This is a phase 1, open-label, dose-escalation trial of AGEN2034 with a solid tumor population to determine the recommended phase 2 dosage and to assess the safety and tolerability of different AGEN2034 dose levels in subjects with advanced refractory cervical cancer.

**BACKGROUND**

- AGEN2034 is a novel, fully human monoclonal immunoglobulin G4 (IgG4) antibody designed to block PD-1 from interacting with its ligands PD-L1 and PD-L2.
- Blockade of receptor-ligand interactions has been demonstrated in vitro and in animal models.
- The current study (NCT03104699) evaluates AGEN2034 in patients with advanced refractory cervical cancer.

**OBJECTIVE**

- To assess the safety and tolerability of different AGEN2034 dose levels in patients with recurrent, unresectable or metastatic cervical cancer in order to determine the recommended phase 2 dosage.
- To assess the feasibility and determine the optimal phase 2 dose of AGEN2034 in patients with recurrent, unresectable, or metastatic cervical cancer.

**METHODS**

1. **Patient selection:** Open-label, phase I/II dose-finding study of AGEN2034 with a phase 2 expansion in patients with recurrent solid tumor cancers ongoing.

2. **Evaluation Criteria:** Evaluable patients are those with advanced refractory cervical cancer.

3. **Phase 1:** Dose-escalation study in phase 1 will be conducted in 3 cohorts: 10 mg/kg q3w, 10 mg/kg q2w, and 3 mg/kg q2w. The study will enroll 10 patients per cohort; therefore, there are 2 PRs in the overall cervical cancer group.

**RESULTS**

- **Safety and Tolerability:** 17 patients reported serious TEAEs, with gastrointestinal disorders being the most common system organ class (n=5 patients).
- The most common TEAEs were gastrointestinal disorders (n=15), infectious and infestations (n=13), and laboratory abnormalities (n=13).

**DISCUSSION**

- AGEN2034 is pharmacologically active, well-tolerated PD-1 antagonist demonstrating safety and efficacy in patients with advanced refractory malignancies including cervical cancer.
- No OLs were observed in the Phase 1 portion of the study.
- TEAEs are ongoing under active analysis as no more severe than grade 3.
- Receptor occupancy results from the current study can be comparable to those available for commercially available PD-1 antagonists.
- The phase 3 expansion in patients with relapsed/refractory cervical cancer is continuing in multiple countries.

**REFERENCES**


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