESULTS (continued)

FPA150 demonstrates Dose-Dependent Antitumor Activity in vivo and Elicits Complete Tumor Regression in Combination with PD-L1 Blockade

FPA150 is a human IgG1 monoclonal antibody with high affinity binding to B7-H4 (≥100-fold) and dose proportionality in vivo. Treatment in combination with PD-L1 blockade results in complete tumor regressions at doses as low as 0.3 mg/kg.

FPA150 was selected and Engineered to Possess Both T Cell Checkpoint Blockade and Enhanced ADCC Activities

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- FPA150 selected for its ability to relieve suppression of T cell activation by B7-H4
- Overexpression of B7-H4 in tumors relative to healthy tissues is predicted to provide a favorable therapeutic index for a B7-H4 antibody that possesses ADCC activity

METHODS

First-in-Human Phase 1a/b Study of FPA150 in B7-H4+ Advanced Solid Tumors

Phase 1a: Baseline Demographics and Prior Therapy

Phase 1a: Treatment Emergent AEs in More than 10% of Patients

RESULTS (continued)

Acknowledgments

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