A Phase 1, Multiple-Dose Study to Evaluate the Safety and Tolerability of XmAb®819 in Patients With Relapsed or Refractory Clear Cell Renal Cell Carcinoma

Study Overview

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Background and Preclinical Evidence

- The XmAb®819 format antibody provides avid tumor targeting and selectivity (Figure 1, Figure 2).
- XmAb®819 is administered as an IV infusion on Days 1, 8, and 15 in a 3+3 dose escalation (Figure 3).

Study Design

- This study has a novel trial design with dose escalation, priming dose, step-up doses determined by biomarkers, and intradose schedule.
- Treatment includes a priming dose on Day 1 followed by higher weekly and escalation doses on the day of the first priming dose, and up to an inpatient (IV/day) cycle (Figure 4).
- Imaging is performed at screening, at the time of the first priming dose, and at all end of treatment (EOT) assessment visits.

Key Inclusion Criteria

- Patients must have measurable disease by RECIST v1.1 as assessed by the local site investigator or radiology department.

Key Exclusion Criteria

- History of allergic or anaphylactic/hypersensitivity reaction to mAb therapy.
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- Recent treatment with any investigational therapeutic agents for any condition.

Exploratory Objectives

- To assess the incidence, timing, and severity of cytokine release syndrome (Figure 5).

Reference


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