FPA150 (B7-H4 antibody) Phase 1 Update in Advanced Solid Tumors: Monotherapy and in Combination with Pembrolizumab

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METHODS

Study Schema: Phase 1a/b Study of FPA150 + Pembrolizumab in Advanced Solid Tumors

OBJECTIVES

Phase 1b Monotherapy FPA150 and Phase 1a Combination: Baseline Demographics and Prior Therapy

RESULTS

Safety Summary

Phase 1b Monotherapy FPA150: Days on Study and Response by Tumor Type

DEMOGRAPHICS

Phase 1b Monotherapy FPA150 and Phase 1a Combination: Baseline Demographics and Prior Therapy

Efficacy Data

High affinity binding to B7-H4 IgV ectodomain

Phase 1a/1b Expansion Phase 1b Monotherapy FPA150 (20 mg/kg)

Ph 1a/1b Pembrolizumab in B7-H4+ Ovarian Cancer

Safety: Phase 1b Monotherapy FPA150 (N=42)

One patient had a Grade 4 event (hypotension) and a Grade 3 event (death due to sepsis). Neither event was treatment-related.

No patient discontinued FPA150 due to treatment-related toxicity

9 SAEs in 7 patients:

- One event each of the following: sepsis (G3), hypotension (G4), CNS metastases (G3), gastrointestinal reflux (G2), hemorrhage (G3), nausea (G3), abdominal pain (G3), gastrointestinal obstruction (G3), dyspnea (G2)

- No patient discontinued FPA150 due to treatment-related toxicity

- One patient had >G3 event (G4 hyponatremia and G5 sepsis) Typhus

Safety: Phase 1b Combination FPA150 + Pembrolizumab in ovarian Cancer

Increased tumor infiltration of CD8+, CD3 T cells and NK (CD16+GEmbr) cells observed in responding or stable tumors after treatment with monotherapy FPA150

Observation: CD3+ and CD8+ T cell infiltration is enhanced with FPA150 monotherapy

Lack of off-target toxicity suggests B7-H4 is a potential target

- 2 confirmed PRs in ovarian cancer (one in dose escalation and one at RD of 20 mg/kg G3R)

- 11 patients with SD remain on therapy as of 9-Aug-2019

- Combination is well tolerated in the first 4 patients treated with FPA150 at 20 mg/kg pembrolizumab G3R

- Initiated enrollment in Phase 1b Combination Expansion cohort in August 2018

- Lack of off-target toxicity suggests B7-H4 may also be a potential target for anti-CD47 agents

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